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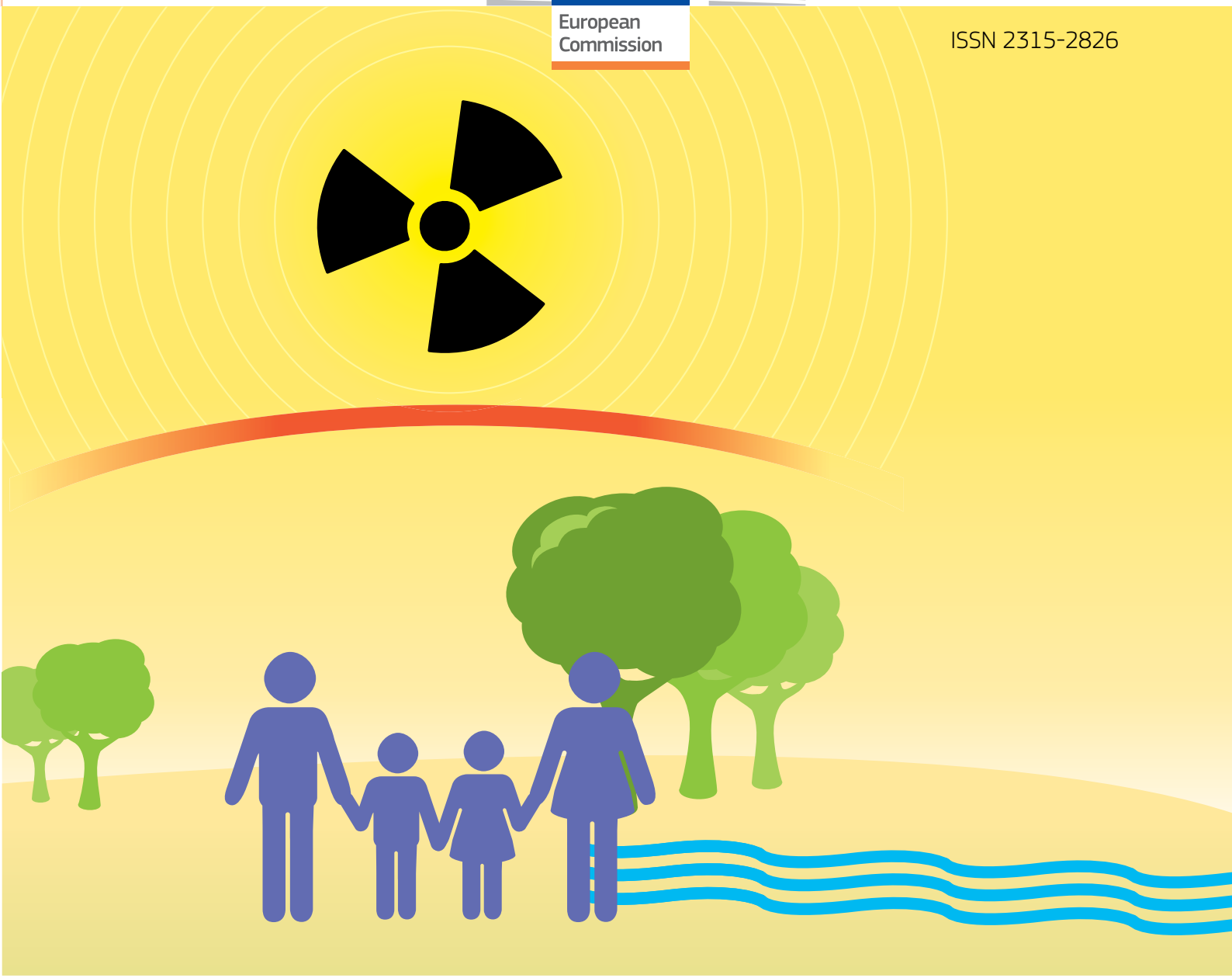

# Radiation Protection

N° 188

## Technical Recommendations for Monitoring Individuals for Occupational Intakes of Radionuclides

Energy

Final Report of Service Contract ENER/2014/NUCL/SI2.680087

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EUROPEAN COMMISSION

# RADIATION PROTECTION N° 188

# Technical Recommendations for Monitoring Individuals for Occupational Intakes of Radionuclides

Directorate-General for Energy
Directorate D — Nuclear Energy, Safety and ITER
Unit D.3 — Radiation Protection and Nuclear Safety
2018

# FOREWORD

Luxembourg, July 2018

Under the terms of the Treaty establishing the European Atomic Energy Community, the Community, establishes uniform safety standards to protect the health of workers and of the general public against the dangers arising from ionizing radiation. The most recent version of such standards is contained in Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionizing radiation.

Directive 2013/59/Euratom introduces, *inter alia*, principles for the operational protection of workers exposed to ionising radiation, including requirements for the monitoring of individuals for occupational intakes of radionuclides.

In 2014, the European Commission launched a project with the objective to establish a European reference document in the area of internal exposure as guidance for the practical implementation of recent developments in internal dosimetry and to achieve harmonisation of the methodology for the assessment of intakes of radionuclides applied by dosimetry services. The project to develop Technical Recommendations for Monitoring Individuals for Occupational Intakes of Radionuclides (Service Contract Number ENER/2014/NUCL/SI2.68008) was awarded to a consortium led by EURADOS e.V. It was concluded in May 2016.

The main deliverable of the project was the "Technical Recommendations for Monitoring Individuals for Occupational Intakes of Radionuclides" as a single, publishable document. This document presents a complete account of the principles of the subject, together with comprehensive, detailed, authoritative and internally-consistent guidance and recommendations on the practice of individual monitoring and internal dosimetry, taking account of recent developments. The document takes account of Council Directive 2013/59/Euratom, as well as the developments embodied in the ICRP Occupational Intakes of Radionuclides report series. As part of the project, the document has undergone extensive stakeholder consultation.

The Article 31 Group of Experts endorsed the document and recommended it for publication in the Radiation Protection Series of the European Commission.

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# ABSTRACT

This report presents technical recommendations for individual monitoring of workers for occupational intakes of radionuclides. It aims at providing guidance on those aspects of the implementation of the provisions of the Euratom Basic Safety Standards Directive related to individual monitoring of internal exposures, and to encourage harmonisation and the eventual mutual recognition of services. It presents a complete account of the principles of individual monitoring and internal dosimetry, and develops comprehensive guidance and recommendations on best practice. The recommendations cover: (i) roles and duties of dosimetry services; (ii) monitoring programmes; (iii) monitoring methods; (iv) assessment of internal doses from monitoring measurements; (v) accuracy requirements and uncertainty analysis; (vi) quality assurance, and criteria for approval and accreditation; and (vii) radon measurement and dosimetry for workers. Annexes provide supporting information. Topics addressed in the annexes include biokinetic and dosimetric models, monitoring and dosimetry for first responders after a major accident, and the application of internal dosimetry to assessments of risks to health. Finally, there is a set of examples that demonstrate key features of the technical recommendations.



# RÉSUMÉ

Ce rapport présente les recommandations techniques concernant la surveillance individuelle des travailleurs exposés à l'incorporation de radionucléides. Son objectif est de fournir des conseils dans le contexte de la mise en application des dispositions de la Directive Euratom Normes de Base relative à la surveillance individuelle des expositions internes et de favoriser l'harmonisation des bonnes pratiques et la reconnaissance mutuelle des services impliqués. Il présente un panorama complet des principes de la surveillance individuelle de la dosimétrie interne et fournit de façon exhaustive conseils et recommandations sur la meilleure pratique. Ces recommandations portent sur : (i) les rôles et les attributions des services de dosimétrie ; (ii) les programmes de surveillance ; (iii) les méthodes utilisées pour cette surveillance ; (iv) l'évaluation des doses internes ; (v) les exigences relatives à l'exactitude des résultats et l'analyse des incertitudes associées ; (vi) l'assurance de la qualité et les critères d'agrément et d'accréditation ; (vii) les principes de dosimétrie liées à l'exposition professionnelle au radon. Les annexes complètent ces recommandations. Les sujets abordés incluent les modèles biocinétiques et dosimétriques des radionucléides, la surveillance et la dosimétrie des primo-intervenants suite à un accident majeur et l'utilisation des résultats de la dosimétrie interne pour évaluer les risques pour la santé humaine. Une annexe fournit une série d'exemples qui illustrent les points forts des recommandations techniques.

# EXECUTIVE SUMMARY

## Purpose, Context and Scope

This report[1] presents a complete account of the principles of individual monitoring and internal dosimetry, and provides guidance and recommendations on best practice relating to monitoring individuals for occupational intakes of radionuclides. The guidance and recommendations focus on those aspects of the implementation of Council Directives of the EU that are directly related to individual monitoring of internal exposures. A comprehensive set of technical recommendations is provided on:

i. Roles and duties of dosimetry services;
ii. Monitoring programmes;
iii. Monitoring methods;
iv. Assessment of internal doses from monitoring measurements;
v. Accuracy requirements and uncertainty analysis;
vi. Quality assurance, and criteria for approval and accreditation; and
vii. Radon measurement and dosimetry for workers.

After some of the Chapters, Appendices are included that present supplementary material which is relevant to to the subject of the Chapter, but which does not directly support the recommendations made.

Annexes are included after the Chapters at the end of the report, and provide information on related topics, but for which no recommendations are made. Topics addressed in the Annexes include:

i. Biokinetic and dosimetric models;
ii. Monitoring and dosimetry for first responders after a major accident; and
iii. The application of internal dosimetry to assessments of risks to health.
iv. One Annex (Annex II) provides a set of examples that demonstrate key features of the technical recommendations.
v. The final Annex (Annex V) presents a compilation of the full set of recommendations.

The target audience includes internal dosimetry services operating within the EU, as well as competent national and international authorities. The Technical Recommendations are also expected to be of interest to site operators who are responsible for radiation protection programmes, to radiation protection experts who provide advice to site operators, and to manufacturers, laboratories providing bioassay services and government bodies aiming to harmonise regulations and guidance.

It is intended that the Technical Recommendations will be widely applicable across current and future Member States of the EU. They will promote the mobility of occupationally exposed workers within the EU by:

- encouraging the harmonisation of methodologies for the assessment of intakes of radionuclides used by internal dosimetry services in the EU;
- providing the basis for uniform approval criteria for internal dosimetry services; and
- standardising the criteria for the mutual recognition of dose records.

The Technical Recommendations are intended to be primarily informative in nature and do not in themselves make prescriptive or normative statements about practices that must be adopted. Nevertheless, they do make clear where authorities or organisations (e.g. the European Commission, ICRP or ISO) have specified that certain

[1] Referred to subsequently in this summary as the "Technical Recommendations"

methods, practices or conventions are mandatory according to their own regulations or schemes.

The Technical Recommendations bring together requirements and guidance given in:

- EU Council Directive 2013/59/Euratom [EC 2014], which lays down basic safety standards for protection against the dangers arising from exposure to ionising radiation (replacing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom [EC 1996], 97/43/Euratom and 2003/122/Euratom);
- Publications of the International Commission on Radiological Protection (ICRP) relating to occupational intakes of radionuclides, including the Occupational Intakes of Radionuclides report series [ICRP 2015b];
- Standards published by the International Organization for Standardization (ISO) relating to monitoring and dose assessment for workers occupationally exposed to a risk of internal contamination with radioactive material [ISO 2006; 2010b; 2011];
- Relevant reports of the International Commission on Radiation Units and Measurements (ICRU);
- Relevant reports, technical documents and safety guides of the International Atomic Energy Agency (IAEA);
- The report of the European Radiation Dosimetry Group (EURADOS) on the estimation of internal doses from monitoring data [EURADOS 2013];
- Relevant national and international standards, guides, reports and technical documents issued by competent national authorities in EU Member States.

The contents of other reports, guides, technical documents and standards are not reproduced in detail, since this would result in a report of excessive (and unnecessary) length. Rather, the information that can be found in these reports is summarised, and guidance is given on how to make use of the information. This helps to ensure that the Technical Recommendations will not become obsolete when other documents are updated.

The Technical Recommendations could form the basis of Best Practice Guides at the national or organisational level.

## Guide to the Report

A standard format is followed for each Chapter. Most are preceded by a summary of the topics to be addressed, which takes the form of a single main "question" that is addressed, together with a set of subsidiary, more specific questions. Each Chapter then follows the following format:

- List of Special Terms used in the Chapter
- Introduction
- Technical and scientific discussion, with links to other Chapters where appropriate, making reference to:
    - Regulations and Directives
    - International recommendations, standards, guidelines
    - National standards, guides, reports and technical documents
- Tables and Figures
- Recommendations that give specific responses to each question stated at the beginning of the Chapter

A detailed summary of the topics addressed by each Chapter and Annex is presented in Chapter A, Table A.1.

## The Recommendations

Recommendations are presented at the end of each Chapter, except for Chapters A1 and B.

The recommendations are presented in a standard format, and are categorised using one of three grades as described in Chapter A, Table A.2, reproduced below.

| GRADE | Criteria from Clinical Practice Guidelines |
|---|---|
| M | Grade M (mandatory), for recommendations that are legal requirements in accordance with European Directives. These recommendations are made on the basis of regulatory references. |
| I | Grade I (international recommendation) for recommendations formulated by international organisations such as ICRP, IAEA, ICRU, ISO, WHO and ILO, including international Basic Safety Standards. These recommendations are made on the basis of normative references and international standards. The source of the recommendation is indicated in the text of the recommendation. |
| A | Grade A (advisory recommendation) for expert decisions of the authors of the Technical Recommendations, based on best practices identified by review of the literature, or derived from a consensus of the opinions of recognised experts, or from professional agreements justified by expert feedback on occupational cases. Advisory recommendations have been subjected to extensive consultation and peer reviews conducted during the preparation of the Technical Recommendations. |

Chapter A2 (Implementation by Internal Dosimetry Services: Duties, Partners and Approval) provides five recommendations relating to the formal implementation by Internal Dosimetry Services of individual monitoring and dosimetry after intakes of radionuclides.

Chapter C (Monitoring Programmes) provides 19 recommendations relating to making decisions on the need for an individual monitoring programme; the design of the programme; and the application of different measurement techniques and procedures for assessment of internal doses.

Chapter D (Methods of Individual and Workplace Monitoring) provides 39 recommendations relating to the choice of measurement method(s) for the determination of radionuclides incorporated into the body and the implementation of these methods.

Chapter E (Routine and Special Dose Assessment) provides 29 recommendations relating to: interpretation of monitoring data; dose assessment and interpretation for routine monitoring and special monitoring; monitoring and dosimetry for wound cases and cutaneous contamination; monitoring and dose assessment in the event of decorporation therapy; and radiation protection for pregnant and breastfeeding workers.

Chapter F (Accuracy Requirements and Uncertainty Analysis) provides six recommendations relating to the circumstances under which uncertainties in assessed dose should be evaluated and the use of information on uncertainties.

Chapter G (Quality Assurance and Criteria for Approval and Accreditation) provides 14 recommendations relating to the quality assurance of assessed internal doses; establishing the reliability of monitoring data and dose assessments; accreditation; participation in intercomparison exercises; and recording and reporting of results.

Chapter H (Radon Measurement and Dosimetry for Workers) provides 15 recommendations relating to the general approach to protecting workers against radon exposures; measurement strategies; the use of individual monitoring; dose assessment; quality assurance; and risk communication strategies.

The full set of recommendations is presented in Annex V, which should be considered as part of this Executive Summary.

# RÉSUMÉ

## But, Contexte et champ d'application

Ce rapport[2] présente l'ensemble des principes de la surveillance individuelle et de la dosimétrie interne et fournit par ailleurs des conseils et des recommandations de bonnes pratiques pour la surveillance des travailleurs exposés au risque d'incorporation de radionucléides. Son but est de permettre la mise en application des mesures relatives à la surveillance individuelle de l'exposition interne figurant dans les directives du Conseil de l'Union européenne (UE). Un ensemble complet de recommandations techniques est proposé, portant sur:

i. Les rôles et les devoirs des services de dosimétrie;

ii. Les programmes de surveillance;

iii. Les techniques de surveillance;

iv. Les estimations des doses internes à partir des résultats des mesurages;

v. Les exigences en termes d'exactitude et d'incertitude;

vi. L'assurance qualité, et les critères d'agrément et d'accréditation;

vii. Le mesurage du radon et sa dosimétrie pour les travailleurs.

A la fin de certains chapitres, ont été ajoutés des appendices fournissant des informations complémentaires utiles à la compréhension de l'objectif du chapitre, mais non directement reliées aux recommandations faites.

Des annexes ont été insérées à la fin du rapport pour illustrer ou compléter sur des sujets proches les thèmes abordés dans les différents chapitres. Contrairement aux éléments présentés dans les chapitres, les informations figurant dans les annexes ne font pas l'objet de recommandations. Les sujets abordés comprennent:

i. Les modèles biocinétiques et dosimétriques;

ii. La surveillance et la dosimétrie des primo-intervenants suite à un accident nucléaire majeur;

iii. L'application de la dosimétrie interne aux estimations des risques sanitaires.

iv. Une annexe (Annexe II) fournissant une série d'exemples qui illustrent les points forts des recommandations techniques.

v. Une dernière annexe (Annexe V) proposant une compilation de toutes les recommandations du rapport.

L'audience ciblée comprend les services de dosimétrie interne opérant au sein de l'UE, mais aussi les autorités compétentes nationales ou internationales. Les recommandations techniques s'adressent également aux opérateurs des sites industriels, responsables des programmes de radioprotection, aux experts en radioprotection qui conseillent les industriels, aux fournisseurs, aux laboratoires assurant les mesurages in vivo and in vitro, et enfin aux organismes gouvernementaux qui assurent l'harmonisation de la règlementations et des guides.

Ces recommandations techniques devront être très largement applicables par tous les états membres actuels et futures de l'UE. Elles doivent permettre la mobilité des travailleurs exposés au sein de l'UE par :

[2]Identifié dans la suite de ce sommaire, par les termes "recommandations techniques"

- L'encouragement de l'harmonisation des méthodologies des services de dosimétrie pour les estimations des incorporations de radionucléides, au sein de l'UE;
- La fourniture d'informations basiques permettant d'uniformiser les critères d'agrément des services de dosimétrie; et
- La normalisation des critères de reconnaissance mutuelle de l'archivage de la dosimétrie.

Ces recommandations techniques sont prévues pour être en première intention informatives et ne sont pas, en elles même, des exigences strictes ou normatives sur les pratiques à mettre en place. Elles indiquent toutefois clairement lorsque des obligations portant sur les méthodes, les pratiques et les conventions ont été spécifiées par les autorités ou les organismes tels que la Commission Européenne, la CIPR ou l'ISO en accords avec leur réglementation ou leurs principes

Les recommandations techniques rassemblent les exigences et les conseils figurant dans:

- La Directive 2013/59/Euratom [EC 2014] du Conseil de l'UE, qui établit les normes de base de la protection contre les dangers des expositions aux rayonnements ionisants (en remplacement des Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom [EC 1996], 97/43/Euratom et 2003/122/Euratom);
- Les Publications de la Commission Internationale de Protection Radiologique (CIPR) relatives aux incorporations professionnelles des radionucléides, incluant les séries de rapports "Occupational Intakes of Radionuclides" [ICRP 2015b];
- Les normes publiées par l'ISO (Organisation Internationale de normalisation) relatives à la surveillance et aux estimations dosimétriques pour les travailleurs exposés à un risque de contamination interne aux composés radioactifs [ISO 2006; 2010b; 2011];
- Les rapports pertinents de l'ICRU (International Commission on Radiation Units and Measurements);
- Les rapports pertinents, documents techniques et guides de sécurité de l'AIEA (Agence Internationale de l'Energie Atomique);
- Le rapport EURADOS (European Radiation Dosimetry Group) sur l'estimation des doses internes à partir des résultats de la surveillance individuelle [EURADOS 2013];
- Les normes pertinentes nationales ou internationales, les guides, rapports and documents techniques élaborés par les autorités nationales compétentes des états membres de l'UE.

Les contenus des autres rapports, guides, documents techniques et normatifs ne sont pas reproduits dans leurs totalités pour ne pas alourdir la taille de ce rapport. Un résumé des informations disponibles dans ces documents a cependant été incorporé pour permettre aux lecteurs de les utiliser. Cette démarche permet d'assurer la pérennité des recommandations techniques au cas où un des autres documents viendrait à être modifié.

Les recommandations techniques pourraient être la base de guides de bonnes pratiques à un niveau national ou international.

## Manuel de rédaction du rapport

Un format standard a été adopté pour tous les chapitres. La plupart des chapitres sont précédés d'un sommaire introductif sur les sujets abordés, qui prennent la forme d'une question principale suivie de questions subsidiaires ou plus spécifiques. Le plan de chaque chapitre suit ensuite le modèle suivant :

- Liste des termes spécifiques utilisés dans le chapitre
- Introduction

- Discussions techniques et scientifiques, en relation avec les autres chapitres, faisant référence:
    - Aux textes règlementaires et aux directives
    - Aux recommandations, normes et guides internationaux
    - Aux normes, guides, rapports et documents techniques nationaux
- Tableaux et Figures
- Recommandations qui doivent donner des réponses adaptées aux questions posées au début du chapitre.

Un sommaire détaillé de tous les sujets abordés dans chaque chapitre et dans les annexes est présenté dans le Chapitre A, Tableau A.1.

## Les Recommandations

Les recommandations sont fournies à la fin de chaque chapitre, sauf pour les chapitre A1 et B.

Les recommandations sont présentées sous une forme standardisée et sont catégorisées à l'aide d'une des trois gradations décrites dans le chapitre A, Tableau 2, reproduit ci-dessous.

| GRADE | Critères retenus à partir des Guides de bonnes pratiques cliniques |
|---|---|
| M | Grade M (obligatoire), pour les recommandations qui résultent des exigences issues des Directives Européennes. Ces recommandations proviennent de références règlementaires. |
| I | Grade I (recommandation internationale) pour les recommandations formulées par des organisations internationales comme la CIPR, l'AIEA, l'ICRU, l'ISO, l'OMS et l'ILO, incluant aussi les normes de base internationales de sûreté. La provenance des recommandations est indiquée dans le texte de la recommandation. |
| A | Grade A (recommandation conseillée) les recommandations établies par décision d'experts des auteurs des recommandations techniques à partir des meilleures pratiques, identifiées par l'analyse de la littérature scientifique, ou issues d'un consensus d'experts reconnus dans le domaine ou provenant d'accords professionnels justifiés par le retour d'expériences sur des cas réels d'exposition professionnelle. Ces recommandations conseillées ont fait l'objet d'intenses consultations et d'évaluations par des pairs pendant l'élaboration des recommandations techniques. |

Le chapitre A2 (Mise en œuvre par les services de dosimétrie interne: devoirs, partenaires et agrément) propose cinq recommandations relatives à la mise en œuvre formelle de la surveillance individuelles et de la dosimétrie interne après incorporation de radionucléides par les services de dosimétrie.

Le chapitre C (Programmes de surveillance) propose 19 recommandations relatives à la prise de décisions sur la nécessité d'établir un programme individuel de surveillance, à la conception de ce programme et à sa réalisation à l'aide des différentes techniques de mesure et aux procédures d'estimation des doses internes.

Le chapitre D (Méthodes de surveillance Individuelle et collective) propose 39 recommandations relatives à la sélection de (ou des) la technique(s) de mesure appropriée(s) pour la quantification des radionucléides incorporés et la mise en œuvre de ces techniques.

Le chapitre E (Estimation des doses en systématique ou après incident) propose 29 recommandations relatives à l'interprétation des résultats de la surveillance, aux estimations dosimétriques en systématique ou après incident, à la surveillance et la

dosimétrie en cas de blessures ou de contamination cutanée, à la surveillance et l'estimation dosimétrique en cas de traitement par décorporation et à la radioprotection spécifique pour les femmes enceintes ou allaitantes.

Le chapitre F (Exigences d'exactitude et analyses des incertitudes) propose six recommandations relatives aux situations lors desquelles les incertitudes sur les doses calculées devraient être évaluées et les conditions d'utilisations de ces incertitudes.

Le chapitre G (Assurance de la qualité et critères d'agrément et accréditation) propose 14 recommandations relatives à l'assurance de la qualité des doses internes évaluées; à l'établissement de la fiabilité des résultats de la surveillance et des estimations dosimétriques; à l'accréditation; à la participation à des exercices d'intercomparaison; et à l'archivage et à la transmission des résultats.

Le chapitre H (Mesurage du radon et dosimétrie pour les travailleurs) propose 15 recommandations relatives à l'approche générale de la protection des travailleurs contre les expositions au radon; aux stratégies de mesurage; à l'intérêt d'une surveillance individuelle; à l'estimation dosimétrique; à l'assurance de la qualité; et aux stratégies de communication sur le risque lié à l'exposition au radon.

La totalité des recommandations ont été regroupée dans l'annexe V, qui doit être considérée comme faisant partie intégrante de ce résumé.

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# GLOSSARY

**Absorbed dose** *D*: The energy absorbed per unit mass:

$$D = \frac{d\bar{\varepsilon}}{dm}$$

where
$d\bar{\varepsilon}$ is the mean energy imparted by ionising radiation to the matter in a volume element,
dm is the mass of the matter in this volume element.
In these Technical Recommendations, absorbed dose usually denotes the dose averaged over a tissue or an organ:

$$D_T = \frac{1}{m_T}\int D\,dm$$

where $m_T$ is the mass of the organ or tissue T, and D is the absorbed dose in the mass element dm. The SI unit of mean absorbed dose is joule per kilogram, and its special name is the gray (Gy); 1 Gy = 1 J $kg^{-1}$. [EC 2014; EURADOS 2013]

**Absorption**: Transfer of material into blood, regardless of mechanism. Generally applies to dissociation of particles and the uptake into blood of soluble substances and material dissociated from particles. [ICRP 2015b]

**Absorption Type**: Classification of inhaled materials according to their rates of absorption from the respiratory tract into blood. The absorption Types are defined in ICRP Publication 66 for the original Human Respiratory Tract Model (HRTM) and in ICRP Publication 130 for the revised HRTM. [EURADOS 2013]

**Accreditation**: tool established on an international scale to build trust with regard to the action of organisations of a very specific type, which are broadly called conformity assessment bodies, comprising testing laboratories, calibration laboratories, inspection bodies, certifying bodies and environmental verifiers.

**Accuracy:** Characteristics of an analysis or determination that ensures that both the bias and precision of the resulting quantity remains within specified limits. [ISO 2006]

**Activity**: The activity of an amount of a radionuclide at a given time t is the quotient of dN by dt, where dN is the expectation value of the number of →*nuclear transformations* in the time interval dt:

$$A = \frac{dN}{dt}$$

The SI unit of activity is the becquerel (Bq); 1 Bq = 1 $s^{-1}$. [EC 2014]

**Aerosol:** A colloid of solid or liquid particles dispersed in a gas, usually air.

**Alimentary tract transfer factor** $f_A$: The fraction of activity entering the alimentary tract that is absorbed into blood, taking no account of losses due to →*radioactive decay* or endogenous input of activity into the tract. See also *Fractional absorption in the gastro-intestinal tract* $f_1$. [ICRP 2015b]

**AMAD** (Activity Median Aerodynamic Diameter): The aerodynamic diameter $d_{ae}$ is a physical parameter describing the particle size of radioactive →*aerosols*, and corresponds to the diameter of a unit density (1 g $cm^{-3}$) sphere that has the same terminal settling velocity in air as the particle of interest. It is used as a measure when deposition depends principally on inertial impaction and sedimentation, typically when $d_{ae}$ is more than approximately 0.3 μm. When an aerosol is assigned a specific AMAD value, it means that 50% of the activity in that aerosol is associated with particles of aerodynamic diameter greater than the AMAD.

**AMTD** (Activity Median Thermodynamic Diameter): The thermodynamic diameter $d_{th}$ is a physical parameter describing the particle size of radioactive →*aerosols*, and corresponds to the diameter of a spherical particle that has the same diffusion coefficient in air as the particle of interest. It is used as a measure when deposition depends principally on diffusion, typically when $d_{th}$ is less than approximately 0.3 µm. When an aerosol is assigned a specific AMTD value, it means that 50% of the activity in that aerosol is associated with particles of thermodynamic diameter greater than the AMTD.

**Annual dose**: →*Committed effective dose* resulting from all →*intakes* occurring during a calendar year. [ISO 2011]

**Apparent intake**: The →*intake* that is consistent with the daily excretion observed after the effect of a →*decorporation* therapy has vanished. In principle, it corresponds to the real intake minus the →*activity* removed from the body as a result of the therapy.

**Approval**: The formal recognition of an expert or service by the →*competent authority*. Council Directive 2013/59/Euratom requires Member States of the European Union (EU) to implement arrangements for recognition of →*radiation protection experts* and →*medical physics experts*, as well as →*occupational health services* and →*dosimetry services*, in relation to the type of practice.

**Audit**: A systematic, independent and documented process for obtaining objective evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled. [ISO 2015a]

**Authorisation**: The granting by a competent authority or other governmental body of written permission for a person or organisation (the operator) to conduct specified activities. Authorisation could include, for example, licensing (issuing a licence), certification (issuing a certificate) or registration. The term authorisation is also sometimes used to describe the document granting such permission. Authorisation is generally a more formal process than approval. Approval is typically used to represent any form of consent from the competent authority that does not meet the definition of authorisation.

**Bioassay**: Any procedure used to determine the nature, activity, location, retention or excretion of radionuclides in (or from) the body by (direct) →*in vivo measurement* or by (indirect) →*in vitro analysis* of material excreted or otherwise removed from the body. [ICRP 2015b]

**Bioassay sample**: A biological sample excreted or otherwise removed from the body in order to assess the presence of radionuclides. For incorporation monitoring procedures, urine and faeces samples are mainly used.

**Biokinetic model**: A mathematical model describing the →*intake*, →*uptake* and retention of a radionuclide in various organs or tissues of the body and the subsequent excretion from the body by various pathways. [EURADOS 2013]

**Biological half-time**: The time required for a compartment of a biological system to eliminate (in the absence of additional input and radioactive decay) half of its radionuclide content. [ICRP 2015b]

**Calibration phantom**: A surrogate person, or or part of a person, used for calibration of *in vivo* measurement systems. A phantom is constructed to allow placement of radionuclides in a geometry approximating internal distributions. A phantom could be used as an appropriate blank. [ISO 2010b]

**Calibration standard**: A reference radioactive material used for equipment calibrations. Radionuclide standards used for equipment calibrations must be those designated as →*certified reference materials* (CRM), →*transfer reference standards* (TRS) or standards directly compared with appropriate CRMs, and where available, using the same measuring apparatus. [ISO 2010b]

**Cascade impactor**: A low speed impaction device for use in sampling both solid and liquid →*aerosols*; consists of four pairs of jets (each of progressively smaller size)

and sampling plates working in series and designed so that each plate collects particles of one size range. [ISO 2010b]

**Certified Reference Material** (CRM): A reference material, characterised by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated →*uncertainty* and a statement of the metrological →*traceability*. [ISO 2010b]

**Clearance**: The removal of material from an organ or tissue towards (for example) blood, the lymphatic system or an excretion pathway. For the HRTM, clearance takes place as a combination of particle transport within the respiratory tract (mucociliary transport) and to the lymphatic system, and absorption into blood.

**Committed effective dose** $E(\tau)$: A weighted average of →*equivalent doses* to target tissues, determined by taking the sum of the products of the committed equivalent doses to individual organ or tissue regions and the appropriate tissue weighting factors ($w_T$). In Publication 60, $E(\tau)$ is defined as:

$$E(\tau) = \sum_T w_T H_T(\tau)$$

In ICRP Publication 103, $E(\tau)$ is calculated from the average of male and female committed equivalent doses to individual organs or tissue regions:

$$E(\tau) = \sum_T w_T \cdot \left[ \frac{H_T^M(\tau) + H_T^F(\tau)}{2} \right]$$

where $H_T^M$ and $H_T^F$ are the equivalent doses to the tissues or organs T of the Reference Adult Male and Reference Adult Female, respectively, and $w_T$ is the tissue weighting factor for tissue T, with:

$$\sum_T w_T = 1$$

The SI unit for committed effective dose is the sievert (Sv), 1 Sv = J $kg^{-1}$.

**Committed equivalent dose** $H(\tau)$**:** The integral over time (t) of the →*equivalent dose* rate in tissue or organ T that will be received by an individual as a result of an intake. The integration time $\tau$ is 50 y for occupational exposures. The SI unit for committed effective dose is the sievert (Sv), 1 Sv = J $kg^{-1}$.

**Competent authority**: an authority or system of authorities designated by Member States as having legal authority for the purposes of Council Directive 2013/59/Euratom. [EC 2014]

**Computational phantom**: An anthropomorphic →*phantom* based on medical tomographic images where the anatomy is described by a three-dimensional array of small volume elements (voxels) specifying the density and the atomic composition of the various organs and tissues of the human body. [EURADOS 2013]

**Conditional probability**: The conditional probability P(A|B) measures the →*probability* of an event A given that another event B is known or assumed to have occurred. It is defined as the quotient of the joint probability that events A and B both take place, and the probability of B:

$$P(A|B) = \frac{P(A \cap B)}{P(B)}$$

**Confidence interval**: The interval about an estimate of a stated quantity, within which the expected value of the quantity is expected to lie (with a specified probability). When $T_1$ and $T_2$ are two functions of the observed values such that, θ being a population parameter to be estimated, the probability $P(T_1 \leq \theta \leq T_2)$ is at least equal to $(1 - \alpha)$ [where $(1 - \alpha)$ is a fixed number, positive and less than 1], the interval between $T_1$ and $T_2$ is a two-sided $(1 - \alpha)$ confidence interval for θ. [ISO 2010b; ISO/IEC 2014]

**Confirmatory monitoring programme**: →A *monitoring programme* carried out to confirm assumptions about working conditions, for example that significant →*intakes* have not occurred. [ISO 2006b]

**Contamination monitoring**: Monitoring in the workplace conducted to detect and measure radionuclide contamination on surfaces.

**Controlled area:** A designated area subject to special rules for the purpose of protection against ionising radiation, or to prevent the spread of radioactive contamination and to which access is controlled. [EC 2014]

**Correlation**: The relationship between two or several random variables within a distribution of two or more random variables. [ISO/IEC 2014]

**Creatinine**: A substance produced in muscle tissue by the metabolism of creatinine phosphate, which is taken in the diet primarily in meats, is filtered by the kidneys and eliminated in urine. The reference values of urinary excretion of creatinine for adult male is 1.7 g $d^{-1}$, and for adult female is 1.0 g $d^{-1}$. [ICRP 2002]

**Critical Organ:** That part of the body that is most susceptible to radiation damage resulting from the specific exposure conditions under consideration, taking into account the dose that various parts of the body receive under the exposure conditions.

**Critical Value,** $M_c$: The maximum value for the result of a single measurement in a →*monitoring programme* where it is safe to assume that the corresponding extrapolated →*annual dose* will not exceed a predefined dose level. In the IDEAS Guidelines it is called Critical Monitoring Quantity. [ISO 2011; EURADOS 2013].

**Cumulative distribution function**: A function giving, for every value x, the →*probability* that the random variable X is less than or equal to x [ISO/IEC 2014]:

$$F(x) = P(X \leq x)$$

For a discrete variable, it is defined by

$$F(x) = \sum_{X_i \leq x} P(X_i)$$

and for a continuous variable, by

$$F(x) = \int_{-\infty}^{x} P(X)dX$$

The $p^{th}$ percentile $x_p$ with $0 \leq p \leq 100$ is defined by

$$F(x_p) = \frac{p}{100}$$

**Cyclone**: An inertial impaction device for use in →*aerosol* sampling, sometimes used to mimic deposition in the respiratory tract; a rotating conical column of air results in inertial impaction of particles at positions along the conical wall of the sampler that depend on aerodynamic diameter of the particles.

**Decision Threshold** (DT): A fixed value of a measured quantity that, when exceeded by the result of a measurement quantifying a physical effect (e.g. the presence of a radionuclide in a sample), may be taken to indicate that the physical effect is present [ISO 2010a, 2010b]. The DT is the critical value of a statistical test for the decision between the hypothesis that the physical effect is not present and the alternative hypothesis that it is present. When the critical value is exceeded by the result of an actual measurement, this is taken to indicate that the hypothesis should be rejected. The statistical test is designed in such a way that the →*probability* of wrongly rejecting the hypothesis (Type I error) is, at most, equal to a given value, $\alpha$. The DT is an *a-posteriori* quantity, evaluated after a particular measurement in order to decide whether the result of the measurement is

significant. The DT is also referred to as the "critical level" or the "minimum significant activity". [EURADOS 2013]

**Decontamination**: The complete or partial removal of contamination by a deliberate physical, chemical or biological process. [IAEA 2014]

**Decorporation**: Methods to enhance the elimination of radionuclides from the body in order to reduce the radiation dose to an individual accidentally contaminated internally with radionuclides. Methods include the use of chelating agents or substances which prevent absorption to blood or deposition in organs.

**Deposition**: In the context of inhalation, the initial processes determining how much of the material in the inhaled air remains in the respiratory tract after exhalation. Deposition of material occurs during both inhalation and exhalation.

**Detection Efficiency**: The ratio of the number of particles or photons detected by a radiation detector, to the number of particles or photons emitted from the radiation source during the same time period. [ICRU 2003]

**Detection Limit** (DL): The smallest true value of a measured quantity which ensures a specified →*probability* of being detectable by the measurement procedure [ISO 2010a; 2010b]. The DL is the smallest true value that is associated with the statistical test and hypothesis in accordance with the→*Decision Threshold*, as follows: if in reality the true value is equal to or exceeds the DL, the probability of wrongly not rejecting the hypothesis (Type II error) is at most equal to a given value, β. The DL is an *a priori* quantity, evaluated for a particular measurement method in advance of the performance of a measurement. The detection limit is sometimes referred to as the minimum detectable activity (MDA), lower limit of detection (LLD) or limit of detection (LOD). [EURADOS 2013]

**Deterministic effect**: Injury in populations of cells, characterised by a threshold dose and an increase in the severity of the reaction as the dose is increased further. Also termed *tissue reaction*. [ICRP 2007]

**Direct measurement**: A generic term for any type of →*in vivo measurement* of →*incorporated* radionuclides (i.e. whole body measurement, lung measurement, thyroid measurement etc.). [ICRP 2015b]

**Dose assessment**: The process of assessing or estimating a dose to an individual based on the results of appropriate measurements. In this process the data are interpreted and doses are calculated using →*biokinetic models* and →*dosimetric models*.

**Dose coefficient**: →*Committed equivalent dose* to an organ or tissue T per unit →*intake* $h_T(\tau)$, or →*committed effective dose* per unit intake $e(\tau)$, where $\tau$ is the time period in years over which the received dose is calculated. The integration time is 50 y for occupational exposures. [EURADOS 2013]

**Dose limit**: The value of the →*effective dose* (where applicable, →*committed effective dose*) or the →*equivalent dose* in a specified period which must not be exceeded for an individual. [EC 2014]

**Dose of record**: The effective dose, assessed by summing the measured personal dose equivalent $H_p(10)$ and the →*committed effective dose* retrospectively determined for the →*Reference Worker* using results of →*individual monitoring* of the worker and ICRP →*reference models*. [ICRP 2015b]

**Dose per unit content function** *z(t)*: A set of values of z(t) representing the →*committed effective dose* or →*committed equivalent dose* to an organ $r_T$ per unit predicted activity content in the body or in a given organ (Sv $Bq^{-1}$), or per daily excretion. [ICRP 2015b]

**Dose record**: A record which contains the results of individual monitoring of a worker, required for all workers classified in category A, and for workers classified in category B only if national regulations require individual monitoring for workers in this category. [EC 2014]

**Dosimetric model**: A model used to estimate the mean →*absorbed dose* in each target organ or tissue resulting from →*nuclear transformations* of radionuclides present in the body. They are based on reference →*computational phantoms* and →*Monte Carlo* radiation transport codes.

**Dosimetry Service**: A body or an individual competent to calibrate, read or interpret individual monitoring devices, or to measure the activity of radionuclides in the human body or in biological samples, or to assess doses, whose capacity to act in this respect is recognised by the →*competent authority*. [EC 2014]

**Effective dose** *E*: A weighted average of →*equivalent doses* to organs or tissues, determined by taking the sum of the products of the equivalent doses in organs or tissues and the appropriate →*tissue weighting factors* ($w_T$). In ICRP Publication 60 the effective dose is defined as

$$E = \sum_T w_T H_T$$

In ICRP Publication 103, *E* is calculated from the average of male and female equivalent doses to individual organs or tissue regions:

$$E = \sum_T w_T \cdot \left[ \frac{H_T^M + H_T^F}{2} \right]$$

where $H_T^M$ and $H_T^F$ are the equivalent doses to the tissues or organs T of the Reference Adult Male and Reference Adult Female, respectively, and $w_T$ is the tissue weighting factor for tissue T, with:

$$\sum_T w_T = 1$$

The SI unit for effective dose is the sievert (Sv); 1 Sv = J $kg^{-1}$.

**Emergency**: A non-routine situation or event involving a radiation source that necessitates prompt action to mitigate serious adverse consequences for human health and safety, quality of life, property or the environment, or a hazard that could give rise to such serious adverse consequences. [EC 2014]

**Emergency worker**: Any person having a defined role in an emergency and who might be exposed to radiation while taking action in response to the emergency. [EC 2014]

**Equivalent dose** $H_T$: A weighted sum of →*absorbed doses* in an organ or tissue T, determined by taking the sum of the products of the absorbed doses due to different radiation types and the appropriate →*radiation weighting factors* ($w_R$). The SI unit for equivalent dose to an organ or tissue is the sievert (Sv); 1 Sv = J $kg^{-1}$.

**Error (of measurement)**: The result of a measurement minus the value of the measurand. A corrected measurement result is not the value of the measurand — that is, it is in error — because of imperfect measurement of the realised quantity due to random variations of the observations (random effects), inadequate determination of the corrections for systematic effects, and incomplete knowledge of certain physical phenomena (also systematic effects). Neither the value of the realised quantity nor the value of the measurand can ever be known exactly; all that can be known is their estimated values. [ISO/IEC 2014]

**Excretion rate**: Within the scope of this report, the excretion rate is the amount of activity excreted via urine or faeces during a 24-hour sampling period, with the decay of the radionuclide having been corrected for at the end of the 24-hour period. A special case is tritiated water (HTO) where the excretion rate is in general given in terms of the activity concentration in the excreted material. [EURADOS 2013]

**Exposure**: The state or condition of being subject to irradiation. External exposure is exposure to radiation from a source outside the body, and internal exposure is exposure to radiation from a source within the body.

**Exposure conditions**: A compilation of information describing the radionuclide(s) and associated chemical compound(s) to which workers are exposed, location and nature of any exposure event, time pattern of exposure, route of intake, physical and chemical characteristics of the material and whether →*personal protective equipment* is used.

**Fitting procedure**: Search for a set of values of the parameters of a mathematical model that predicts the values of a measured quantity, that is not inconsistent with observed measurement results.

**Fractional absorption in the gastro-intestinal tract** ($f_1$): The fraction of an element directly absorbed from the gastro-intestinal tract into blood, used in the Publication 30 [ICRP 1979] gastro-intestinal tract model. In the Human Alimentary Model (HATM), $f_1$ is replaced by $f_A$ (→*alimentary tract transfer factor*). [ICRP 2015b]

**Health detriment**: Reduction in length and quality of life occurring in a population after radiation exposure, including those detriments arising from →*tissue reactions*, cancer and severe genetic disorder. [EC 2014]

***In vitro* analysis**: Measurements to determine the presence of, or to measure the amount of, radioactive material in the excreta or in other biological materials removed from the body. [ISO 2010b]

***In vivo* monitoring**: Measurements of radioactive material in the human body utilising instrumentation that detects radiation emitted from the radioactive material in the body. [ISO 2010b]

**Incorporation**: Any process by which radioactive material is taken into the body by inhalation, ingestion, injection, absorption through intact skin, or via a wound.

**Indirect measurement**: Generic term for any kind of →*in vitro analysis* of material excreted or otherwise removed from the body (e.g. urinary and faecal analysis). The term is also includes air sampling measurements. [EURADOS 2013]

**Individual monitoring**: Monitoring by means of equipment worn by individual workers, or measurement of the quantities of radioactive materials in or on the bodies of individual workers, or measurement of radioactive material excreted by individual workers. [ISO 2006b]

**Intact skin**: Physically and functionally complete skin layer without scratches, wounds or cracks.

**Intake**: The total activity of a radionuclide entering the body from the external environment. Acute intake is defined as a single intake, taken to occur instantaneously; and chronic intake is defined as a protracted intake over a specified period of time. [EC 2013; ICRP 2015b]

**Intake pattern**: The rate of →*intake* of a →r*adionuclide* expressed as a function of time.

**Intake route**: The process by which a →*radionuclide* enters the body: inhalation, ingestion, absorption through the skin or via a wound.

**Intercalibration:** A programme of measurements conducted using a single standard, a set of standards or reference values to establish a common basis for measurement.

**Intercomparison:** A programme of measurement or information interpretation using participants' standards or references, to assess the comparability of results.

**Internal Dosimetry Service**: A (part of the) →*dosimetry service* that is capable of performing individual monitoring measurements and assessing doses from intakes of radionuclides.

**Investigation Level** (IL): A preset level, expressed in protection quantities, above which the cause or the implications of an →*intake* should be examined. Investigation Levels can be set for any operational parameter related to the individual or to the working environment. [ICRP 2015b]

**Licensee**: A natural or legal person who was granted a licence for a given practice.

**License**: permission granted in a document by the →*competent authority* to carry out a practice in accordance with specific conditions laid down in that document. [EC 2014]

**Local dose** (**Localised skin dose**): →*Equivalent dose* to the skin averaged over an area of 1 $cm^2$ at a nominal depth of 0.07 mm and at the respective point of interest. [ICRU 1997]

**Lognormal distribution**: The distribution of a random variable *x* when its logarithm *ln(x)* is normally distributed with mean $\mu$ and standard deviation $\sigma$. Its →*probability density function* (PDF) is given by:

$$f(x) = \frac{1}{\sqrt{2\pi}\sigma} e^{\left[-\frac{1}{2}\left(\frac{\ln(x)-\mu}{\sigma}\right)^2\right]}$$

The geometric mean and the geometric standard deviation of the lognormal distribution are respectively $\mu_g = e^m$ and $\sigma_g = e^\sigma$.

**Material-specific parameter value**: A model parameter value whose value can change depending on the physico-chemical properties of the material to which a worker is exposed.

**Maximum Likelihood Method**: A →*fitting procedure* that can be applied for the assessment of →*intake* from measurement data. The method searches for the maximum probability of observing the data given a value of intake (likelihood function of intake) on the basis of the →*scattering factors* and of the bioassay values per unit intake predicted by the biokinetic models. When the dataset consists of positive values only, an explicit equation of the intake can be obtained. See details in Annex 2 of [EURADOS 2013].

**Medical Physics Expert**: An individual or, if provided for in national legislation, a group of individuals, having the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to medical exposure, whose competence in this respect is recognised by the →*competent authority*. [EC 2014]

**Monitoring**: Measurement of dose or contamination for the purpose of the assessment or control of →*exposure* to radiation or radioactive material, and the interpretation of the results. [ISO 2006b]

**Monitoring interval**: Period between two times of measurement (used in →*routine monitoring programmes*). [ISO 2006b]

**Monte Carlo method**: Method of simulation using random or pseudo-random sampling of input variables of systems described by stochastic models; suitable for probabilistic calculation because of its relatively fast convergence when a large number of input variables are considered. Relevant applications are the simulation of interactions of ionising radiation or error propagation in uncertainty analysis.

**National Dose Register**: →*Dose records* must be submitted to a data system for individual radiological monitoring established by a Member State in accordance with the provisions of Annex X of Council Directive 2013/59/EURATOM. This data system may be realised either as a network or as a National Dose Register. [EC 2014]

**Normal distribution**: (Laplace-Gauss distribution): The probability distribution of a continuous random variable x with mean $\mu$ and standard deviation $\sigma$. Its →*probability density function* (PDF) is given by:

$$f(x) = \frac{1}{\sqrt{2\pi}\sigma} e^{\left[-\frac{1}{2}\left(\frac{x-\mu}{\sigma}\right)^2\right]}$$

**Nuclear transformation**: Process by which the nucleus of an unstable atom changes its nature by emitting excess energy in form of radiation, including alpha particles, beta particles, gamma rays and conversion electrons. See also →*Radioactive decay*.

**Observed chi-squared**: Calculated value derived from the normalised residuals between bioassay measurement results and model-predicted values; used as a test statistic to reject a fit of model predictions to the bioassay data. A mathematical definition is provided in section 6.3 of [EURADOS 2013].

**Occupational exposure**: →Exposure of workers, apprentices and students, incurred in the course of their work. [EC 2014]

**Occupational Health Service**: A health professional or body competent to perform medical surveillance of exposed workers and whose capacity to act in that respect is recognised by the →*competent authority*. [EC 2014]

**Outlier:** An observation that lies an abnormal distance from other values in a random sample from a population.

**Outside worker**: Any exposed worker who is not employed by the →*undertaking* responsible for the →*supervised* and →*controlled areas*, but performs activities in those areas, including, apprentices and students. [EC 2014]

**Personal protective equipment (PPE)**: Protective clothing, helmets, goggles, or other equipment designed to protect the wearer's body from exposure to hazardous materials.

**Phantom**: A physical or mathematical surrogate of a person, or of part of a person.

**Poisson distribution**: Probability distribution of a positive or null integer variable with mean $\lambda$, standard deviation $\sqrt{\lambda}$ and probability:

$$P(x) = e^{-\lambda}\frac{\lambda^x}{x!}$$

The probability of a nuclear transformation occurring within a specified time interval follows a Poisson distribution.

**Precision**: The closeness of agreement between independent test results obtained under stipulated conditions. Precision depends only on the distribution of random errors and does not relate to the true value or the specified value. The measure of precision is usually expressed in terms of imprecision and computed as a standard deviation of the test results. Less precision is reflected by a larger standard deviation. "Independent test results" means results obtained in a manner not influenced by any previous result on the same or similar test object. Quantitative measures of precision depend critically on the stipulated conditions. Repeatability and reproducibility conditions are particular sets of extreme conditions.

**Probability**: A real number between 0 and 1 associated with a random event. It can be related to a relative frequency of occurrence derived from many observations, or to a degree of belief that an event will occur. For a high degree of belief, the probability is near 1. [ISO/IEC 2014]

**Probability density function (PDF)**: (for a continuous random variable) The derivative (when it exists) of the distribution function:

$$f(x) = \frac{dF(x)}{dx}$$

$f(x)dx$ is the "probability element": $f(x)dx = P(x < X < x + dx)$. [ISO/IEC 2014]

**Probability distribution** (of a random variable): A function giving the probability that a random variable takes any given value or belongs to a given set of values. The probability on the whole set of values of the random variable equals 1. [ISO/IEC 2014]

**Prospective dose assessment**: A predictive →*dose assessment* for a postulated →*intake*, usually estimated using default exposure assumptions and model parameter values.

**Qualified expert**: A person having the knowledge and training needed to carry out physical, technical or radiochemical tests enabling doses to be assessed, and to

give advice in order to ensure effective protection of individuals and the correct operation of protective equipment, whose capacity to act as a qualified expert is recognised by the competent authorities. A qualified expert may be assigned the technical responsibility for the tasks of radiation protection of workers and members of the public [EC 1996]. In Council Directive 2013/59/Euratom [EC 2014] the term qualified expert was replaced by →*radiation protection expert*, →*medical physics expert* and →*radiation protection officer*.

**Quality assurance**: All those planned and systematic actions necessary to provide adequate assurance that a structure, system, component or procedure will perform satisfactorily in compliance with agreed standards. →*Quality control* is a part of quality assurance. [EC 2014]

**Quality control**: The set of operations (programming, coordinating, implementing) intended to maintain or to improve quality. It includes monitoring, evaluation and maintenance at required levels of all characteristics of performance of equipment that can be defined, measured, and controlled. [EC 2014]

**Quality management**: Management with regard to quality. Quality management can include establishing quality policies and quality objectives and processes to achieve these quality objectives through quality planning, →*quality assurance*, →*quality control* and quality improvement. [ISO 2015a]

**Quality management system**: A set of interrelated or interacting elements of an organisation to establish quality policies and quality objectives, and processes to achieve those objectives [ISO 2015a]

**Radiation Protection Expert** (RPE): an individual or, if provided for in the national legislation, a group of individuals having the knowledge, training and experience needed to give radiation protection advice in order to ensure the effective protection of individuals, and whose competence in this respect is recognised by the →*competent authority*. [EC 2014]

**Radiation Protection Officer** (RPO): an individual who is technically competent in radiation protection matters relevant for a given type of practice to supervise or perform the implementation of the radiation protection arrangements. [EC 2014]

**Radiation Protection Programme** (RPP): A programme that ensures protection and safety through the adoption of management structures, policies, procedures and organisational arrangements that are commensurate with the nature and extent of the risks. RPPs relate to all phases of a practice from design through process control to decommissioning.

**Radiation weighting factor** $w_R$: A dimensionless factor by which a contribution of radiation type R to the →*absorbed dose* in an organ or tissue is multiplied to reflect the relative biological effectiveness of that radiation type. It is used to derive the organ equivalent dose from the mean absorbed dose in an organ or tissue. [ICRP 2015b]

**Radioactive decay**: Process by which the nucleus of an unstable atom loses energy by emitting radiation, including alpha particles, beta particles, gamma rays and conversion electrons. See also →*Nuclear transformation*.

**Radioactive progeny**: The series (chain) of radionuclides formed as a consequence of the decay of a (parent) radionuclide. Also termed *daughters* or *decay products*.

**Recording level** (RL): A preset level above which a result should be recorded, lower values being ignored. [ICRP 2015b]

**Reference level:** In planned exposure situations, reference levels (i.e. →*recording level*, →*investigation level*) are dose values which are used to decide on the assignment of workers to →*individual monitoring programmes* and to evaluate the suitablility of those programmes. [ISO 2006] In an →*emergency* exposure situation or in an existing exposure situation, a reference level is the level of →*effective dose* or →*equivalent dose* to an organ or activity concentration above which it is judged

inappropriate to allow exposures to occur as a result of that exposure situation, even though it is not a limit that may not be exceeded. [EC 2014]

**Reference Male/Reference Female**: An idealised male or female with anatomical and physiological characteristics defined by ICRP for the purpose of radiological protection. The anatomical and physiological characteristics are defined in ICRP Publication 89 [ICRP 2002]. [EURADOS 2013]

**Reference model**: According to ICRP, a model adopted for the →*Reference Worker*. A reference biokinetic model describes the intake, uptake, distribution, and retention of a radionuclide in various organs or tissues of the body, and the subsequent excretion from the body by various pathways. In Council Directive 2013/59/Euratom, standard values and relationships for occupational exposures are those recommended in chapter 1 of ICRP Publication 119 and updates approved by Member States. [EU 2014; ICRP 2015b]

**Reference phantom**: The →*computational phantom* of the human body (i.e. a male or female voxel phantom based on medical imaging data) defined in Publication 110 [ICRP 2009] with anatomical characteristics reasonably similar to those of the →*Reference Male* and the →*Reference Female*. [ICRP 2015b]

**Reference Person:** An idealised person, for whom the →*equivalent doses* to organs and tissues are calculated by averaging the corresponding doses of the →*Reference Male* and the →*Reference Female*. The equivalent doses for the Reference Person are used for calculation of →*effective dose.* [ICRP 2015b]

**Reference Worker**: The adult →*Reference Person* combined with the →*reference biokinetic and dosimetric models* and their parameter values, as defined in ICRP's Occupational Intakes of Radionuclides (OIR) report series [ICRP 2015b; ICRP 2016b; ICRP 2017] for the Reference Worker (systemic biokinetic models, Human Respiratory Tract Model, Human Alimentary Tract Model, and dosimetric models). The structure and parameter values of biokinetic models of the Reference Worker are invariant on the sex, age, race, and other individual-specific characteristics, and are based on the →*Reference Male* parameter values where sex-specific models are available. [ICRP 2015b]

**Registrant**: A natural or legal person who is granted a registration for a given practice.

**Registration**: A permission granted in a document by the →*competent authority*, or granted by national legislation, through a simplified procedure, to carry out a practice in accordance with conditions laid down in national legislation or specified by a competent authority for this type or class of practice. [EC 2014]

**Relative biological effectiveness** (RBE): The ratio of a dose of a low-LET reference radiation to a dose of the radiation under consideration that gives an identical biological effect. RBE values vary with the dose, dose rate, and biological endpoint considered. [EURADOS 2013]

**Respiratory protective equipment** (RPE): →*Personal protective equipment*. designed to protect the wearer's respiratory tract against inhalation of airborne hazardous materials that would normally cause adverse health effects.

**Retrospective dose assessment**: A →*dose assessment* derived from measurements of →*radionuclide* activities in the body, in →*bioassay samples* and in air samples, made after an →*exposure*.

**Routine monitoring programme**: →A *monitoring programme* associated with continuing operations, intended to demonstrate that working conditions, including the levels of individual dose, remain satisfactory, that meets regulatory requirements. [ISO 2006b]

**Scattering factor** (SF): The geometric standard deviation of the →*lognormal distribution* of →*bioassay* measurements. The value takes into account measurement →*uncertainties* arising from counting statistics (Type A component) and uncertainties due to all other sources (Type B component). Note that this

document adopts the notation used in the IDEAS Guidelines, whereas in the ISO standards the scattering factor is indicated with the symbol $K_{SF}$. [EURADOS 2013, ISO 2011]

**Sensitivity analysis**: Quantification of the →*uncertainty* on an output variable due to the uncertainty on an input parameter value.

**Source region,** $r_S$: Region of the body containing the radionuclide of interest. The region may be an organ, a tissue, the contents of the alimentary tract or urinary bladder, or the surfaces of tissues as in the skeleton and the respiratory tract. [ICRP 2015b]

**Special monitoring programme**: →A *monitoring programme* performed to quantify significant →*exposures* following actual or suspected abnormal events. [ISO 2006b]

**Stochastic effects (of radiation)**: Malignant disease and heritable effects induced by radiation and for which the →*probability* of an effect occurring, but not its severity, is regarded as a function of dose without threshold. [ICRP 2007]

**Supervised areas**: An area subject to supervision for the purpose of protection against ionising radiation. [EC 2014]

**Target region,** $r_T$: Organ or tissue region of the body in which a radiation →*absorbed dose* is received. [ICRP 2015b]

**Target tissue**, *T*: Organs or tissues in the body for which tissue weighting factors are assigned in the assessment of the →*effective dose*. In many cases, each target tissue T corresponds to a single →*target region* $r_T$. In the case of the extrathoracic airways, thoracic airways, colon, and lymphatic nodes, however, a fractional weighting of more than one target region $r_T$ defines the target tissue. [ICRP 2015b]

**Task-related monitoring programme**: A *monitoring programme* related to a specific operation, conducted to provide information on a specific operation of limited duration, or following major modifications applied to the installations or operating procedures, or to confirm that the →*routine monitoring programme* is suitable. [ISO 2006b]

**Tissue reaction**: See →*Deterministic effect*

**Tissue weighting factor**: A factor by which the →*equivalent dose* to a→*target tissue T* is weighted to represent the relative contribution of that organ or tissue to overall radiation detriment from stochastic effects. [ICRP 2015b] See also →*Effective dose.*

**Traceability**: Ability to trace the history, application or location of an object. [ISO 2015a]

**Transfer Reference Standard** (TRS): Material that contains radionuclide components of interest in chemical and physical forms similar to radiobioassay specimens and that is used to quantify the amount of activity present in a person or sample measured. The radionuclides used for the preparation of the TRS are, when possible, related to →*certified reference materials*. The preparation procedures are verified and documented. [ISO 2010b]

**Triage monitoring programme**: A triage *monitoring programme* consists of frequent individual screening measurements performed at the workplace by local staff using standard laboratory instrumentation to detect whether a potential →*intake* has occurred. [ISO 2016a]

**Uncertainty**: Lack of knowledge of an item, a process or a quantity, due to variability and imprecision. The uncertainty of measurement is a parameter, associated with the result of a measurement, that characterises the dispersion of the values that could reasonably be attributed to the measurement. Uncertainty components are grouped into two categories based on their method of evaluation, "A" and "B". A Type A standard uncertainty is obtained from a probability density function derived from an observed frequency distribution, while a Type B standard uncertainty is obtained from an assumed probability density function based on the degree of belief that an event will occur. [ISO 2010b]

**Undertaking**: A natural or legal person who has legal responsibility under national law for carrying out a practice, or for a radiation source (including cases where the owner or holder of a radiation source does not conduct related human activities). [EC 2014]

**Uptake**: Activity that enters blood from the respiratory tract, gastro-intestinal tract or alimentary tract or through the skin.

**Workplace Monitoring**: Monitoring using measurements made in the working environment. [ISO 2006b]

**Wound**: Any break in the skin, dermis or epidermis as the result of violence, of action with a sharp object, of a chemical burn or a puncture incision.

# List of symbols and abbreviations

| | |
|---|---|
| ADC | Annular Diffusion Channel |
| ADR | Accord européen relatif au transport international des marchandises Dangereuses par Route |
| AI | Alveolar-interstitial region (HRTM) |
| AIDE | Activity and Internal Dose Estimates |
| ALARA | As Low As Reasonably Achievable |
| AMAD | Activity Median Aerodynamic Diameter |
| AMTD | Activity Median Thermodynamic Diameter |
| ANSI | American National Standards Institute |
| ANSM | Agence Nationale de Sécurité du Médicament |
| bb | Bronchiolar region (HRTM) |
| BB | Bronchial region (HRTM) |
| BfS | Bundesamt für Strahlenschutz |
| BOMAB | Bottle Mannikin Absorber |
| Bq | Bequerel - SI unit for activity |
| BSS | Basic Safety Standards |
| CAM | Continuous Air Monitor |
| CDF | Cumulative Distribution Function |
| CE | Council of Europe |
| CEA | Commissariat à l'énergie atomique et aux énergies alternatives |
| CIEMAT | Centro de Investigaciones Energéticas, Medioambientales y Tecnológicas |
| CPG | Clinical Practice Guidelines |
| CURE | Concerted Uranium Research in Europe |
| $d_j$ | Decision factor |
| D | Absorbed dose |
| $D_T$ | Mean absorbed dose in an organ or tissue T |
| $D_T(\tau)$ | Committed absorbed dose |
| DCF | Dose Conversion Factor |
| DDEP | Decay Data Evaluation Project |
| DIL | Derived Investigation Level |
| DL | Detection Limit |
| DT | Decision Threshold |
| DTPA | Diethylene triamine pentaacetic acid |
| $\Delta T$ | Monitoring interval |
| $e(\tau)$ | Committed effective dose coefficient |
| E | Effective dose |
| $E(\tau)$ | Committed effective dose |
| EC | European Commission |

| | |
|---|---|
| EEC | Equilibrium Equivalent Concentration |
| EGSnrc | Electron Gamma Shower softare of the Canadian NRC |
| EID | Electronic Integrating Device |
| ENEA | Agenzia nazionale per le nuove tecnologie, l'energia e lo sviluppo economico sostenibile |
| ET | Extrathoracic airways (HRTM) |
| $ET_1$ | Extrathoracic region 1 (HRTM) |
| $ET'_2$ | Extrathoracic region 2 (HRTM) |
| EU | European Union |
| EURADOS | European Radiation Dosimetry Group |
| EURATOM | European Atomic Energy Community |
| $f_A$ | Alimentary tract transfer factor |
| $f_b$ | Bound fraction (HRTM) |
| $f_r$ | Rapidly dissolved fraction (HRTM) |
| $f_{fs}$ | Physical form safety factor |
| $f_{hs}$ | Handling factor |
| $f_p$ | Unattached fraction |
| $f_{ps}$ | Protection safety factor |
| $f_1$ | Fractional absorption in the gastro-intestinal tract |
| F | Equilibrium factor |
| FDA | US Food and Drug Administration |
| FWHM | Full width at half maximum |
| FZK | Forschungszentrum Karlsruhe |
| gsd | geometric standard deviation |
| GEANT4 | Geometry And Tracking software platform |
| GI | Gastro-intestinal |
| GUI | Graphical User Interface |
| GUM | Guide to the expression of Uncertainty in Measurements |
| Gy | Gray - SI unit for absorbed dose (and also the corresponding committed doses) |
| $h_T(\tau)$ | Committed equivalent dose coefficient to organ or tissue T |
| $H_p(d)$ | Personal dose equivalent at a depth d |
| $H_T$ | Equivalent dose to organ or tissue T |
| $H_T(\tau)$ | Committed equivalent dose to organ or tissue T |
| HATM | Human Alimentary Tract Model |
| HPA | Health Protection Agency |
| HPGe | High Purity Germanium detector |
| HRTM | Human Respiratory Tract Model |
| HTO | Tritiated water |
| HVAC | Heating, Ventilation and Air Conditioning |
| I | Intake |

| | |
|---|---|
| IAEA | International Atomic Energy Agency |
| IARC | International Agency for Research on Cancer |
| ICP-MS | Inductively Couple Plasma Mass Spectrometry |
| ICRP | International Commission on Radiological Protection |
| ICRU | International Commission on Radiation Units and Measurements |
| IDEA | Internal Dose Equivalent Assessment |
| IDS | Internal Dosimety Service |
| IEC | International Electrotechnical Commission |
| IL | Investigation Level |
| ILO | International Labour Organization |
| IMBA | Integrated Modules for Bioassay Analysis |
| IRDG | Internal Radiation Dosimetry Group |
| IRSN | Institut de Radioprotection et de Sûreté Nucléaire |
| ISO | International Organization for Standardization |
| JAERI | Japan Atomic Energy Research Institute |
| KIT | Karlsruher Institut für Technologie |
| KPA | Kinetic Phosphorescence Analysis |
| $LaBr_3$:Ce | Lanthanum bromide detectors |
| LC | Left Colon (HATM) |
| LHS | Latin Hypercube Sampling |
| LLI | Lower Large Intestine (GI-Tract model) |
| LLNL | Lawrence Livermore National Laboratory |
| $LN_{ET}$ | Extrathoracic lymph nodes (HRTM) |
| $LN_{TH}$ | Thoracic lymph nodes (HRTM) |
| LNHB | Laboratoire National Herni Becquerel |
| LSC | Liquid Scintillation Counting |
| *m(t)* | Bioassay function |
| *M* | Result of a bioassay measurement |
| $M_c$ | Critical value |
| MCNP | Monte Carlo N-Particle transport code |
| MDC | Minimum Detectable Concentration |
| MIRD | Medical Internal Radiation Dose |
| MPE | Medical Physics Expert |
| NaI(Tl) | Thallium-activated sodium iodide |
| NCRP | National Council on Radiation Protection and Measurements |
| NEA | Nuclear Energy Agency |
| NORM | Naturally Occurring Radioactive Material |
| NPL | National Physics Laboratory |
| NRC | National Research Council |
| NRL | National Reference Level |

| | |
|---|---|
| OECD | Organisation for Economic Co-operation and Development |
| OHS | Occupational Health Service |
| OIR | Occupational Intakes of Radionuclides |
| ORAU | Oak Ridge Associated Universities |
| ORNL | Oak Ridge National Laboratory |
| PAE | Potential Alpha Energy |
| PAEC | Potential Alpha Energy Concentration |
| PAS | Personal Air Sampler (or Personal Air Sampling) |
| PDF | Probability density function |
| PET | Positron Emission Tomography |
| PHE | Public Health England |
| PPE | Personal Protective Equipment |
| PROCORAD | Association for the Promotion of Quality Control in Radiotoxicological Analysis |
| QA | Quality Assurance |
| QC | Quality Control |
| QMS | Quality Management System |
| $r_S$ | Source region |
| $r_T$ | Target region |
| REAC/TS | Radiation Emergency Assistance Center/Training Site |
| RBE | Relative Biological Effectiveness |
| RC | Right Colon (HATM) |
| RERF | Radiation Effects Research Foundation |
| RH | Relative humidity |
| RiPhyKo | Richtlinie für die physikalische Strahlenschutzkontrolle (German) |
| RL | Recording Level |
| RPE | Radiation Protection Expert |
| RPO | Radiation Protection Officer |
| RS | Rectosigmoid (HATM) |
| $s_b$ | Transfer rate of the bound material (HRTM) |
| $s_r$ | Transfer rate of the rapidly dissolved fraction (HRTM) |
| $s_s$ | Transfer rate of the slowly dissolved fraction (HRTM) |
| SAS | Static Air Sampler (or Static Air Sampling) |
| SF | Scattering Factor |
| SFMT | Société Française de Médecine du Travail |
| SPECT | Single-Photon Emission Computed Tomography |
| SRS | Simple Random Sampling |
| STAR | System for Test Atmospheres with Radon |
| Sv | Sievert - SI unit for equivalent and effective dose (and also the corresponding committed doses) |
| T | Target tissue |

| | |
|---|---|
| TH | Thoracic airways (HRTM) |
| TIMS | Thermal Ionisation Mass Spectrometry |
| ULI | Upper Large Intestine (GI-Tract model) |
| UNSCEAR | United Nations Scientific Committee on the Effects of Atomic Radiation |
| VMC | Voxel Monte Carlo |
| WeLMoS | Weighted Likelihood Monte Carlo Sampling |
| WHO | World Health Organization |
| WL | Working Level |
| WLM | Working Level Month |
| $w_R$ | Radiation weighting factor |
| $w_T$ | Tissue weighting factor |
| z(t) | Dose per unit content function |

# CHAPTER A – Purpose, Context and Scope, and Implementation by Internal Dosimetry Services

## A1. - Purpose, Context and Scope of the Technical Recommendations

### Purpose

In 2009, the European Commission published Technical Recommendations for Monitoring Individuals Occupationally Exposed to External Radiation, Report RP160 [EC 2009]. This replaced guidance RP73, published in 1994. The aim of RP160 is to provide guidance on those aspects of the implementation of the Directives of the European Union (EU) Parliament and of the Council Directives of the European Union (EU) that are directly related to individual monitoring of external radiation, and to encourage harmonisation and the eventual mutual recognition of services. This report presents Technical Recommendations for Monitoring Individuals for Occupational Intakes of Radionuclides[3]. It is intended to be complementary to RP160, and has a similar aim with respect to individual monitoring of internal radiation. The purpose of these Technical Recommendations is to present a complete account of the principles of individual monitoring and internal dosimetry, and to provide comprehensive guidance and recommendations on best practice. The Technical Recommendations are intended to be primarily informative in nature and they do not in themselves make prescriptive or normative statements about practices that must be adopted. They could form the basis of Best Practice Guides at the national or organisational level.

The target audience includes internal dosimetry services operating within the EU, as well as competent authorities. The Technical Recommendations are also expected to be of interest to site operators who are responsible for radiation protection programmes, to radiation protection experts who provide advice to site operators, and to manufacturers, laboratories providing bioassay services and government bodies aiming to harmonise regulations and guidance.

### Context

A number of international organisations provide standards, guidance, advice, and scientific and technical information on topics related to monitoring individuals for occupational intakes of radionuclides. However, no single document presents a complete account of the subject, and so a major aim is to provide recommendations that are comprehensive, detailed, authoritative and internally consistent.

The Technical Recommendations bring together requirements and guidance given in:

- EU Council Directive 2013/59/Euratom [EC 2014], which lays down basic safety standards for protection against the dangers arising from exposure to ionising radiation (replacing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom [EC 1996], 97/43/Euratom and 2003/122/Euratom);
- publications of the International Commission on Radiological Protection (ICRP) relating to occupational intakes of radionuclides;
- standards published by the International Organization for Standardization (ISO) relating to monitoring and dose assessment for workers occupationally exposed to a risk of internal contamination with radioactive material;
- relevant reports of the International Commission on Radiation Units and Measurements (ICRU);

[3] Referred to subsequently in this report as the "Technical Recommendations"

- relevant reports, technical documents and safety guides of the International Atomic Energy Agency (IAEA);
- the report of the European Radiation Dosimetry Group (EURADOS) on the estimation of internal doses from monitoring data;
- relevant national and international standards, guides, reports and technical documents issued by competent authorities in EU Member States.

The most important source documents are summarised in Figure A.1. The primary source for the Technical Recommendations in terms of the legislative environment is Council Directive 2013/59/Euratom[4]. The primary sources for radiation protection principles, biokinetic models, dosimetric models and recommendations on practice are the relevant ICRP Publications, the relevant ISO standards and the IDEAS Guidelines published by EURADOS. The other source documents are important sources for specific topics. Some of the source documents are currently under revision, as indicated by the lightly-shaded boxes in the figure.

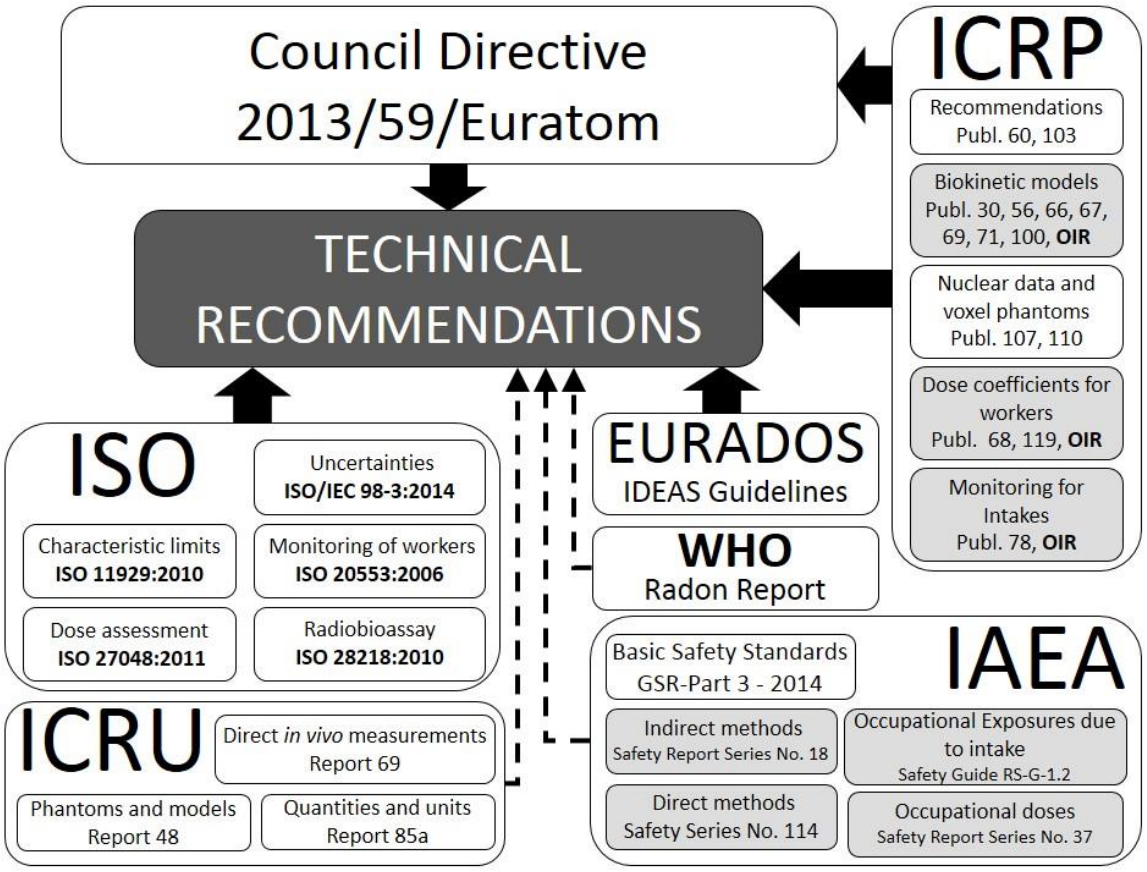



**Figure A.1** The main source documents used in developing the Technical Recommendations (Arrows indicate flow of information. Solid arrows indicate the primary sources.)

ICRP provides biokinetic and dosimetric models and data, intended for the assessment of internal doses resulting from occupational intakes, in a series of publications. Pre-2015 models and data are provided in ICRP Publications 30 (Parts 1–4 and Supplements), 56, 66, 67, 68, 69, 71, 72, 78 and 100 [ICRP 1979-1988; 1989; 1994a; 1993; 1994b; 1995a; 1995b; 1996; 1997; 2006]. Revised and updated models and data are being published in the ICRP Occupational Intakes of Radionuclides (OIR) series of reports (in five parts), commencing in 2015 [ICRP

[4] Referred to subsequently in this report as "the 2013 Directive"

2015b; 2016b; 2017]. While these models and data are essential tools for assessing internal doses, ICRP does not provide comprehensive guidance or recommendations on internal contamination monitoring, neither does it provide practical guidance on the methods for assessing internal doses from individual monitoring data, except in the case of simple situations where the worker is exposed to a single radionuclide, and a single measurement is made using a single monitoring method.

Working Group 13 of ISO Technical Committee 85, Sub Committee 2 (TC85/SC2) has provided three standards on: monitoring of workers exposed to a risk of internal contamination (ISO 20553:2006); performance criteria for radiobioassay (ISO 28218:2010); and internal dose assessment (ISO 27048:2011) [ISO 2006; 2010b; 2011]. These International Standards provide a highly standardised approach that is appropriate for a significant fraction of cases where monitoring and internal dose assessment are required in the event of occupational intakes of radionuclides; however, the approach is not appropriate for complex cases where multiple measurements have been made using different monitoring methods.

EURADOS has issued guidelines on the specific issue of a structured approach to internal dose assessment [EURADOS 2013], while IAEA and ICRU have also provided guidance on specific topics [IAEA 1996a; 1999a; 2000; 2004; ICRU 2003].

Thus, accounts of the principles and practice of individual monitoring and internal dosimetry are spread across a large number of publications and reports, issued by several international organisations, in different styles with different levels of content, and assuming different levels of expertise of the user. Furthermore, many valuable resources are only available at the national level in EU Member States.

The most important recent development with respect to individual monitoring for occupational intakes of radionuclides is the publication in January 2014 of the 2013 Directive [EC 2014] laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation. Member States are required to bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 6 February 2018.

The most important on-going development is the revision of ICRP's biokinetic and dosimetric models and data, currently in the process of being published in the OIR report series. Parts 1-3 of the OIR report series has been published [ICRP 2015b; 2016b; 2017]; Part 4 is expected to be published not before the end of 2018. Part 1 presents the revised Human Respiratory Tract Model for Radiological Protection (HRTM). Part 2-4 present revised systemic biokinetic models for all of the important elements, as well as dose coefficients and bioassay data for the important radionuclides of those elements. While major revisions and updates are being made to many of the biokinetic and dosimetric models, there is no fundamental change to the concepts and principles of internal dosimetry, and for the user, the main changes will be changes to numerical values of dose coefficients and bioassay data.

The publication of the OIR report series has implications for the implementation of the 2013 Directive, as is made clear by the following quotes, taken from the Directive.

Article 13 states that:

> *For the estimation of effective and equivalent doses, the appropriate standard values and relationships shall be used.*

Article 4, paragraph 96, states that:

> *"standard values and relationships" means values and relationships recommended in chapters 4 and 5 of ICRP Publication 116 for the estimation of doses from external exposure and chapter 1 of ICRP Publication 119 for the estimation of doses from internal exposure, including updates approved by Member States. Member States may approve the use of specific methods in specified cases relating to the physico-chemical properties of the radionuclide or other features of the exposure situation or of the exposed individual;*

The reference to Publication 119 [ICRP 2012] indicates that, for the present, the dosimetry system described in ICRP Publication 60 [ICRP 1991] should be used by default (in particular the values given in Publication 60 for the radiation weighting factors, $w_R$, and tissue weighting factors, $w_T$, should be used), rather than the more recent dosimetry system described in ICRP Publication 103 [ICRP 2007]. The reason for this statement is that, in practice, the Publication 103 dosimetry system cannot be used for internal dosimetry until the models and data described in ICRP's OIR report series are published. Anticipating this event, paragraph 11 of the Preamble to the Directive states that:

> *For internal exposure, while ICRP has consolidated in ICRP Publication 119 all earlier publications (on the basis of ICRP Publication 60) on dose coefficients, updates of this publication will be provided and the coefficients that are tabulated in it will be superseded by values based on the radiation and tissue weighting factors and phantoms laid down in ICRP Publication 103. The Commission will invite the group of experts referred to in Article 31 of the Euratom Treaty to continue to monitor scientific developments and the Commission will make recommendations on any updated values, relationships and coefficients, including those for exposure to radon, taking relevant opinions of the group of experts into account.*

Following publication of the OIR report series, it is anticipated that Working Group 13 of ISO TC85/SC2 will then revise the ISO standards on monitoring and dose assessment in order to take account of the revised dose coefficients and bioassay data.

The Technical Recommendations have therefore been developed so that they will be equally applicable both before and after adoption of the OIR report series by the European Commission and subsequently by competent authorities.

## Scope

This report explains the principles of individual monitoring and internal dosimetry, and presents comprehensive, detailed, authoritative and internally-consistent guidance and recommendations on practice. The emphasis is on individual monitoring and internal dosimetry during normal operations, although Annex III addresses monitoring for first responders after a major radiation accident at a nuclear facility, and Annex IV addresses internal dosimetry performed for the purpose of assessment of risks to health. Monitoring of the general public following a radiation accident or incident is not addressed. The Technical Recommendations take account of all recent developments and are fully up-to-date. They also take account of expected future developments, such as the developments embodied in the OIR report series, as discussed above. Ethical issues and human dignity are also addressed briefly.

As noted above, the Technical Recommendations do not in themselves make prescriptive or normative statements. Nevertheless, they do make clear where authorities or organisations (e.g. the European Commission, ICRP or ISO) have specified that certain methods, practices or conventions are mandatory according to their own regulations or schemes. In the case of ICRP and ISO, a specified method would become mandatory if a dosimetry service wishes to state that their methods are consistent with ICRP recommendations, or that their methods comply with the requirements of a certain ISO standard.

It is intended that the Technical Recommendations will be widely applicable across current and future Member States of the EU. The Technical Recommendations will promote the mobility of occupationally exposed workers within the EU by:

- encouraging the harmonisation of methodologies for the assessment of intakes of radionuclides used by internal dosimetry services in the EU,
- providing the basis for uniform approval criteria for internal dosimetry services, and
- standardising the criteria for the mutual recognition of dose records.

Exposures to radionuclides of all of the elements included within the scope of the OIR report series are considered in these Technical Recommendations.

The following issues are not directly addressed at a detailed level in the Technical Recommendations because they would be better addressed in detailed technical manuals or medical protocols:

- design of monitoring instruments;
- radiochemical analysis methods;
- removal of contamination on skin or clothing;
- therapeutic protocols for decorporation treatment.

Table A.1 lists the topics addressed in each Chapter and Annex.

**Table A.1** Chapter headings and topics

| Chapter | Topic |
|---|---|
| **A. Purpose, Context, Scope; Implementation by Internal Dosimetry Services** | The purpose, context and scope of this report |
| | Guide for the user on how to use this report |
| | The structure and content of each chapter and annex |
| | Status of the technical recommendations presented (i.e. informative vs. normative) |
| | Explanation of the system used for the classification of the recommendations |
| | Formal implementation of individual monitoring and dose assessment for occupational intakes of radionuclides by internal dosimetry services:<br>• Roles, duties and tasks<br>• Partners of the internal dosimetry service<br>• Required competencies of a bioassay laboratory<br>• Required competencies of a dose assessments service<br>• Management competencies<br>• Criteria for approval |
| **B. General principles** | Overview of monitoring and internal dosimetry |
| | Dosimetric and operational quantities |
| | Biokinetic and dosimetric models |
| | Methods for the assessment of intakes of radionuclides: Fundamental aspects including bioassay functions |
| | Dose assessment: Basic principles (including dose coefficients and dose per unit content) |
| **C. Monitoring programmes** | Information required in order to make decisions on the need for an individual monitoring programme |
| | Identification of workers for whom individual monitoring may be required |
| | Determination of the need for an individual monitoring programme |
| | Design of individual monitoring programmes |
| | The four categories of monitoring programmes (routine, special, confirmatory, task-related) |
| | Choice of monitoring method, monitoring intervals, frequency of measurements, models and assumptions for dose assessment |

| | |
|---|---|
| | Monitoring programme design for short-lived radionuclides |
| | Documentation of monitoring programmes |
| **D.**<br>**Monitoring techniques** | *In vivo* monitoring (detectors, background reduction, measurement geometries for generic radionuclides, measurement geometries for specific radionuclides, calibration, detection limit, decision threshold, uncertainties) |
| | *In vitro* (bioassay) monitoring (sample collection, sample preparation, measurement techniques [including alpha spectrometry, mass spectrometry, liquid scintillation counting, gamma spectrometry], identification and quantification of radionuclides, detection limit, decision threshold, uncertainties) |
| | Workplace monitoring techniques (personal air sampling, particle sampling statistics, static air sampling, PAS:SAS ratios, continuous air monitors, radon exposure monitoring, filter media, radionuclide measurements, system performance, calibration, sample measurements, detection limit, decision threshold, uncertainties) |
| **E.**<br>**Routine and special dose assessment** | Interpretation of monitoring data (information required from the workplace, additional information provided by individual monitoring, effect of confounding factors) |
| | Dose assessment in practice – Routine Monitoring |
| | Dose assessment in practice – Special Monitoring |
| | Criteria for selection of dose assessment software |
| | Dose assessment for intakes of short-lived radionuclides |
| | Monitoring and dosimetry for cutaneous contamination of intact skin |
| | Monitoring and dosimetry for wound cases |
| | Monitoring and dose assessment in the event of "decorporation therapy" |
| | Radiation protection for pregnant and breastfeeding workers |
| **F.**<br>**Accuracy requirements and Uncertainty analysis** | Sources of uncertainty |
| | Quantification of uncertainties |
| | Determination of the likely range of doses given a set of bioassay data |
| | Identification of the important sources of uncertainty |
| | Criteria for judging the acceptability of uncertainty related to a monitoring programme |
| | Provision of information on uncertainty associated with a dose assessment |
| **G.**<br>**Quality assurance and criteria for approval and accreditation** | Dose recording and reporting (recording levels, how long to retain data, traceability, communication of results, provision of information to workers) |
| | Quality assurance and quality control – reliability of monitoring data |
| | Quality assurance and quality control –reliability of dose assessments |

| | |
|---|---|
| | Accreditation/certification according to ISO / IEC standards |
| | Ethical aspects |
| | Participation in national & international intercomparisons (benefits, requirements, *in vivo* measurement intercomparisons, *in vitro* (sample bioassay) measurement intercomparisons, promotion of harmonisation) |
| **H.**<br>**Special Topic: Radon measurement and dosimetry for workers** | The EU's protection policy for radon exposure of workers |
| | Characteristics and behaviour of radon |
| | Risks from radon and communication strategies |
| | Measurement of radon, radon progeny and aerosol parameters, including detector types and quality assurance |
| | Measurement strategies for workplace and individual monitoring to demonstrate compliance with reference levels and dose limits, including detector choice, period of measurement and deployment of detectors |
| | Assessment of dose from exposure to radon |
| **Annex I.**<br>**Reference biokinetic and dosimetric models** | The models used in ICRP Publication 68, and the models used in the OIR report series |
| **Annex II.**<br>**Examples of monitoring programme design and internal dose assessment** | Examples that demonstrate the application of key features of the Technical Recommendations |
| **Annex III.**<br>**Monitoring and internal dosimetry for first responders in a major accident at a nuclear facility** | Measurements and internal dose assessments for first responders, who may be at significant risk of contamination during the emergency phase |
| **Annex IV.**<br>**Internal dosimetry for assessment of risk to health** | Internal dose assessment for accidental intakes, compensation cases and epidemiological studies |
| **Annex V.**<br>**Compilation of the Technical Recommendations** | |

## Guide to the Report

The Glossary at the beginning of this report defines and explains special terms that the reader may not be familiar with. This is followed by a list of mathematical symbols and commonly-used abbreviations.

Most of the following Chapters are preceded by a summary of the topics to be addressed. This summary takes the form of a single main "question" that is addressed, together with a set of subsidiary, more specific questions. Each Chapter then follows the following format:

- List of Special Terms used in the Chapter
- Introduction
- Technical and scientific discussion, with links to other Chapters where appropriate, making reference to:
    - Regulations and Directives

    - International recommendations, standards, guidelines
    - National standards, guides, reports and technical documents
- Tables and Figures
- Recommendations that give specific responses to each question stated at the beginning of the Chapter

After some of the Chapters, Appendices are included that present supplementary material which is relevant to to the subject of the Chapter, but which does not directly support the recommendations made.

The Special Terms list at the beginning of each Chapter identifies those special terms that are relevant for the understanding of the content of the Chapter. If necessary, readers should refer to the Glossary to familiarise themselves with the meaning of each special term before proceeding.

Chapter A1 and Chapter B do not provide recommendations or a set of questions to be answered, because the former Chapter describes the purpose, context and scope of this report, while the latter explains the basic principles of monitoring and internal dosimetry.

Annexes are included after the Chapters at the end of the report, and provide information on related topics, but for which no recommendations are made. Annex V presents a compilation of the Recommendations.

An extensive reference list of source documents is given at the end of the report.

The contents of other reports, guides, technical documents and standards are not reproduced in detail, since this would result in a report of excessive (and unnecessary) length. Rather, the information that can be found in these reports is summarised, and guidance is given on how to make use of the information. This helps to ensure that the Technical Recommendations will not become obsolete when other documents are updated.

The recommendations given in each Chapter are made by consensus within the team of authors of these Technical Recommendations, after assessment of the available evidence. The content of each recommendation has been validated as a consensus statement using the method described in the Clinical Practice Guidelines (CPG) [Field 1990; Shekelle 1999; Cluzeau 2003; Guyatt 2010; Eccles 2012]. The purpose of the CPG method is to provide a small number of concise, unambiguous recommendations, graded according to the identified levels of evidence, which address the questions asked. Based on evidence-based practice, the Technical Recommendations categorise a recommendation using one of three grades, as described in Table A.2.

Each recommendation is identified by the letter of the Chapter (one character) and by the number of the recommendation within the Chapter (two digits). One of the three grades is assigned to the recommendation (one character: M, I or A). For example, the identifier C02 is allocated to the 2$^{nd}$ recommendation of Chapter C (a grade I recommendation).

**Table A.2** Classification of the Recommendations

| GRADE | Criteria from Clinical Practice Guidelines |
|---|---|
| M | Grade M (mandatory), for recommendations that are legal requirements in accordance with European Directives. These recommendations are made on the basis of regulatory references. |
| I | Grade I (international recommendation) for recommendations formulated by international organisations such as ICRP, IAEA, ICRU, ISO, WHO and ILO, including international Basic Safety Standards. These recommendations are made on the basis of normative references and international standards. The source of the recommendation is indicated in the text of the recommendation. |
| A | Grade A (advisory recommendation) for expert decisions of the authors of the Technical Recommendations, based on best practices identified by review of the literature, or derived from a consensus of the opinions of recognised experts, or from professional agreements justified by expert feedback on occupational cases. Advisory recommendations have been subjected to extensive consultation and peer reviews conducted during the preparation of the Technical Recommendations. |

# A2 – Implementation by Internal Dosimetry Services: Duties, Partners and Approval

***MAIN QUESTION***

***Q1*** *What are the roles and duties of an Internal Dosimetry Service and which competencies are required?*

***Subsidiary questions***

***Q2*** *Who are the main partners of internal dosimetry services?*

***Q3*** *What types of criteria should be set for approval of an internal dosimetry service?*

## Special Terms used in this Chapter

Accreditation, Approval, Dosimetry Service, Internal Dosimetry Service, Competent Authority, National Dose Register, Occupational Health Service

## Introduction – General Remarks on Internal Dosimetry Services

Section A2 explains how individual monitoring and dosimetry after intakes of radionuclides should be formally implemented by internal dosimetry services[5]. The duties of an internal dosimetry service (IDS) and the tasks to be performed are described. The main partners of a dosimetry service and their roles are identified. The types of criteria to be set for the approval of an IDS are outlined.

***Q1****: What are the roles and duties of an Internal Dosimetry Service and which competencies are required?*

In the 2013 Directive [EC 2014] a dosimetry service is defined as:

> *a body or an individual competent to calibrate, read or interpret individual monitoring devices, or to measure radioactivity in the human body or in biological samples, or to assess doses, whose capacity to act in this respect is recognised by the competent authority.*

An IDS may perform all types of bioassay measurements or it could use or provide only one technique (e.g. *in vivo* monitoring), depending on the scope of the service. Typically, measurements of activity concentrations in air are performed by the undertaking and not by the IDS, and so these measurements are omitted in this definition. However, the assessment of doses following intakes of radionuclides must be included in the service's portfolio. The dosimetry service should interact with the Occupational Health Service (OHS) which performs the medical surveillance of workers. Depending on national regulations, the OHS could perform some of the tasks of the IDS (for example, the dose assessment could be performed by the OHS using monitoring measurements provided by the IDS). Apart from the means of implementation, the requirements for the tasks performed are the same.

[5] The term internal dosimetry service (IDS) is used in this report to avoid confusion with dosimetry services monitoring external exposures. This does not exclude the possibility that an IDS is part of a general dosimetry service performing individual monitoring for both external and internal exposures.

Article 79 of the 2013 Directive requires Member States to arrange for recognition of dosimetry services (as well as for Occupational Health Services, Radiation Protection Experts (RPE) and Medical Physics Experts (MPE)) by the competent authority [EC 2014]. The Basic Safety Standards of the International Atomic Energy Agency [IAEA 2014] also call for regulatory authorisation or approval of these services. The legal and regulatory frameworks for radiation protection in Member States are required to include regulations about the implementation of monitoring programmes, dose recording and reporting, which must then be followed by the IDS [EC 2014]. When, in the future, (most of) these aspects are harmonised throughout Europe, the approval of an IDS in several Member States should be possible.

## Competencies required of an Internal Dosimetry Service

The main tasks to be performed by the IDS may be divided into three groups:

- bioassay laboratory (i.e. activity measurements),
- dose assessments (i.e. calculations and reporting of doses), and
- management (i.e. planning and implementation of monitoring programmes).

Depending on national regulations, the tasks of the IDS may or may not be performed within a single institution or group. If multiple institutions or persons are involved in performing the monitoring, effective communication between the parties involved should be guaranteed. One important aspect for all of these groups of tasks is the competency of the service's personnel; arrangements to ensure the continuity of expertise of these services are explicitly required in Article 14 of the 2013 Directive [EC 2014]. Therefore proper education and regular training of the service's staff are essential. Knowledge management and knowledge transfer to younger members of staff should be considered by the IDS.

### Bioassay Laboratory

The IDS may act as a bioassay laboratory, applying *in vivo* and/or *in vitro* techniques to perform measurements of radionuclide activities. Laboratories should be suitably designed and equipped; the design of a bioassay laboratory is similar to any other radiochemical or spectrometry laboratory. A location remote from other laboratories that could give rise to radionuclide emissions is a desirable choice for a bioassay laboratory, since low-level activity measurements are required. In the case of bioassay sample analysis, precautions for handling potentially infectious material should be taken into account. The routine procedures applied in the laboratories should be documented and the staff performing them should be trained accordingly.

Performance criteria for bioassay measurements are specified by ISO 28218:2010 [ISO 2010b]. Details and recommendations about measurement techniques and the requirements specified by this ISO standard and other literature may be found in **Chapters D** and **G** of this report. Competent authorities and IDS laboratories are recommended to follow this guidance, which also includes information on quality control and quality assurance programmes to be established by the IDS. Furthermore it is highly recommended to implement a quality management system. This system should follow the requirements of the ISO 9001:2015 standard on quality management [ISO 2015c] and the ISO/IEC 17025:2005 standard on technical competencies of testing laboratories [ISO/IEC 2005]. The system should be certified or accredited according to these two standards; accreditation and/or certification with regular internal and external auditing have been shown to be a factor that promotes continuous improvement in an organisation. Furthermore the laboratory should regularly participate in intercomparison exercises to demonstrate the quality of its measurements. Competent authorities are recommended to make participation in intercomparison exercises mandatory for approved IDS. However, competent authorities or delegated laboratories should then be able to provide this type of exercise on a regular basis. Details and recommendations about quality management systems, intercomparison exercises and accreditation of bioassay laboratories are provided in **Chapter G** of this report.

The 2013 Directive sets no requirements on retaining measurement results. However it is recommended to retain this information, as well as the traceability chain for each measurement, for later inspection and re-evaluation of the measurements.

### Dose Assessments

The IDS must be able to calculate committed doses based on the results of monitoring measurements [EC 2014]. Typically the intake (Bq) is also assessed during the calculations. The biokinetic and dosimetric models and data that should be employed in these calculations are recommended in ICRP Publications 30, 56, 66, 67, 71, 78, 100, 110 and 119 [ICRP 1979; 1989; 1993b; 1994a; 1994b; 1995b; 1997; 2006; 2009b; 2012]. Updated versions of the models are being published in the OIR report series [ICRP 2015b; 2016b; 2017]. ISO standards on "Monitoring of workers occupationally exposed to a risk of internal contamination with radioactive material" (ISO 20553:2006) [ISO 2006] and on "Dose Assessment for the monitoring of workers for internal radiation exposure" (ISO 27048:2011) [ISO 2011] as well as "Guidelines for the Estimation of Committed Effective Dose from Incorporation Monitoring Data" (IDEAS Guidelines) [EURADOS 2013] describing the process of dose calculations are available. The procedures applied at the IDS and the software used for the calculations (especially if a dedicated software tool is employed by the IDS) should be documented properly, and the models applied should be specified. The staff performing the calculations should be trained accordingly. Details and recommendations about dose assessment methods are provided in **Chapter E** of this report. Regulations and requirements about recording and reporting of results (as presented in **Chapter G** of this report) should be implemented by the IDS. Documentation must be clear and concise and enable an independent recalculation of doses at later times.

Intercomparison exercises on dose assessments based on case studies (e.g. [Hurtgen 2005; IAEA 2007]) are a useful tool to monitor the competencies of the IDS and to train staff. However, this type of exercise is not currently performed frequently and competent authorities should consider ways for providing them on a regular basis.

### Management

The facilities of the IDS, its capabilities and the services offered must be fully documented. This documentation is required for approval of the IDS but also supports contact with workers, customers and authorities. The IDS implements (parts of) the monitoring programme for internal contamination (see **Chapter C**), and so it should have access to the documentation of the monitoring programme and the underlying rationale and assumptions. In the case of routine monitoring, the IDS should implement mechanisms to record information on the monitoring intervals, and to record that the workers comply with them. Mechanisms to record information on the doses assessed after routine measurements in previous monitoring intervals should also be established. The former will ensure that the requirements of the programme will be fulfilled; the latter is required for calculation of the annual dose of record.

## Partners of Internal Dosimetry Services

***Q2**: Who are the main partners of internal dosimetry services?*

Article 4 of the 2013 Directive [EC 2014] defines several roles in relation to the individual monitoring of workers. The main role is that of the IDS, which has already been described. The "undertaking", which is defined as:

> *a natural or legal person who has legal responsibility under national law for carrying out a practice, or for a radiation source.*

is a natural partner that should interact with the IDS by providing the opportunity to perform the required bioassay measurements, and by providing the information required for the dose assessment. Additional information that would improve the reliability of the dose assessment can often only be provided by the undertaking (e.g. by the responsible radiation protection officer). Therefore it is recommended that the

IDS should establish direct contacts with the undertaking to ensure contact points for further enquiries in a dose assessment procedure and for consultation about further measures (e.g. special monitoring) to be taken if required. In the case of outside workers who are not directly employed by the undertaking, contacts with the employers should also be established in order to receive further information (for example, information about previous intakes that might be used in the dose assessment).

Another role which interacts with the IDS is that of the Occupational Health Service (OHS), whose main duty according to Article 80 of the 2013 Directive is to perform medical surveillance of radiation workers. Medical examinations and information from individual monitoring of workers both provide an important input to this surveillance. Thus there should be effective links between the OHS and the IDS. The 2013 Directive also specifies the role of the Radiation Protection Expert (RPE). An RPE should have the knowledge, training and experience needed to give radiation protection advice in order to ensure the effective protection of individuals. The duties associated with the role include advising on individual monitoring programmes. Here the RPE should provide advice during the definition of the monitoring programme, working with the IDS and OHS, and again the three roles (IDS, OHS and RPE) should interact effectively. Depending on national regulations, different tasks are performed within these roles, and several roles could be performed by single persons or bodies.

All Member States are required to establish a competent authority designated for the legal duties required by the 2013 Directive. This could be achieved either by establishing a single competent authority or by setting up a system of these authorities. Regarding individual monitoring, one task of the competent authority is the approval of dosimetry services, occupational health services and radiation protection experts. Criteria for approval should be defined by the competent authority.

The IDS should establish contact points at the competent authority, the OHS, at other dosimetry services and at the data system for individual radiological monitoring. National regulations may implement the latter either as a network or as a National Dose Register, following Articles 43, 44, 51 and the provisions of Annex X of the 2013 Directive. The IDS should itself take measures to be available for communication within a reasonable time with undertakings (who are its customers), with other IDS (who constitute its peer group for the sharing of expertise) and with the competent authorities (who define and supervise the criteria for approval).

## Approval of Internal Dosimetry Services

***Q3**: What types of criteria should be set for approval of IDS?*

The 2013 Directive [EC 2014] requires Member States to implement a system for approval and recognition of dosimetry services. A minimum set of requirements to be fulfilled by an IDS should be laid out and a formal procedure for approval should be defined by the competent authority. An IDS seeking approval should document its facilities, procedures, capabilities and the services to be approved in a formal request to the competent authority, which will then review (and, if all criteria are met, allow) the request. Depending on national regulations, regular auditing of the IDS by the approving authority may be required as part of the formal procedure; accreditation audits and/or participation in intercomparison exercises could replace these reviews.

The criteria for approval are in the areas of:

- **Management and Quality Assurance:** The service should demonstrate that it is reliable and has the necessary staff, expertise, resources and facilities for providing and maintaining the service offered. A quality management system (see **Chapter G**) is helpful in demonstrating this. Certification of the service's management system to ISO 9001:2015 [ISO 2015c] and accreditation of the laboratory services to ISO/IEC 17025:2005 [ISO/IEC 2005] is recommended here but may not be required by national legislation (see **Chapter G**).
  Since specialised expertise is required to perform internal dosimetry, the minimum requirements on education and training of the IDS staff should be

defined by the competent authority and should be included in approval requirements.

- **Bioassay Measurements:** Established measurement methods (see **Chapter D**) to be applied by the IDS should be specified (or referenced) in the request for approval. Minimum performance criteria for the methods applied should be laid out by the competent authority in the approval criteria. Here, ISO 28218:2010 [ISO 2010b] may be used as a reference document. The regular monitoring of these criteria (e.g. by intercomparison exercises) should be required for the (re)-approval of the IDS.
- **Dose Assessments:** A reference/standard procedure for evaluating (routine) monitoring data (see **Chapter E**) should be specified by the IDS. Depending on national regulations, this could be approved by the competent authority. Guidelines for the evaluation of non-routine cases (expert assessments) should also be specified by the IDS (see **Chapter E**). Explicit reference to the biokinetic models applied in internal dose assessments should be made; together with the use of the standard procedure, this will ensure that results are objective and standardised, and independent of the evaluating IDS. Documentation of all methods for handling monitoring data and the results of dose assessments should be required, and reviewed as part of the approval process.
- **Reporting:** Criteria on the availability of the service (e.g. response times) and schedules for the reporting of results should be defined in the criteria for approval. Reliable methods for documenting monitoring programmes and the results of dose assessments should also be required. ISO 20553:2006 [ISO 2006] may be used as a reference document. Formal requirements on the documentation (i.e. the data that should be reported, and the format, see **Chapter G**) should be defined in the criteria for approval. The link to the data system for individual radiological monitoring (e.g. the National Dose Register, if implemented by the Member State) should be defined. National legislation relating to record keeping and handling of personal data should also be taken into account.

Details and recommendations on these topics may be found in the corresponding Chapters of this report. Table A.3 summarises the important topics for an IDS and its approval. It also provides links to the corresponding Chapters and provides references to the main standards and documents that address these topics.

**Table A.3** Compilation of topics of relevance for Internal Dosimetry Services.

| Topic | Chapter in this Report | References |
|---|---|---|
| Accreditation | G | ISO 9001:2015 [ISO 2015c]<br>ISO 15189:2012 [ISO 2012a]<br>ISO/IEC 17025:2005 [ISO/IEC 2005] |
| Dose Assessment (general methodology) | B, E | ICRP OIR ("2015 onwards")[ICRP 2015b]<br>ICRP 78 ("pre-2015") [ICRP 1997]<br>ISO 27048:2011 [ISO 2011]<br>IAEA Safety Standards Series R-G-1.2 [IAEA1999a] (superseded) |
| Monitoring Programmes | C | ISO 20553:2006 [ISO 2006]<br>ISO 16637:2016 [ISO 2016b] |
| *In vitro* monitoring | D | IAEA Safety Series 18 [IAEA 2000] |
| *In vivo* monitoring | D | ICRU Report 69 [ICRU 2003]<br>IAEA Safety Series 114 [IAEA 1996a] |
| Dose Assessment (procedures) | E | ISO 27048:2011 [ISO 2011]<br>IDEAS Guidelines [EURADOS 2013] |
| Performance Criteria for Radiobioassay Measurements | D, G | ISO 28218:2010 [ISO 2010b]<br>ISO 11929:2010 [ISO 2010a] |
| Intercomparison Exercises | D,G | ISO 13528:2015 [ISO 2015b]<br>ISO/IEC 17025:2005 [ISO/IEC 2005] |
| Quality Assurance | D, G | ISO 9001:2015 [ISO 2015c]<br>ISO/IEC 17025:2005 [ISO/IEC 2005]<br>ISO 28218:2010 [ISO 2010b] |
| Quality Control | D, G | ISO 28218:2010 [ISO 2010b] |
| Quality Management (general principles) | G | ISO 9001:2015 [ISO 2015c] |
| Quality Management (laboratory requirements) | G | ISO 15189:2012 [ISO 2012a]<br>ISO/IEC 17025:2005 [ISO/IEC 2005] |
| Record Keeping | G | ISO 20553:2006 [ISO 2006] |
| Training of Staff | D, E, G | ISO 9001:2015 [ISO 2015c]<br>ISO 15189:2012 [ISO 2012a]<br>ISO/IEC 17025:2005 [ISO/IEC 2005] |

## Recommendations

| R# | G | Text of the recommendation |
|---|---|---|
| | | ***Q1**: What are the roles and duties of an Internal Dosimetry Service and which competencies are required?* |
| A01 | M | Competent authorities in the Member States must implement a system for approval/recognition of internal dosimetry services that perform monitoring for internal contamination by measurements of activity directly in the body and/or in excreta sample (urine/faeces), and the subsequent dose assessments [EC 2014]. |
| A02 | A | Internal dosimetry services may also be approved to perform monitoring by measurement of activity-in-air samples, and to perform the subsequent dose assessments. |
| A03 | A | Competent authorities in the Member States should aim to harmonise these systems for approval of dosimetry services to enable mutual recognition of the services throughout Europe. |
| | | ***Q2**: Who are the main partners of internal dosimetry services?* |
| A04 | A | Internal dosimetry services should establish communication with the radiation protection units of the customer (i.e. the undertaking, and in the case of outside workers also the employer), the Occupational Health Services, the data system for individual radiological monitoring (e.g. a National Dose Register) and other internal dosimetry services. |
| | | ***Q3**: What types of criteria should be set for approval of an internal dosimetry service?* |
| A05 | I | The criteria defined by the competent authority for approval of internal dosimetry services should address:<br>• Definitions or references to established methods for bioassay measurements that should be applied by internal dosimetry services.<br>• Minimum performance criteria for the measurement procedures and ways to monitor compliance with the criteria.<br>• Specification by the IDS of reference procedures for evaluating (routine) monitoring data and the subsequent dose assessment.<br>Minimum requirements on the reporting and documentation of measurements and dose assessments should be specified by the competent authority.<br>Several ISO standards on these topics are available [ISO 2006; 2010b; 2011; 2015c; ISO/IEC 2005] |

Grade: M = Mandatory, I = International, A = Advisory

# CHAPTER B – General Principles of Monitoring Individuals for Occupational Intakes of Radionuclides

## Special Terms used in this Chapter

Absorbed dose, Bioassay, Biokinetic model, Clearance, Committed dose, Deposition, Deterministic effect, Dosimetric model, Equivalent dose, Effective dose, Excretion rate, Individual monitoring, Intake, Internal dosimetry, Monitoring, NORM, Nuclear transformation, Occupational exposure, Organ, Radiation weighting factor, Radionuclide decay, Radionuclide decay data, Reference model, Relative biological effectiveness, Retention, Source organ, Stochastic effect, Target organ, Tissue, Tissue reaction, Tissue weighting factor, Uptake.

## Intakes of Radionuclides, Monitoring and Internal Dosimetry: An Overview

*Internal dosimetry* addresses the determination of ionising radiation doses resulting from the intake of radioactive materials into the body by inhalation, ingestion, absorption through intact skin or via wounds. Internal doses may be determined for particular organs or tissues in the body, or, using the concept of effective dose, for the whole body. It is not possible to measure internal doses directly, although the activity of a radionuclide in the body can be measured or estimated. *Individual monitoring* for internal contamination is the direct or indirect measurement ("bioassay") of the amount of a radionuclide in the body, and the retrospective assessment of intakes and subsequent internal doses using the results of such measurements. Measurements of air concentrations of radionuclides in the workplace may also be used to estimate intakes and resulting internal doses. Assessments of effective dose may be used to demonstrate compliance with legal requirements for dose limitation (although the contributions from external exposure must also be taken into account).

Occupational exposures to radioactive materials may result from working in the nuclear industry, particularly in fuel production and reprocessing plants, but other occupations can also give rise to exposures at work. These include working in NORM industries, scientific research using radio-labelled compounds, the manufacture of labelled pharmaceuticals and the manufacture of sealed and unsealed radioactive sources. Radionuclides are also used extensively in clinical settings, both for diagnosis (e.g. $^{99m}$Tc-labelled compounds for SPECT imaging and $^{11}$C- or $^{18}$F-labelled compounds for PET imaging) and for therapy (e.g. treatment of hyperthyroidism and thyroid cancer metastases with $^{131}$I, radioimmunotherapy with compounds labelled with $^{131}$I or $^{90}$Y), and medical staff can be occupationally exposed as a result. For workers, the most frequent route of intake is inhalation. Intakes by ingestion are not usually expected, since eating or drinking in controlled areas in workplaces is not permitted and inadvertent ingestion is limited by the use of personal protective equipment (PPE). However, when contamination levels in the workplace environment are significant (such as may arise as a result of mining and milling of NORM), ingestion may occur as a result of contamination of the mouth or lips, or transfer to the mouth from the hands. In the event of accidents, wounds may represent an additional route of intake.

ICRP's OIR report series, Part 1 [ICRP 2015b], gives a clear statement of the purpose of internal dosimetry in the context of occupational exposure. Paragraph (2) states that:

> *An adequate assessment of occupational internal exposure resulting from intakes of radionuclides is essential for the design, planning and authorisation of a facility or activity, for the optimisation of radiation protection of workers, for operational radiation protection and for the retrospective demonstration of compliance with regulatory requirements*.

Internal dosimetry may also be used for the purpose of assessment of risks to health. In almost all cases, assessment of the risk or severity of any adverse effects on health resulting from an intake of a radionuclide includes an assessment of internal doses to

organs or tissues in the body. Assessment of health risks requires the assessment of absorbed doses to organs and tissues; equivalent doses to organs and effective dose are radiation protection quantities and should not be used for the purpose of individual health risk assessment [ICRP 2007]. Stochastic risks to health (most notably, cancer risks) are evaluated from assessed doses making use of information on the relationship between risk and dose such as that provided by epidemiology studies, notably the follow up of Japanese A-bomb survivors [RERF 2005]. At high doses, the likelihood and severity of tissue reactions leading to severe deterministic health effects may be assessed by comparing absorbed doses to organs and tissues with threshold doses associated with a particular tissue reaction for a specified organ/tissue and radiation type.

The principles and practice associated with the various steps involved in the assessment of internal dose are addressed in detail later in this report. This overview explains the dose assessment process in outline, so that when the reader is making use of the material presented later in the report, it will be clear how the detailed material fits into the overall scheme.

Since internal doses cannot be measured directly, they have to be calculated using mathematical models describing the biokinetic behaviour of radionuclides in the body, and the transport and absorption of ionising radiation within the body (**this chapter and Annex I**). The main steps in the calculation of internal dose from first principles, using the result of a monitoring measurement (**Chapters C and D**) as the starting point, are described below and summarised in Figure B.1.

a. Calculation of the radionuclide **intake**

    1. from a bioassay measurement of the activity of a radionuclide in the body of a worker, using a reference biokinetic model to predict the retention of the radionuclide; ***or***

    2. from a bioassay measurement of the activity of a radionuclide in an excreta sample provided by the worker, using a reference biokinetic model to predict the excretion rate of the radionuclide; ***or***

    3. from a measurement of the activity concentration of a radionuclide in an air sample, using data on reference breathing rates **(inhalation only)**; ***or***

    4. from multiple bioassay measurements obtained using one or more monitoring methods

b. Modelling of the **intake** process to determine the location(s) in the body (e.g. regions of the respiratory tract; organs in the gastro-intestinal tract) where the radionuclide is deposited or through which it transits and the amounts deposited in those locations

c. Modelling of the **clearance** of the radionuclide from the initial site of deposition, to determine the amount cleared and rates of clearance

d. Modelling of the **uptake** of the radionuclide from the initial deposition site to the blood and then to the rest of the body

e. Determination of the amounts then **deposited** in the various organs and tissues of the body, and the rates at which the radionuclide is removed from these organs and tissues

f. Determination of the number of **nuclear transformations** (i.e. radionuclide decays) that occur in the organs and tissues of the body over a specified period of time after the intake. This period of time is the dose commitment period (50 years for occupational exposure)

g. Calculation of the amounts of **energy deposited** in each target organ as a result of a single nuclear transformation in each source organ, using published compilations of radionuclide decay data and simulations of radiation-matter interactions based on anatomical phantoms and computer codes

h. Calculation of the **committed absorbed dose** received by each organ over the dose commitment period, from the amount of energy deposited per unit mass of the organ from all nuclear transformations (determined as in (f))

i. Calculation of the **committed equivalent dose** received by each organ over the dose commitment period, determined by applying the appropriate radiation weighting factors to the absorbed dose for each radiation type

j. Calculation of the **committed effective dose**, determined by applying the appropriate tissue weighting factors to the committed equivalent dose for each organ and then summing in order to determine a weighted average.

Steps a–f require the application of biokinetic models to determine the time-dependent distribution of the radionuclide throughout the body, while steps g–j require the application of dosimetric models to determine absorbed and equivalent doses to organs and tissues, and the effective dose.

In practice (**Chapter E; Annex II**), a bioassay measurement of a specified radionuclide is interpreted using published, tabulated data for retention per unit intake, excretion rate per unit intake, dose per unit intake, and dose per unit content. Various software packages are also available for assessing doses from bioassay measurements (**Chapter E**). These software packages are particularly useful when multiple bioassay measurements obtained using different monitoring methods are to be assessed. The evaluation of uncertainties on assessed doses is discussed in **Chapter F**.

Following completion of a dose assessment, Internal Dosimetry Services are required to use formalised arrangements for recording and reporting the results. Formal quality management systems governing the operation of the dosimetry service are also required, and increasing emphasis is being placed on accreditation to national and/or international standards (**Chapters G and H**).

In general terms, a broadly standardised approach to the assessment of internal dose is used, as described by Steps a–j, above. The general approach (as opposed to its implementation) does not depend on the identity of the radionuclide, nor does it depend on the physical or chemical form of the material taken into the body. The approach is also independent of the precise conditions of an occupational exposure (intake route, time pattern of intake, etc.). Of course, each of the steps described above require data and/or models that are specific to each radionuclide (e.g. radionuclide decay data), to the material (e.g. inhaled particle size, chemical compound), or to the element (e.g. the systemic biokinetic model), with the result that computed dose coefficients and retention and excretion functions are specific to a particular radionuclide, material and the exposure conditions.

However, some exposure situations require special attention. These include exposures to radionuclides due to intakes *via* skin or wounds; exposures that are followed by decorporation therapy; exposures of pregnant and breastfeeding workers; occupational exposure to radon; exposures of workers to radionuclides resulting from a major accident at a nuclear facility; and exposures to radionuclides that require individual assessment of risks of stochastic and deterministic effects on health (**Chapter E, sections E4, E5 and E6, Chapter H, Annex III and Annex IV**).

Assessments of health risks require specific consideration of issues such as the relative biological effectiveness (RBE) for the biological end-point of interest, and tissue reactions at high absorbed doses.

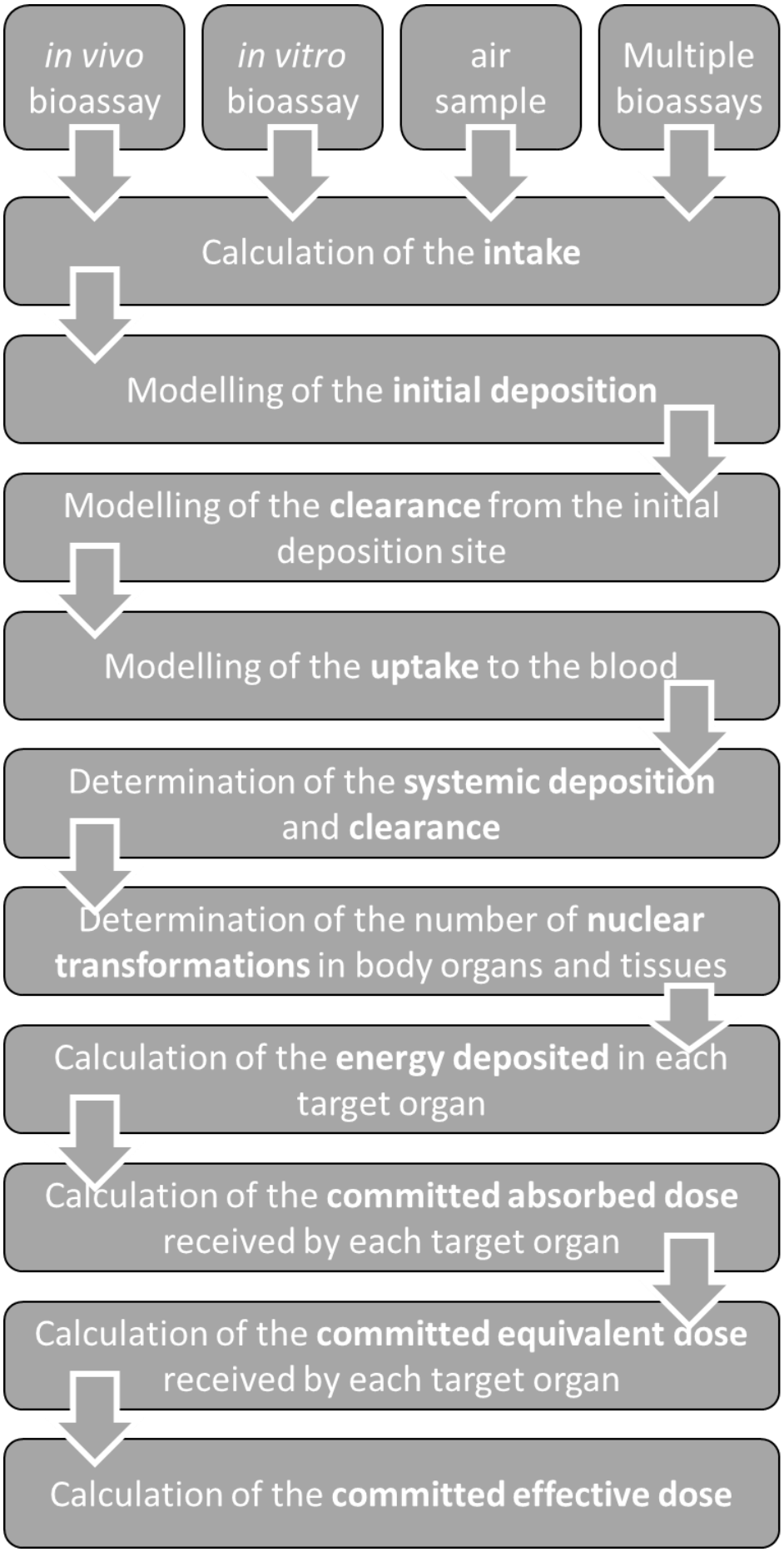



**Figure B.1** Steps in the calculation of internal dose

## Dosimetric and Operational Quantities

### Equivalence of Different Notations

Different definitions and notations for the dosimetric and operational quantities have been used in internal dosimetry over the years, not without some risks of confusion. A joint working group of ICRP and the Medical Internal Radiation Dose (MIRD) Committee of the U.S. Society of Nuclear Medicine has presented a proposal for harmonisation [Bolch 2009]. The notation adopted by ICRP in the OIR report series [ICRP 2015b] is a slight modification of this proposal. In this report, the same nomenclature as is used in the OIR report series is adopted. For the sake of clarity and uniformity, it is used here also when referring to quantities and numerical values presented by ICRP in previous publications using the slightly different notation of ICRP Publication 68 [ICRP 1994b]. Table B.1 shows the relations between the three nomenclatures:

**Table B.1** Comparison of nomenclature used in ICRP Publication 68 [ICRP 1994b], MIRD/ICRP proposal [Bolch 2009] and OIR report series [ICRP 2015b]

| Quantity or parameter | [ICRP 1994b] | [Bolch 2009] | [ICRP 2015b] |
|---|---|---|---|
| Source region | $S$ | $r_S$ | $r_S$ |
| Target region/tissue | $T$ | $r_T$ | $r_T$ / $T$* |
| Dose integration period | $\tau$ | $T_D$ | $\tau$ *or 50*** |
| Committed absorbed dose in target | $D_T(\tau)$ | $D(r_T,T_D)$ | $D_T(50)$** |
| Committed equivalent dose to target | $H_T(\tau)$ | $H(r_T,T_D)$ | $H_T(50)$** |
| Committed equivalent dose coefficient | $h_T(\tau)$ | $h(r_T,T_D)$ | $h_T(50)$** |
| Committed effective dose | $E$ | $E$ | $E$ |
| Committed effective dose coefficient | $e(\tau)$ | $e(T_D)$ | $e(50)$** |

* T - target tissues for which tissue weighting factors have been assigned
** Adult workers only

### Physical Dose Quantities

The basic physical dose quantity is the *absorbed dose*, $D$. It is used for all types of ionising radiation and any irradiation geometry. It is defined as the quotient of $d\bar{\varepsilon}$ by $dm$, where $d\bar{\varepsilon}$ is the mean energy imparted by ionising radiation to a mass d$m$ of matter, that is:

$$D = \frac{d\bar{\varepsilon}}{dm} \qquad \text{(Eq. B.1)}$$

The SI unit is J kg$^{-1}$ and its special name is gray (Gy).

In radiation protection the absorbed dose is in general averaged over a target region $r_T$ and is given the name *organ absorbed dose* $D_T$. A target region can be either an organ (the liver or kidneys, for example) or a tissue (e.g. muscle tissue). In some cases the quantity of interest is not the averaged dose for the whole organ or tissue, but rather the averaged dose for regions containing the radiosensitive cells in the organ or tissue. Examples of such regions are the walls of the human alimentary tract [ICRP 2006], the airway walls of the human respiratory tract [ICRP 1994a; ICRP 2015b], the skeleton, and the skin (where dose is assessed for a thin layer at a depth of 70 μm from the skin surface [ICRP 1977]). In some other cases, the dose to an organ or tissue is calculated by weighting doses estimated separately for its sub-regions. This is the case for doses to the extrathoracic region of the respiratory tract, doses to the lungs and doses to the colon (see **Annex I**). Similarly, the dose to lymphatic nodes is considered to be the mass-weighted sum of the doses to the lymphatic nodes in the extrathoracic airways, the thoracic lymph nodes and the lymphatic nodes outside the respiratory tract regions [ICRP 2015b].

## Radiation Protection Quantities

Some types of radiation are more effective than others in causing biological effects. To account for this, the quantity *equivalent dose to a target region* $r_T$ is defined by

$$H_T = \sum_R w_R \cdot D_{R,T} \qquad \text{(Eq. B.2)}$$

where

$D_{R,T}$ mean absorbed dose to the target organ or tissue $r_T$ due to radiation type $R$

$w_R$ radiation weighting factor.

The nominal values of $w_R$ are derived from considerations of the scientific evidence for the radiotoxicity of the different types of radiation. They are a set of rounded values averaged over both sexes and all ages of a reference population, and refer specifically only to stochastic effects. According to ICRP [ICRP 1991; 2007] the radiation weighting factor is 1 for photons, electrons, positrons, beta particles, and muons, and 20 for alpha particles, fission fragments and heavy ions. For neutrons $w_R$ is a function of neutron energy, and ICRP Publication 103 [ICRP 2007] has introduced a continuous function, replacing the step function presented in the 1990 Recommendations [ICRP 1991]. It has also updated the $w_R$ value for protons (reduced from 5 to 2) and introduced a value for charged pions (2). Because $w_R$ is dimensionless, the SI unit of the equivalent dose to an organ is also J $kg^{-1}$, and it is given the special name sievert (Sv) to distinguish it from the absorbed dose to an organ.

Some radionuclides (e.g., $^{99m}$Tc, $^{123}$I, $^{125}$I, and $^{201}$Tl) emit Auger electrons, which have very short ranges (comparable to the dimension of a DNA strand) in the tissues. Therefore, the biological effects of these low-energy electrons may be greater than those of electrons and beta particles when the radionuclide is incorporated into the DNA of the cell nucleus. ICRP acknowledges that for Auger electron emitters bound to DNA, a larger $w_R$ (of about 20) may be appropriate but it does not recommend a specific value [ICRP 2003; 2007].

**Table B.2** Radiation weighting factors $w_R$ given in ICRP Publication 60 [ICRP 1991] and ICRP Publication 103 [ICRP 2007]

| Radiation type | ICRP Publication 60 | ICRP Publication 103 |
|---|---|---|
| Photons | 1 | 1 |
| Electrons and muons | 1 | 1 |
| Protons and charged pions | 5[a] | 2 |
| Alpha particles, fission fragments, heavy ions | 20 | 20 |
| Neutrons | $= \begin{cases} 5 & E_n < 10\,keV \\ 10 & 10\,keV \le E_n \le 100\,keV \\ 20 & 100\,keV < E_n \le 2\,MeV \\ 20 & 2\,MeV < E_n \le 20\,MeV \\ 5 & E_n > 20\,MeV \end{cases}$ | $= \begin{cases} 2.5 + 18.2 \cdot e^{-[\ln(E_n)]^2/6} & E_n < 1\,MeV \\ 5.0 + 17.0 \cdot e^{-[\ln(2E_n)]^2/6} & 1\,MeV \le E_n \le 50\,MeV \\ 2.5 + 3.25 \cdot e^{-[\ln(0.04 \cdot E_n)]^2/6} & E_n > 50\,MeV \end{cases}$ |

[a]In ICRP Publication 60 the value of 5 applies only to protons.

Internal exposures have two peculiarities in comparison with external irradiation:

(i) the radiation sources (i.e. the organs and tissues where the incorporated radionuclides have accumulated) are inside the body,

(ii) the irradiation continues as long as the radionuclides remain inside the body, with a rate that changes with time.

The dose rate to the target region $r_T$ delivered by each source region $r_S$ is integrated over a given time period $\tau$ after intake:

$$H_T(\tau) = \int_0^\tau \dot{H}_T(t)dt = \sum_{r_S} \int_0^\tau A(r_S,t)\, S_w(r_T \leftarrow r_S,t)dt \qquad \text{(Eq. B.3)}$$

where

$\dot{H}_T(t)$ equivalent dose rate in the target organ or tissue $r_T$ at time $t$;

$A(r_S,t)$ activity (in Bq) in the source region $r_S$ at time $t$;

$S_w(r_T \leftarrow r_S,t)$ quantity representing the mean equivalent dose rate to target region $r_T$ at time $t$ per unit activity present in source tissue $r_S$, in $Sv \cdot (Bq \cdot s^{-1})$.

The activity $A(r_S,t)$ varies with time as a consequence of the physical decay of the radionuclide and of the transport and exchange of material between the different organs and tissues, and thus take into consideration the biokinetics of the incorporated material. The factor $S_w$ depends on the type and energy of emitted radiations, on sizes and shapes of the source and the target regions and on their relative distance, e.g. it depends on the anatomy of the subject. For occupational exposures $S_w$ is considered to be time-independent.

The time-integrated quantity $H_T(\tau)$ is given the name *committed equivalent dose*, meaning that it is the dose to the target organ due to the initial intake and committed over (i.e. received over) a time period $\tau$. In general, the integration period $\tau$ is taken to be 50 years after the intake for workers and up to age 70 years for members of the public. Since the age of the reference adult is considered to be 20 years at the time of intake, the period of integration for adult members of the public is the same as for workers. In the event of intakes of different radionuclides, the total committed equivalent dose to an organ is the sum of the contributions of each radionuclide.

The *effective dose* was introduced in ICRP Publication 26 [ICRP 1977] as a risk-related quantity for assessment of detriment from radiation-induced stochastic effects such as cancer and hereditary effects. It is a weighted mean value of the equivalent doses to a selected number of target tissues for which explicit tissue weighting factors $w_T$ are recommended. In the methodology of ICRP Publications 26 and 60 the effective dose E is defined by:

$$E = \sum_T w_T \cdot H_T \qquad \text{(Eq. B.4)}$$

Similarly, as for $w_R$, the nominal values of $w_T$ are based on considerations of the scientific evidence for the radiosensitivity of different tissues. The $w_T$ values were chosen to represent the contributions of individual organs to the overall radiation detriment from stochastic effects. They are rounded values averaged over both sexes and all ages of a reference population.

The values of $w_T$ used for the calculation of the dose coefficients compiled in ICRP Publication 119 [ICRP 2012] are those given in ICRP Publication 60 and are listed in column 2 of Table B.3.

Tissues with explicit $w_T$ values include the colon and a generic tissue called 'remainder'. These are not specifically defined as targets in the dosimetric models (see below) used for the calculation of the factors $S_w(r_T \leftarrow r_S,t)$. Therefore, specific rules have been established for the calculation of equivalent doses to these tissues.

The equivalent dose to the colon $H_{colon}$ is defined by:

$$H_{colon} = 0.57 \cdot H_{ULI} + 0.43 \cdot H_{LLI} \qquad \text{(Eq. B.5)}$$

where $H_{ULI}$ and $H_{LLI}$ are the equivalent doses to the walls of the upper and lower large intestine, respectively [ICRP 1993b]. The equivalent dose to the remainder tissue is the mass-weighted average of the equivalent doses for 10 listed organs and tissues: adrenals, brain, extrathoracic airways, small intestine, kidneys, muscle, pancreas, spleen, thymus and uterus [ICRP 1994b]. If, however, the highest equivalent dose among all target tissues is the equivalent dose to one of the 10 remainder organs and tissues listed above, then the "splitting rule" applies: that is, half of the tissue weighting factor for the remainder (i.e. 0.025) is assigned to that highest tissue equivalent dose and the other half is assigned to the mass-weighted average of the equivalent doses for the other remainder tissues.

**Table B.3** Tissue weighting factors $w_T$ given in ICRP Publication 60 [ICRP 1991] and ICRP Publication 103 [ICRP 2007]

| Organ | ICRP Publication 60 | ICRP Publication 103 |
|---|---|---|
| Gonads | 0.20 | 0.08 |
| Red bone marrow | 0.12 | 0.12 |
| Colon | 0.12 | 0.12 |
| Lung | 0.12 | 0.12 |
| Stomach | 0.12 | 0.12 |
| Urinary bladder | 0.05 | 0.04 |
| Breast | 0.05 | 0.12 |
| Liver | 0.05 | 0.04 |
| Oesophagus | 0.05 | 0.04 |
| Thyroid | 0.05 | 0.04 |
| Skin | 0.01 | 0.01 |
| Bone surface | 0.01 | 0.01 |
| Brain | - | 0.01 |
| Salivary glands | - | 0.01 |
| Remainder | 0.05 | 0.12 |

ICRP Publication 103 has introduced changes to the definition of effective dose. To reflect the concept that effective dose has to be applied to a large population group of all ages and both sexes rather than to individuals, sex-averaged organ equivalent doses are used for its calculation:

$$E = \sum_T w_T \cdot \frac{(H_T^M + H_T^F)}{2} \qquad \text{(Eq. B.6)}$$

where $H_T^M$ and $H_T^F$ are the equivalent doses to target T for the Reference Male and Female, respectively.

According to the formalism of ICRP Publication 103, the equivalent dose to the colon is calculated as the mass-weighted average of the equivalent doses to the right colon ($h_{RC}$), the left colon ($h_{LC}$) and the rectosigmoid ($h_{RS}$):

$$H_{colon} = 0.4 \cdot h_{RC} + 0.4 \cdot h_{LC} + 0.2 \cdot h_{RS} \qquad \text{(Eq. B.7)}$$

The remainder dose is the arithmetic mean of the dose to 13 organs and tissues: adrenals, extrathoracic airways, gallbladder, heart, kidneys, lymphatic nodes, skeletal muscle, oral mucosa, pancreas, prostate (for the Reference Male), small intestine, spleen, thymus, and uterus/cervix (for the Reference Female). The "splitting rule" does not apply in the Publication 103 scheme, and therefore the effective dose is (formally) additive. Moreover, the values of $w_T$ have been changed in ICRP Publication

103 [ICRP 2007] to account for new knowledge on radiation effects (column 3 of Table B.3).

## Use of Effective Dose

Effective dose as defined by ICRP is intended for use as a protection quantity on the basis of reference values, and is calculated for reference persons, not for specific individuals. Article 4, paragraph 96 of the the 2013 Directive [EC 2014] clearly states that the "standard values and relationships" to be used for the estimation of effective and equivalent doses are those recommended by ICRP. The same article allows Member States to

> *…approve the use of specific methods in specified cases relating to (…) other features (…) of the exposed individual*

The "specified cases" indicated in the text of the 2013 Directive could be those cases for which fitting of the predictions of the reference models to individual bioassay data is required, as might be necessary in the case of special monitoring (see **Chapter E3**). It is recognised that ICRP considers that effective dose to the Reference Person should be calculated for specified exposure conditions (ICRP Publication 130, Paragraph (13)) only allowing changes to parameters related to the physico-chemical properties of the incorporated material (such as the particle size distribution of an inhaled aerosol, AMAD, or its absorption and transfer rates after inhalation: $f_r$, $s_r$, $s_s$, $f_b$ and $s_b$, or ingestion: $f_1$ or $f_A$).

However, it is recommended here that the results of dose assessments in which parameter values describing features of the exposed individual have been changed should also be designated as equivalent dose or effective dose. This is consistent with the above-mentioned paragraph 96 of the 2013 Directive, provided that the methods used are approved at national level by the competent authority. In this context, it is noted that absorption characteristics ($f_r$, $s_r$, $s_s$, $f_b$, $s_b$, $f_1$ and $f_A$) may also depend on individual physiology and not only on material-specific factors.

For individual risk assessment, absorbed organ doses calculated separately for the various radiation types should be used together with specific risk coefficients. For this purpose, the differences in the biological effects of different radiations are better accounted for by using the relative biological effectiveness (RBE) rather than $w_R$, especially for deterministic effects. Whereas $w_R$ has been defined as a set of rounded values averaged over both sexes and all ages of a reference population, and refers specifically only to stochastic effects, experimentally-determined values of RBE are available which are dependent on dose, dose rate, fractionation, and the cells or tissues in which the effect is being assessed [ICRP 2003].

## Dose Coefficients

The dose coefficient, $h_T(50)$ or $e(50)$, is the committed organ equivalent dose or committed effective dose (integrated over 50 years for adult workers) per unit intake of a radionuclide, with the unit Sv $Bq^{-1}$. Effective dose coefficients have been published for the intake routes inhalation and ingestion in ICRP Publication 119 [ICRP 2012] using the scheme defined in ICRP Publication 60 [ICRP 1991] and biokinetic and dosimetric models described in Publications 30, 66 and 68 [ICRP 1979-1988; 1994a; 1994b]. The OIR report series [ICRP 2015b] provides revised dose coefficients calculated with improved versions of the biokinetic and dosimetric models, including a revision of the ICRP Publication 66 Human Respiratory Tract Model (HRTM) [ICRP 1994a], a Human Alimentary Tract Model (HATM) that supersedes the Publication 30 gastro-intestinal tract model [ICRP 1979], physiologically realistic systemic models and anthropomorphic computational phantoms [ICRP 2006; 2009b; 2015b]. More details on the models are given in the following paragraphs and in **Annex I**.

Dose coefficients are specified for different routes of intake, particle size, and absorption Type. Dose coefficients include the contribution to dose of progeny radionuclides produced within the body as a result of in-growth after incorporation of the parent radionuclide. Progeny radionuclides may also be present in the external environment and may be inhaled or ingested together with the parent radionuclide, in

which case the contribution to the dose due to their direct intake must be calculated separately.

### Bioassay Functions

For the interpretation of bioassay measurements, retention and excretion functions (*m(t)*) are needed. These functions, expressed as a fraction of the intake, predict the activity present in selected organs, in the total body or in excreta samples as a function of time after intake. They are used to calculate intake and then the committed equivalent dose to organs and/or committed effective dose, as described below (Eqs. B.9-B.11).

In ICRP Publication 78 [ICRP 1997] and in the OIR report series [ICRP 2015b], retention functions are given for total body (i.e. activity in all compartments of the biokinetic model including the contents of urinary bladder, gastro-intestinal (or alimentary) tract), lungs (activity in all compartments of the thoracic region of the respiratory tract including thoracic lymph nodes), skeleton (activity in all trabecular and cortical bone compartments and in active and inactive marrow) and other specified organs such as thyroid. These functions are calculated for various times after an acute intake by a specified intake route (i.e. inhalation or ingestion).

In the ICRP Publications mentioned above, urinary and faecal excretion functions are given as the activity excreted over 24 hours at several times after an acute intake. The values are decay-corrected to the end of the sampling interval.

It should be noted that the bioassay data given in the OIR report series were derived using male biokinetics. Female organ doses were also calculated, with the assumption of male biokinetics. This simplifying assumption is considered by ICRP to be appropriate for the monitoring of workers when tissue/organ absorbed doses are far below the thresholds for tissue reactions.

### Dose per Unit Content Function

When standard assumptions are appropriate, a simplified assessment of committed equivalent dose to organs $H_T$ and committed effective dose $E$ can be obtained from the result $M$ of the measurement of the activity of a radionuclide in the body, in an organ or in daily excretion, by means of the dose per unit content functions, *z(t)*, as described below (Eq. B.12).

Values of the dose per unit content functions *z(t)* are provided by ICRP in its OIR report series and in their accompanying electronic data. They are calculated by dividing the dose coefficient by the corresponding bioassay function [ICRP 2015b]:

$$z(t) = \frac{e(50)}{m(t)} \qquad \text{(Eq. B.8)}$$

These functions represent the committed effective dose or committed equivalent dose to an organ per unit activity content in the body or in a given organ, or per unit daily excretion at a given time t after intake. Similarly to the dose coefficients, they are specified for different routes of intake, particle size, and absorption Type. Their use allows the intermediate steps of calculating the intake value and applying dose coefficients to be omitted, thus avoiding the potential mistake of using different versions of the same model or different model parameter values in a calculation.

## Biokinetic and Dosimetric Models

As already mentioned in the introduction to this chapter, occupational intakes of radioactive material occur mainly via inhalation. The safety regulations adopted in the workplace, when followed, should be sufficient to prevent any intake via ingestion and via absorption through intact skin (with the exception of incorporation of tritium through intact skin). In the event of accidents, however, wounds are an additional possible pathway of incorporation. Whatever the intake route, radioactive material entering the body can be retained at the site of incorporation, and then directly cleared from the body or absorbed into the blood *(uptake)*. In this case, radionuclides

enter the systemic circulation and are distributed to selected organs and tissues, where they are retained before being transported back to the blood and/or excreted. From blood, the radionuclides may also be subsequently recycled back to the organs. All these intake, incorporation, transfer and clearance processes are described using compartmental models.

General compartmental models, valid for all radionuclides, are provided by ICRP for the most common intake routes of inhalation and ingestion (i.e. for the respiratory tract and for the gastro-intestinal (or alimentary) tract). Additionally, a number of element-specific systemic models describe the behaviour of the radionuclides after they have entered the blood circulation.

The fate of a radionuclide after intake may thus be described by combining the available biokinetic models. With the help of specific software it is possible to calculate the time-activity functions $A(r_S,t)$ in each source region $r_S$ (Equation B.3). In the same way it is possible to calculate the bioassay functions, i.e. the time-activity functions describing the retention in the whole body, in selected organs and tissues, and the activity in urinary and faecal excretion samples. The bioassay functions are needed to interpret the results of *in vivo* or *in vitro* measurements, as described in **Chapter E**.

While in the body, the material emits penetrating and non-penetrating radiation as a result of radioactive decay, which releases energy both into the organ or tissue where the radionuclide is deposited (source region $r_S$) and into the surrounding regions (target region $r_T$). The processes of radiation transport within the body and of energy deposition in the target regions are described by means of dosimetric models.

The outputs of the biokinetic and dosimetric models used in internal dosimetry are linearly related to intake. Therefore the dose, organ retention and excretion at any time after a given intake is the quantity predicted by the models for a unit intake (1 Bq) multiplied by the intake.

The following sections briefly summarise the main features of the models commonly used in occupational radiation protection, notably the models recommended by ICRP. Further details on the models are given in **Annex I** and in the related ICRP Publications where they are presented.

## Biokinetic Models

### Inhalation

The biokinetic behaviour of inhaled material is described by the Human Respiratory Tract Model (HRTM) of ICRP Publication 66 [ICRP 1994a], which is used for the calculation of the dose coefficients and bioassay functions according to ICRP Publication 60 recommendations and weighting factors [ICRP 1991] and summarised in ICRP Publication 119 [ICRP 2012]. In this model the respiratory tract is treated as two tissues: the extrathoracic (ET) and the thoracic airways (TH), and further subdivided into regions according mainly to their characteristic mean retention time and their different sensitivities to radiation. The thoracic airways consist of bronchial (BB), bronchiolar (bb) and alveolar-interstitial (AI) regions and the thoracic lymph nodes ($LN_{TH}$). The extrathoracic airways are the anterior nasal passage ($ET_1$), the posterior nasal passages, including pharynx and larynx ($ET'_2$) and the extrathoracic lymph nodes ($LN_{ET}$). The main processes characterising the biokinetics of radionuclides in the respiratory tract are deposition and clearance:

- The fractional deposition of an aerosol in each region depends mainly on its particle size distribution and on the related geometric standard deviation. For practical applications, the Activity Median Aerodynamic Diameter (AMAD) and the Activity Median Thermodynamic Diameter (AMTD) are used to characterise the sizes of the aerosol particles. Values of the fractional deposition have been calculated for a particle size range of practical interest (0.6 nm – 100 μm) taking into account characteristic parameters such as air flow for the ET regions, and lung size and breathing rate for the thoracic regions.
- Clearance of material is described by two competitive processes:

(i) the movement of particles inside the regions of the respiratory tract towards the gastro-intestinal (or alimentary) tract and lymph nodes (particle transport), and

(ii) absorption into blood.

Additionally, some material deposited in the anterior extra-thoracic region is removed by extrinsic means such as nose-blowing. The model assumes that the rate of absorption is the same for all respiratory tract regions except in the anterior nose, where none occurs. Removal rates due to particle transport and absorption to blood are taken to be independent of each other. It is further assumed that all clearance rates are independent of age and sex. For all elements, default values of parameters are recommended, according to whether the absorption is considered to be fast (Type F), moderate (M) or slow (S). Gases or vapours, for which instantaneous uptake into blood may be recommended, are considered to be Type V (very fast) materials.

The relevant parameters for characterising an inhaled substance are therefore its aerosol size, expressed in terms of the AMAD, which influences the amount of activity deposited in each region of the respiratory tract, and its absorption Type, which influences the rate of transfer to blood.

In the OIR report series, a revised version of the HRTM is presented [ICRP 2015b] and is used in the calculations of the dose coefficients and bioassay functions made according to ICRP Publication 103 recommendations and weighting factors [ICRP 2007]. In the revised HRTM, the distribution of the deposit between regions of the ET airways is modified, a simpler structure of the thoracic airways is introduced and new values of the absorption parameters for default Types F, M and S are adopted. Additionally, the OIR reports series recommends and uses material-specific rates of absorption for a number of elements and compounds for which reliable and consistent information is available.

### Ingestion

The biokinetic behaviour of ingested material is described by the gastro-intestinal (GI) tract model of ICRP Publication 30 [ICRP 1979] and by the Human Alimentary Tract Model (HATM) of ICRP Publication 100 [ICRP 2006]. The GI tract model is a 4-compartment-structure consisting of stomach, small intestine, upper and lower large intestine, with generic values of the transfer coefficients. Material present in the small intestine can be absorbed into blood to a varying extent, depending on the element and its chemical form. The fraction of material entering the circulation (fractional absorption) is expressed by the parameter $f_1$, and values of $f_1$ are given for each element/compound. The GI tract model was used for the calculation of the dose coefficients and bioassay functions according to ICRP Publication 60 and summarised in ICRP Publication 119.

The HATM is a more realistic model with a more complex and detailed structure, and contains many more compartments than the GI tract model, including the initial compartments of oral cavity and oesophagus, which have mean retention times of only a few seconds. The HATM allows for absorption to blood from nearly all sections of the alimentary tract, and for radionuclide deposition and retention in the oral mucosa or walls of the stomach and intestines, where radiosensitive cells are located. From there, radionuclides can be subsequently recycled back into the contents of the alimentary tract. The total fractional intestinal absorption is thus the combined effect of processes occurring in different regions of the alimentary tract and is quantified using the parameter $f_A$.

The default assumption is that absorption of an element and its radioisotopes to blood occurs only in the small intestine, so that in most practical cases the values of $f_A$ coincide with $f_1$ as defined for the GI tract model. Absorption from other regions is included only where information to support it is available. The HATM is used in the calculations of the dose coefficients and bioassay functions presented in the OIR report series.

### Wounds

Internal exposure resulting from wounds almost always arises as a result of accidents in the workplace, and provision of generic dose coefficients or bioassay functions would be of limited value. Indeed, as stated in Paragraph 80 of ICRP Publication 130 [ICRP 2015b]:

> *Uptake from wounds can vary greatly depending on the circumstances of a particular incident, and in practice, the assessment of internal contamination is treated on a case-by-case basis.*

For that reason ICRP does not give detailed advice on assessing doses from intakes of radionuclides from wound sites. Nonetheless, wound exposures occur and intake and dose need to be assessed. For this purpose, the wound model presented by the United States National Council on Radiation Protection and Measurements (NCRP) may be applied [NCRP 2007]. It describes the clearance from the wound site to the blood either directly or by transport via the regional lymph nodes, and consists of five compartments. In this model the compartments do not correspond to organs or tissues, but rather to different physical or chemical states of the radionuclides at the wound site. Seven default wound categories are defined according to the Type and solubility of the material involved. With this model it is possible to calculate the input function describing transfer of activity into the systemic circulation.

### Systemic Circulation

Whereas the HRTM and HATM intake models have general structures and parameter values, the systemic models, describing the fate of a radionuclide in the body after absorption into blood, are element-specific with regard to model structure as well as parameter values. Most of the systemic models used for the calculation of the dose coefficients and bioassay functions according to ICRP Publication 60 and summarised in ICRP Publication 119 are simple structures with one-way flow from blood to excretion, passing through the systemic organs. Such structures were originally introduced in ICRP Publication 30 [ICRP 1979-1988]. More physiologically realistic compartmental structures, accounting for feedback of activity from extravascular repositories to blood (recycling models), were used only for a subset of elements. In the OIR report series all systemic models follow the physiologically descriptive modelling scheme applied on a more limited scale in the earlier publications. All models include explicit routes for biological removal of systemic activity in urine and faeces. Additional excretion pathways, such as sweat, are also depicted in the models for some elements.

## Dosimetric Models

Stylised computational phantoms of human anatomy were used together with radiation transport codes to calculate the dose coefficients according to ICRP Publication 60 recommendations and weighting factors and summarised in ICRP Publication 119. These phantoms are constructed using mathematical surface equations to describe internal organ anatomy and exterior body surfaces of reference individuals [Cristy 1980; 1987], and as such are limited in their ability to capture anatomic realism. The computational phantoms of the ICRP adult Reference Male and Reference Female have been used for the dose coefficients presented in the OIR report series. Such anthropomorphic phantoms are based on segmented, voxelised medical tomographic data of real individuals that have been scaled to the reference anatomical characteristics specified in ICRP Publication 89 [ICRP 2002].

For all radiation transport and dose calculations, radionuclides are assumed to be uniformly distributed throughout source regions, and target cells are assumed to be uniformly distributed throughout target regions. Specific approaches are used in the case of skeletal dosimetry. Improvements in the OIR report series over previous calculation methods include a more refined treatment of the dependence of the absorbed fraction on particle energy, marrow cellularity, and bone-specific spongiosa

micro-architecture [Bolch 2002; Watchman 2005]. Moreover, special considerations are taken into account for alpha and beta emissions in a number of important cases, including:

- Doses to target cells in the walls of the respiratory tract airways from radionuclides deposited on the surface of the lumen [ICRP 1994a].
- Doses to target cells in the alimentary tract from radionuclides in the lumen [ICRP 2006].
- Doses to cells adjacent to inner bone surfaces (50 μm layer) and all red marrow from radionuclides on bone surfaces and within mineral bone

No dosimetric models are recommended by ICRP for calculating doses to the wound location. Some indications for this type of calculation may be found in the NCRP report describing the wound model [NCRP 2007].

## Intake and Dose Assessment

Dose assessment generally involves three stages:

1. individual and/or workplace monitoring measurements;
2. assessment of intake from the measurements;
3. calculation of dose from the assessed intake.

**Chapters C**, **D** and **E** describe in detail how a monitoring programme should be established and conducted, and how the measurements should be interpreted. In a simple situation where a single measurement $M$ is made, the intake $I$ can be estimated by comparing the result of the measurement with the appropriate value predicted by the corresponding bioassay function $m(t)$ at time $t$ after intake:

$$I = \frac{M}{m(t)} \qquad \text{(Eq. B.9)}$$

For routine monitoring, the assumed time of a suspected acute intake corresponds to the mid-point of the monitoring interval. If more measurements are available (as is the case for special monitoring, see **Chapter C**) then the best estimate of the intake $i$ should be determined from the set of measurements, preferably using the maximum likelihood method (**Chapter E**).

From an estimated value of a radionuclide intake $I$, the committed equivalent doses $H_T$ to target regions $r_T$ and the committed effective dose $E$ are evaluated by multiplying the intake by the appropriate dose coefficients:

$$H_T = I \cdot h_T(50) \qquad \text{(Eq. B.10)}$$

$$E = I \cdot e(50) \qquad \text{(Eq. B.11)}$$

The dose may also be calculated directly from the result of the measurement $M$ using the dose per unit content functions z(t):

$$E = M \cdot z(t) \qquad \text{(Eq. B.12)}$$

The effective dose of an individual for a given period of exposure, the dose of record ($E$), is thus the sum of the effective dose from external exposures during that period, and the 50-year committed doses from intakes in the same period:

$$E \cong H_p(10) + \sum_j e_{j,inh}(50) \cdot I_{j,inh} + \sum_j e_{j,ing}(50) \cdot I_{j,inh} \qquad \text{(Eq. B.13)}$$

where

$e_{j,inh}(50)$ committed effective dose coefficient for each injected radionuclide $j$

$e_{j,ing}(50)$ committed effective dose coefficient for each ingested radionuclide $j$

$I_{j,inh}/I_{j,ing}$ corresponding intakes by inhalation and ingestion.

In the case of an intake via a wound, the resulting dose should also be taken into account (see **Chapter E4**).

Values of the bioassay functions and the dose coefficients depend on the parameter values selected or specified for the dosimetric and biokinetic models. It is therefore of crucial importance to select the most realistic conditions of exposure in order to obtain the correct dose coefficient from the databases published by ICRP. Knowledge of the following aspects is required:

- Radionuclide: element, isotope and chemical form;
- Route of intake: inhalation, ingestion or wound;
- For inhalation,
    - particle size in terms of activity median aerodynamic diameter (AMAD)
    - respiratory tract absorption parameter values or absorption Type: fast (F), moderate (M) or slow (S);
    - classification of gases and vapours according to their solubility and reactivity (classes SR-0–2 as defined in ICRP Publication 66); this classification is no longer used in the revised HRTM presented in the OIR report series.
- For ingestion, absorbed fraction of ingested activity ($f_1$ or $f_A$).

By default, inhalation of an aerosol with an AMAD of 5 μm is assumed for occupational exposures. ICRP Publication 68 allocates absorption Types and $f_1$ values to groups of compounds of each element, in some cases allocating a single absorption Type and $f_1$ value to all compounds of an element. The OIR report series also allocates absorption Types and $f_A$ values, although the absorption parameter values associated with each absorption Type have been revised (see **Annex I**). For some important compounds, specific absorption parameter values are assigned [ICRP 2015b].

When the exposure situation is clearly inconsistent with the set of parameter values proposed for the Reference Worker, and the expected level of dose warrants a specific investigation, case-specific models and parameter values may be selected. Corresponding case-specific dose coefficients should then be calculated with appropriate software. The procedure to do so is explained in **Chapter E**.

In the event of exposure by incorporation of a radionuclide from a wound, dose coefficients for injection may be applied. When case-specific dose coefficients are required, these may be calculated using the wound model of NCRP [NCRP 2007] and the systemic models of ICRP discussed in this chapter and in **Annex I**. The dosimetry of wound cases is explained in **Chapter E4**.

In the event of exposure resulting from radionucide deposition on the intact skin, there is an external contamination, and the individual is in fact radioactive until this external contamination is removed. Absorption into the body can occur during this period. Dosimetry Services in charge of the survey of workers handling radio-isotopes may be required to address risks from both internal and external contamination, i.e. risk to the basal cells below the surface of the skin (at a depth of 0.07 mm) and risk from systemic uptake. The dosimetry of intact skin and its possible absorption is explained in **Chapter E4**. The topic is likely to require cooperation between external dosimetry and internal dosimetry experts. The inclusion of the topic of risks from external contamination in this report should not, however, be taken to imply that internal dosimetry services have a formal duty to address this topic.

Dose assessment after decorporation therapy is explained in **Chapter E5**.

# CHAPTER C – Monitoring Programmes

***MAIN QUESTION***

***Q1*** *What is the overall purpose of an individual monitoring programme in the context of occupational intakes of radionuclides, and how does it relate to general radiation protection programmes?*

***Subsidiary questions***

***Q2*** *What types of information are required in order to make decisions on the need for, and design of, an individual monitoring programme?*

***Q3*** *How should workers be identified for whom individual monitoring may be required?*

***Q4*** *How should the need for an individual monitoring programme be determined and what type of monitoring programme should be selected?*

***Q5*** *What requirements should be considered when designing a routine monitoring programme?*

***Q6*** *What requirements should be considered when designing other types of monitoring programme?*

***Q7*** *How should potential exposures to short-lived radionuclides (e.g. such as are used for medical applications) be taken into account when designing a monitoring programme?*

***Q8*** *How should a monitoring programme and its implementation be documented?*

## Special Terms used in this Chapter

Confirmatory monitoring, Controlled Areas, Critical Organ, Individual monitoring, Investigation level, Monitoring interval, Recording level, Routine monitoring, Special monitoring, Task-related monitoring, Undertaking, Workplace monitoring.

## Introduction – General Remarks/Monitoring Programmes

This chapter describes how to make decisions on the need for, and design of, an individual monitoring programme in the context of a radiation protection programme, and how the different measurement techniques and procedures for assessment of internal doses should be applied.

***Q1:** What is the overall purpose of an individual monitoring programme in the context of occupational intakes of radionuclides, and how does it relate to general radiation protection programmes?*

An individual monitoring programme for occupational intakes of radionuclides is employed to verify and document adequate protection of workers. In summary, it consists of the specification of:

- Measurements (see **Chapter D**)
  - Monitoring method(s) to be employed (e.g. whole body *in vivo* monitoring, urine bioassay or air sampling)
  - Sample collection times (for bioassay sampling)
  - Measurement techniques to be used (e.g. gamma or mass spectrometry)
  - Monitoring intervals (repetition periods for measurements in routine monitoring)
- Dose assessments (see **Chapter E**)
  - Biokinetic and dosimetric models to be used
  - Procedures and reference assumptions for dose assessments
- Dose recording (see **Chapter G**)
  - Documentation and Record Keeping
  - Quality Assurance

The definition of the purpose of the monitoring programme (i.e. its strategy and objectives) and its organisation (e.g. methods for selection of monitoring intervals in routine monitoring, measurement techniques, models) should be documented.

According to the 2013 Directive, the undertaking is responsible for the radiation protection of exposed workers [EC 2014]. Radiation protection is one element in ensuring the overall health and safety of workers. General radiation protection programmes – which include the monitoring programmes (i.e. measurement procedures, protocols, intervals and the dose assessment procedures as integral parts thereof [ICRP 2015b]) – need to be set up by the undertaking. According to ISO 20553:2006 [ISO 2006], the monitoring programmes are implemented to:

> *…verify and document that the worker is protected adequately against the risks from radionuclide intakes and that the protection complies with legal requirements.*

In this context, the term monitoring is defined as [ISO 2006]:

> *the assessment or control of exposure to radiation or radioactive material*

It includes measurement of activities of radionuclides retained in the body or excreted therefrom, as well as the interpretation of the results of measurements using biokinetic and dosimetric models. In the case of internal contamination, monitoring can either be **individual monitoring** (i.e. bioassay measurements) and/or **workplace monitoring** (i.e. measurement of contamination of surfaces, air sampling). Both types of monitoring could also be combined in a programme; in these cases, workplace monitoring is typically used as a trigger for dedicated individual monitoring measurements where needed. The techniques/methods applied for these measurements are described in **Chapter D**. For workers liable to receive significant doses (i.e. > 1mSv $y^{-1}$) from intakes of radionuclides, the measurements performed within a monitoring programme should provide the data necessary to enable the subsequent dose assessment (see **Chapter E**). ICRP [ICRP 2015b] recommends that:

> *the emphasis in any particular monitoring programme should be on the formal assessment of doses to those workers who are considered likely to receive routinely a significant fraction of the relevant dose limit, or who work in areas where exposures could be significant in the event of an accident.*

Recommendations on monitoring programmes for occupational exposure to radionuclides are provided by the International Atomic Energy Agency [IAEA 1999a], the International Commission on Radiological Protection [ICRP 1997; 2015b] and the International Organization for Standardization [ISO 2006; 2015d; 2016b].

## Categories of Monitoring Programmes and Selection of a Programme

***Q2*** *What types of information are required in order to make decisions on the need for, and design of, an individual monitoring programme?*

Decisions on the selection of workers for whom individual monitoring may be required, the need for a monitoring programme and the design of the monitoring programme all require information relating to exposure conditions in the workplace. The types of information required are as follows:

a. the radionuclide(s) to which workers may be exposed, and the radiations emitted by their decay
b. the decay rate(s) of the radionuclide(s)
c. retention of the radionuclide(s) in the body or excretion from the body as a function of time after an acute intake
d. working practices and sources of exposure to radionuclides
e. the likely route(s) of intake (primarily, inhalation and/or ingestion)
f. potential time patterns of intake
g. physical form of the materials to which workers may be exposed (e.g. whether particulate or vapour, particle size distribution)
h. chemical form of these materials

Previous workplace monitoring or individual monitoring may also provide useful information.

The need for the information identified in items a, b and c above is discussed in [ISO 2006]. Reference sources of radionuclide decay data (item b) are discussed in **Chapter D**, while the use of biokinetic models to predict retention and excretion behaviour (item c) is discussed in **Chapters B** and **E**. Information of the types identified in items a, d, e, f, g and h above should be sought from sources within the workplace. These types of information are also required for the interpretation of individual monitoring data, and so their collection and use are discussed in detail in **Chapter E1**.

***Q3*** *How should workers be identified for whom individual monitoring may be required?*

For workers at workplaces which bear the risk of intake of radionuclides, individual monitoring programmes should be considered. ICRP [ICRP 2015b] recommends that:

> *In general, the assignment of an internal exposure monitoring programme to an individual should be based on the likelihood that the individual could receive an intake of radioactive material exceeding a predetermined level, as a result of normal operations or in the event of an accident.*

Without distinguishing internal and external doses, Paragraph 41 of the 2013 Directive sets the formal requirement that:

> *Member States shall ensure that category A[6] workers are systematically monitored (…) that monitoring for category B workers is at least sufficient to demonstrate that such workers are correctly classified.*

Most often, monitoring programmes for intakes of radionuclides are applied for workers in controlled areas. Experience has shown that for several types of operations

[6] For the purpose of surveillance and monitoring, the 2013 Directive uses categories A and B to distinguish workers that are liable to receive effective doses larger than 6 mSv per year (category A) from those with lower doses (category B). (Article 40 of [EC 2014])

(e.g. processing of plutonium or handling large quantities of $^{131}I$ in medical applications) individual monitoring should always be considered. Examples of these types of operations or facilities can be found in [IAEA 1999a; ISO 2006; ICRP 2015b]. The special case of pregnant and breastfeeding workers, for whom additional protection measures (e.g. additional monitoring) may be required, is discussed in **Chapter E6** of this report.

Judgements on the need for individual monitoring of particular groups of workers should take into account previous experience of the type of operation and the facility, information from current workplace monitoring, and past workplace and individual monitoring, if available; if not not available, the decision factor approach described by IAEA and ISO [IAEA 1999a; ISO 2016b] may be used. This approach is described in more detail in the text addressing *Q4*.

The same principles are applied for outside workers, who are not employed by the undertaking itself. Here, cooperation with the employer of these workers should be established to make sure all legal requirements are met.

***Q4*** *How should the need for an individual monitoring programme be determined and what type of monitoring programme should be selected?*

In general, individual monitoring programmes may be divided into four categories [IAEA 1999a; ISO 2006; ICRP 2015b]:

- **Routine Monitoring**, which is performed for exposure situations with a possibility of (undetected) accidental or chronic intakes.
- **Special Monitoring**, which is performed either to better quantify significant exposures or following actual or suspected accidental intakes.
- **Confirmatory Monitoring**, which is performed to check assumptions made in setting up a radiation protection programme or to check the effectiveness of protective measures.
- **Task-Related Monitoring**, which is similar to routine monitoring but is performed at specific operations of limited duration.

The four categories are not mutually exclusive. A combination of them could be implemented by the undertaking; for example, a special monitoring programme should be initiated after a significant intake has been detected as a result of routine monitoring.

In the case of exposure to short-lived radionuclides (e.g. in nuclear medicine applications) the dose is dominated by external exposure and individual monitoring methods aimed at quantifying chronic or undetected inadvertent intakes of these radionuclides (i.e. routine or task-related monitoring) may not be required. Even if the assessment of the likely exposures demonstrates the need for such monitoring, it may not be feasible for radionuclides with a half-life shorter than that of $^{131}I$ ($T_{1/2} \approx 8$ d). In this case, **triage monitoring**, which consists of frequent screening measurements using simple equipment such as dose rate meters or contamination monitors, may be applied. If the result of a screening measurement is above a defined threshold, individual monitoring measurements (e.g. urine analysis) should be performed [ISO 2016b].

The selection of a monitoring programme is part of the general radiation protection programme at a workplace and should start with workplace characterisation and identification of the work situations which bear a risk of intake of radionuclides for the worker, quantification of the likely/possible magnitude of the intake (the latter is usually estimated for the period of one year) and estimation of the committed effective doses resulting from these intakes. Decisions about the need for individual monitoring should not take into account personal protective measures, which are considered as an additional element of safety [IAEA 1999a]. Individual monitoring should, however, be performed to assess the effectiveness of the protective equipment. The factors which determine the need for a monitoring programme are [ISO 2006]:

- The magnitude of the likely exposures;
- The need to recognise and evaluate events resulting in intakes (should they occur);
- The need to assess the effectiveness of protective equipment.

Any evaluation of these factors (e.g. via the assessment of a likely annual dose) should take into account all radionuclides and different scenarios in which a worker could be exposed during routine operations. The basis of the evaluation should be available data from earlier monitoring programmes (individual or workplace monitoring) and/or from dedicated measurements currently performed at the workplace to characterise the radiological conditions.

For example, the likely committed effective dose due to exposure of a worker to a specific airborne radionuclide may be estimated by:

$$E(50) = \frac{I \cdot e(50)}{0.001} \qquad \text{(Eq C.1)}$$

where

| | |
|---|---|
| $E(50)$ | the committed effective dose for the radionuclide (mSv) |
| $I$ | intake for the radionuclide (Bq) |
| $e(50)$ | dose coefficient (Sv $Bq^{-1}$) for inhalation of the radionuclide |
| 0.001 | conversion factor from Sv to mSv. |

The likely intake may be estimated by:

$$I = B \cdot T_{work} \cdot C_m$$

where

| | |
|---|---|
| $B$ | mean breathing rate of a sedentary worker (1.2 $m^3$ $h^{-1}$) |
| $T_{work}$ | time spent by the worker in areas where the radionuclide is present in the air breathed (h) |
| $C_m$ | airborne concentration of the radionuclide (Bq $m^{-3}$). |

Further information about the information which can be derived from monitoring data can be found in **Chapter E1**. If no data are available, reference assumptions and models (for example, taken from recommendations by ICRP and IAEA [ICRP 2015b; IAEA 1999a]) could be applied. IAEA and ISO describe an approach for the evaluation that involves calculation of "decision factors" $d_j$ for each radionuclide and operation [IAEA 1999a; ISO 2016b]. These factors are calculated by multiplying the committed effective dose resulting from an intake of all the activity of a radionuclide present at the workplace during a year by safety factors for physical form, handling and protection. These factors could be too restrictive when applied to nuclear medicine practices, and so ISO introduced three further factors to take into account workload, handled activity and inhalable fraction. The decision factor $d_j$ for radionuclide j may be calculated using the following formula [IAEA 1999]:

$$d_j = 1000 \cdot A_j \cdot e_{inh,j}(50) \cdot f_{fs} \cdot f_{hs} \cdot f_{ps} \qquad \text{(Eq. C.2)}$$

where

| | |
|---|---|
| $A_j$ | cumulative activity (Bq) of the radionuclide j present in the workplace over the course of the year |
| $e_j(50)$ | inhalation dose coefficient for radionuclide j (in Sv $Bq^{-1}$) |
| $f_{fs}$: | physical form safety factor based on the physical and chemical properties of the material being handled (as a default, a value of 0.01 is assumed) |

$f_{hs}$: handling safety factor based on experience of the operation being performed and the form of the material (see Table C.1)

$f_{ps}$: protection safety factor based on the use of permanent laboratory protective equipment (see Table C.2)

1000 the conversion factor from Sv to mSv.

Tables with reference values for the safety factors are provided by ISO [ISO 2016b] and are reproduced here as Tables C.1 and C.2.

**Table C.1** Handling Safety Factors (taken from [ISO 2016b] reproduced with kind permission of ISO)

| Process | Handling Safety factors $f_{hs}$ |
|---|---|
| Storage (stock solution) | 0.01 |
| Very simple wet operations | 0.1 |
| Normal chemical operations | 1 |
| Complex wet operations with risk of spills | 10 |
| Simple dry operations | 10 |
| Handling of volatile compounds | 100 |
| Dry and dusty operations | 100 |

**Table C.2** Protection Safety Factors (taken from [ISO 2016b] reproduced with kind permission of ISO)

| Protection measure | Protection safety factors $f_{ps}$ |
|---|---|
| Open bench operations | 1 |
| Fume hood | 0.1 |
| Glove Box | 0.01 |

Three additional factors may be included in the calculation of $d_j$ (Eq. C.2) to take into account the fraction of time the worker is involved in a particular task ($f_{Workload} \leq 1$), the fraction of the total activity that is handled by the worker ($f_{handled\ Activity} \leq 1$) and the fraction of the activity that could be incorporated through aerosolisation or volatilisation ($f_{intake} \leq 1$). For the latter factor a value of $10^{-4}$ is assigned, which represents a conservative approach to the estimation of the potential intake from the handled activity [ISO 2016b].

The calculations should be performed for each radionuclide, and if the latter three factors are applied, for each handling procedure or task. If the sum of the radionuclide-specific decision factors $d_j$ for all radionuclides is less than one, individual monitoring may be considered to be unnecessary. An example calculation may be found in **Annex II**. If individual monitoring is required, radionuclides whose contribution to the worker's dose are small (e.g. when the summed dose is likely to be less than 1 mSv $y^{-1}$ [ISO 2006]) could however be disregarded. If mixtures of radionuclides with a constant composition are observed at a workplace, a single "guide" radionuclide could be measured and the activity of the others may then be inferred. If the uncertainty of the composition leads to an additional uncertainty in dose values that is less than 10%, this approach is acceptable [ISO 2006].

Reference levels, which are defined as dose values above which particular actions or decisions are taken, could be used to assess the need for a monitoring programme

and the suitability of different options. The two reference levels that are employed for this purpose are the Recording Level and the Investigation Level.

- The **Recording Level** (RL) is defined in ISO 20553:2006 [ISO 2006] as

  *the dose above which dose assessments have to be recorded in the individual files/exposure records. Doses which are smaller than this value may be reported as "below recording level".*

  According to [ISO 2006], RLs must be set no higher than 5% of the annual dose limits (i.e. 1 mSv $y^{-1}$ effective dose for a dose limit of 20 mSv $y^{-1}$). If the likely annual doses are lower than the defined RLs no routine monitoring programme is required. However the validity of the assumptions made in the assessment of the likely doses should be checked regularly; a confirmatory monitoring programme could be helpful for performing these checks.

- The **Investigation Level** (IL) is defined in ISO 20553:2006 as the level of dose, exposure or intake which triggers a detailed assessment of the exposure. This is part of the general investigation of the case and, with respect to monitoring programmes, would include confirmation of the exposure estimate, a detailed assessment of doses and application of measures to reduce uncertainties in the assessed dose (**Chapter F**). According to [ISO 2006], ILs must be set at values corresponding to an annual dose no higher than 30% of the annual dose limit (i.e. 6 mSv $y^{-1}$ effective dose for a dose limit of 20 mSv $y^{-1}$). If, during routine monitoring programmes, the assessed doses exceed the IL, an additional special monitoring programme is recommended to support the subsequent assessments.

Reference levels of effective dose of 1 mSv $y^{-1}$ (RL) and 6 mSv $y^{-1}$ (IL) are set or recommended by international standards [IAEA 1999a; ISO 2006; 2011] and have often been subsequently adopted in national legislation. If a significant dose contribution from external irradiation is expected, the values of the reference levels should be lowered to account for expected external exposure. This should be done because the dose of record *E* as defined in ICRP Publication 103 [ICRP 2007] is the sum of the contribution of external exposures, which is usually monitored via measurement of the personal dose equivalent $H_p(10)$, and the contribution of internal exposures, which is usually calculated as committed effective dose *E(50).* External exposures may be determined from past data or from dose restraint (ALARA, "as low as reasonable achievable") restrictions. If no other information is available, the recommendation given in [ISO 2006] should be followed, i.e. the RL and IL should be reduced by a factor of two in cases where external exposure is likely to exceed the committed effective dose.

Figure C.1 summarises the processes of identifying workers for whom individual monitoring may be required, determining the need for an individual monitoring programme and selecting the type of monitoring programme required.

The monitoring itself may be either **workplace monitoring** (measurement of air and surface contamination at workplaces) or **individual monitoring** (*in vivo* bioassay or sample bioassay measurements). ISO 20553:2006 requires that individual monitoring techniques should be used if the worker is liable to receive doses exceeding the ILs. Individual monitoring is also recommended here for workers whose likely annual effective doses may exceed the RL, although following ISO 20553:2006 it is acceptable to use programmes based only on workplace monitoring in these cases. Performing individual monitoring above RLs is already common practice in many organisations. Similarly, workplace monitoring could also be utilised as part of a monitoring programme at higher levels in order to provide information for more accurate dose assessments additional to those provided by individual monitoring.

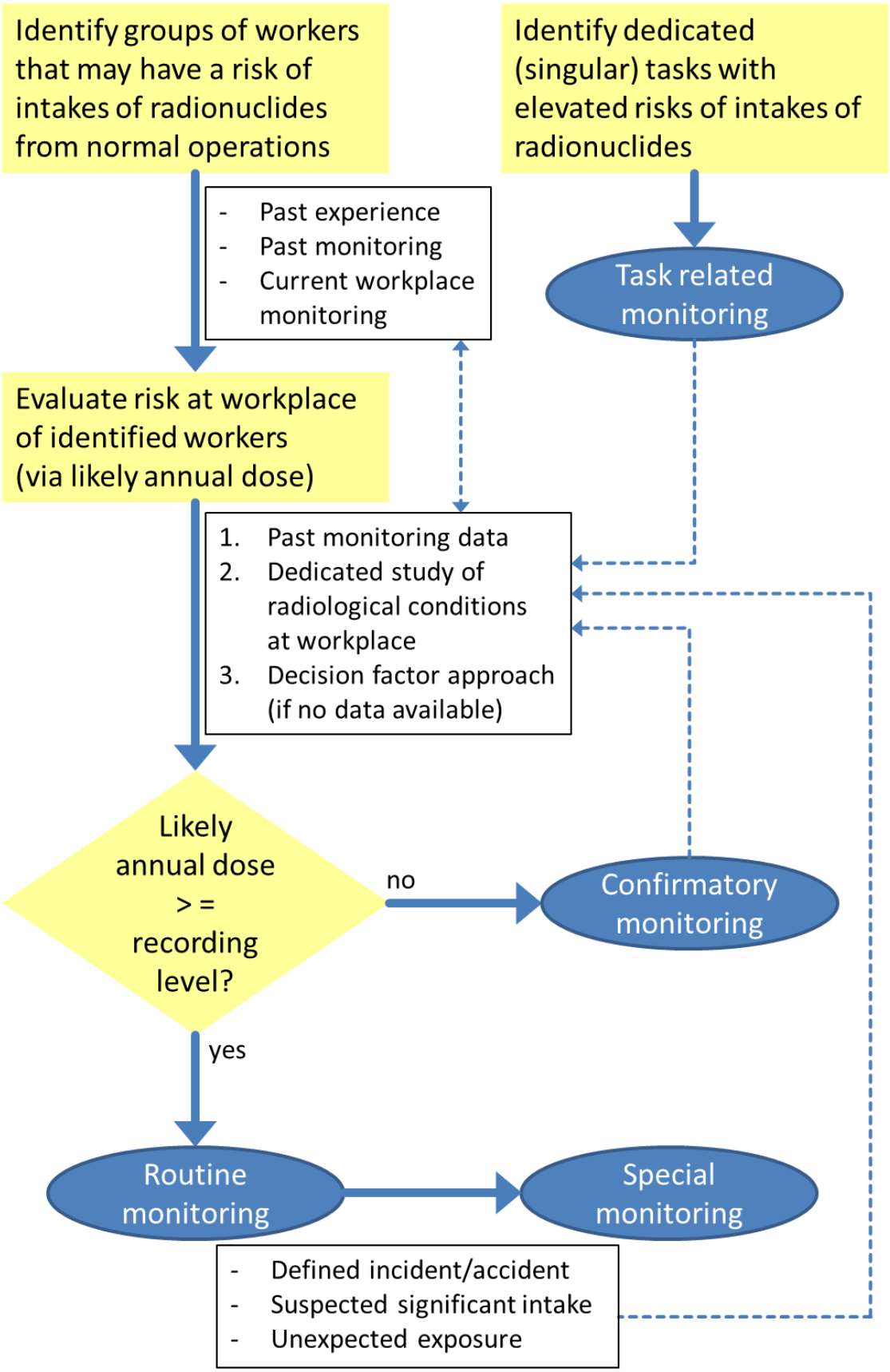



**Figure C.1** Identification of workers, determination of the need for monitoring, and selection of a suitable monitoring programme. Solid lines indicate decisions taken, while dashed lines indicate information flow. See text for details.

The dosimetric performance of a monitoring programme may be evaluated in terms of a minimum detectable dose [Carbaugh 2003; Etherington 2004; Davesne 2011]. These could be calculated for different choices of values for the programme's parameters (i.e. monitoring method, techniques, frequency of measurements) and used for the selection and optimisation of the programme.

Starting from the reference levels, additional derived investigation levels (DILs), expressed in the quantities used for monitoring (i.e. concentration of activity in air, activity in the body or excreted activity), may be calculated using parameter values for the monitoring programme and the reference models provided by ICRP [ICRP 1997, 2015b]. These DILs are a useful and convenient tool in the application of monitoring programmes because the results of measurements may be compared directly to these values in order to evaluate the need for further investigations. However DILs are typically applied only if single radionuclides are encountered at the workplace or if the radionuclide composition is known.

## Routine Monitoring

***Q5*** *What requirements should be considered when designing a routine monitoring programme?*

Routine monitoring programmes are used to demonstrate that working conditions (in terms of levels of individual doses) remain satisfactory and to prove compliance with regulatory requirements. They are implemented if chronic intakes (including repeated small acute intakes) or undetected accidental or non-accidental intakes during work procedures are likely and the annual committed effective doses resulting from these intakes may exceed predetermined RLs. It must be ensured that the routine monitoring programme is able to detect all annual exposures that can exceed this level [ISO 2006]. The assumptions underlying the design of the programme should be reviewed regularly (and certainly after major modifications to working procedures or the working environment). Here an additional confirmatory monitoring programme could be utilised temporarily.

In the description of a routine monitoring programme, four main aspects should be defined:

- The specific purpose of the monitoring programme,
- The type of measurements to be performed,
- the frequency of the measurements, and
- the models and assumptions used for dose assessments following positive measurements.

### Measurements

Selection of the appropriate individual monitoring technique to be applied is determined by a number of factors, including [ICRP 2015b; ISO 2006]:

- Properties of the radionuclide (e.g. radiation emitted by the radionuclide and its progeny, radioactive half-life);
- biokinetic behaviour (e.g. time dependent behaviour of retention and excretion rate);
- technical feasibility and sensitivity of the measurement technique (e.g. limits of detection); and
- the likely committed effective dose and the minimum detectable dose.

Details about bioassay measurement techniques and the selection of an appropriate technique for a given radionuclide are presented in **Chapter D**. In general, and where possible, *in vivo* bioassay measurements (direct measurements) are preferred over both sample bioassay measurements (indirect measurements) and air sampling measurements, because *in vivo* bioassay provides direct information on the amount of the radionuclide in the body.

For actinides, the sensitivity requirements for a routine monitoring programme may not be met by individual monitoring techniques and so (static and/or personal) air sampling may be applied and used as a trigger for individual monitoring measurements. The requirements for the design, performance and management of air sampling programmes are described in a forthcoming ISO standard. The principle features of a monitoring programme utilising air sampling that should be considered are:

- Definition of the objectives of the programme;
- The nature and extent of the programme, and how this varies with potential worker exposure levels;
- Use of static (SAS) and personal (PAS) air samplers:
    - The location and coverage of SAS;
    - Use of air-flow studies to confirm the optimal positioning of SAS;
- Periodic evaluation and validation of the programme;
- Use of an air sampling programme for estimating effective doses.

For many short-lived radionuclides (i.e. half-life <0.5 d) the effective dose is dominated by external exposure and individual monitoring is in most cases not feasible. A triage monitoring programme (see below) may be implemented.

## Monitoring Intervals

In routine monitoring, the measurements are made following a predetermined time schedule. The period between two measurements is called the **monitoring interval**, and the frequency of measurements depends on the physical decay (half-life) and the biokinetic behaviour of the radionuclides, the sensitivity of the measurement technique and the acceptable uncertainty on the assessed dose. [ISO 2006] specifies the following general requirements:

- A routine monitoring programme must be able to reliably detect all annual exposures that can exceed the recommended maximum recording level of 1 mSv $y^{-1}$;
- The uncertainties in the assessed doses resulting from an unknown time interval between intake and measurement are limited so that:
    - The maximum underestimate of the dose resulting from a single intake does not exceed a factor of three;
    - On average, over many monitoring intervals, doses are not underestimated;
- At least two measurements must be performed in a year.

The requirements for a routine monitoring programme may be expressed by the following formulae [ISO 2006]:

$$e(50)\frac{DL}{m(\Delta T)}\frac{365}{\Delta T} \le 1\frac{mSv}{y} \qquad \text{(Eq. C.3)}$$

$$\frac{m\left(\Delta T/2\right)}{m(\Delta T)} \le 3 \qquad \text{(Eq. C.4)}$$

where

| | |
|---|---|
| $e(50)$ | dose coefficient (Sv $Bq^{-1}$) |
| $DL$ | detection limit of the measurement technique (e.g. Bq or Bq $d^{-1}$) |
| $\Delta T$ | monitoring interval (days) |
| $m$(t) | bioassay (retention/excretion) function at t days after intake. |

It should be noted that use of Eq. C.3 may in some circumstances produce an overly pessimistic estimate of the detectable annual dose for a particular monitoring interval and measurement technique. The reason is that the equation does not take into account residual excretion from intakes in earlier monitoring periods. If it is taken into account, the magnitudes of intakes in later periods required to cause m(Δt) to reach the detection limit may be reduced, resulting in a lower detectable annual dose. This issue is examined in more detail in **Annex II**, Example 1.

ICRP [ICRP 1997; 2015b] provides typical values of detection limits for routine bioassay measurements and the biokinetic functions which may be applied for these calculations. Further information on typical and achievable values of detection limits may be found in [Etherington 2004; EURADOS 2013].

For practical purposes it is recommended by ICRP [ICRP 2015b] and ISO [ISO 2006] to assign radionuclides to a maximum monitoring interval of 7, 15, 30, 60, 90 or 180 days.

ISO 20553:2006 [ISO 2006] provides tables with "Methods and maximum time intervals for routine monitoring programmes" for the commonly encountered radionuclides. This table is reproduced here as Table C.3.

**Table C.3** Methods and maximum time intervals for routine monitoring programmes (Table 3 of ISO 20553:2006, reproduced with kind permission of ISO).

| Radionuclide | Absorption Type | *In vitro* analyses | *In vivo* measurements | |
|---|---|---|---|---|
| | | Urine (days) | Whole Body (days) | Thyroid (days) |
| $^{3}$H | HTO | 30 | - | - |
| $^{14}$C | Organic | 7 | - | - |
| | Dioxide | 180 | - | - |
| $^{32}$P | F | 30 | - | - |
| $^{33}$P | F | 30 | - | - |
| $^{35}$S | F | 7 | - | - |
| $^{36}$Cl | F | 30 | - | - |
| $^{51}$Cr | F | (15) | 15 | - |
| $^{54}$Mn | M | - | 90 | - |
| $^{59}$Fe | M | - | 90 | - |
| $^{57}$Co | S | (30) | 180 | - |
| $^{58}$Co | S | (90) | 180 | - |
| $^{60}$Co | S | (180) | 180 | - |
| $^{63}$Ni | M | 15 | - | - |
| $^{75}$Se | M | - | 180 | - |
| $^{89}$Sr | F,S | 30 | - | - |
| $^{90}$Sr | F,S | F:30, S:180 | - | - |
| $^{110m}$Ag | S | - | 180 | - |
| $^{125}$I | F | (90) | - | 90 |
| $^{131}$I | F | (15) | - | 15 |
| $^{137}$Cs | F | (180) | 180 | - |
| $^{226}$Ra | M | 180 | - | - |

NOTE: Where a figure is given in brackets, this is an alternative to the value in one of the other columns, for cases where *in vivo* measurements cannot be carried out.

The values in this table were derived using the following assumptions:

- The ICRP Publication 66 [ICRP 1994a] Human Respiratory Tract Model (HRTM) for inhalation (AMAD = 5 μm), and element-specific retention and excretion functions from ICRP Publication 78 [ICRP 1997][7];
- Acute intake by inhalation at the mid-point of the monitoring interval;
- Typical limits of detection for the different methods as presented in ICRP Publication 78.

The table provides minimum requirements based on the general requirements explained above and is neither exhaustive nor exclusive of other means. The general requirements for monitoring programmes might also be met by the use of more sensitive measurement techniques or the combination of different monitoring methods.

For some radionuclides (e.g. $^{223}Ra$ and the transuranium radio-isotopes), certain methods for individual monitoring can only reliably detect exposures above 6 mSv (e.g. urine monitoring for exposures of $PuO_2$). In these cases, workplace monitoring (e.g. air sampling) should be implemented to ensure detection of lower exposures. Annual bioassay measurements should be performed to demonstrate that the workplace monitoring does not miss a significant intake. More sensitive analytical techniques such as mass spectrometry could potentially overcome this problem (see **Chapter D**).

In cases of exposure to uranium, chemical toxicity as well as radiotoxicity should be taken into account [ISO 2015d]. For actinides and uranium compounds, ISO 20553:2006 also provides tables presenting "methods and maximum time intervals for routine monitoring programmes". The tables are reproduced here as Tables C.4 and C.5.

**Table C.4** Methods and maximum time intervals for routine monitoring programmes for uranium compounds
(Table 4 of ISO 20553:2006, reproduced with kind permission of ISO)

| Material | Abs. Type | *In vitro* analyses | | *In vivo* measurements |
|---|---|---|---|---|
| | | Urine (days) | Faeces (days) | Lungs (days) |
| Uranium hexafluoride | F | 90 | - | - |
| Uranium peroxide | F | 30 | - | - |
| Uranium nitrate | F | 30 | - | - |
| Ammonium diuranate | F | 30 | - | - |
| Uranium tetrafluride | M | 90 | 180 | 180 |
| Uranium trioxide | M | 90 | 180 | 180 |
| Uranium octoxide | S | 90 | 180 | 180 |
| Uranium dioxide | S | 90 | 180 | 180 |

NOTE Both the radiological and chemical toxicity of uranium compounds are taken into account. Faecal sampling is recommended to confirm that air sampling does not underestimate the actual intakes.

[7] The introduction of revised models in the OIR report series may bring variations in the retention and excretion functions and consequently in the values presented in the Tables; this needs to be taken into account in a future revision of ISO 20553:2006.

**Table C.5** Methods and maximum time intervals for routine monitoring programmes of compounds of actinides (except uranium)
(Table 5 of ISO 20553:2006, reproduced with kind permission of ISO)

| Radionuclide | Absorption Type | *In vitro* analyses | | *In vivo* Measurements |
|---|---|---|---|---|
| | | Urine (days) | Faeces (days) | Lungs (days) |
| $^{228}$Th | S | - | 180 | - |
| $^{232}$Th | S | - | 180 | - |
| | M | - | 180 | - |
| $^{237}$Np | M | 180 | 180 | - |
| $^{238}$Pu | S | 180 | 180 | - |
| $^{239}$Pu | S | 180 | 180 | - |
| | M | 180 | 180 | - |
| $^{241}$Am | M | 180 | 180 | 180 |
| $^{244}$Cm | M | 180 | 180 | - |

## Dose Assessment and Recording

If the measurement results are above a critical value (see **Chapter E**) a dose assessment should be carried out. The critical value as defined by ISO 27048:2011 [ISO 2011] should be used unless competent authorities require a different definition (e.g. the decision threshold of the measurement). Interpretation of measurements should commence with the assumption of an inhalation intake at the midpoint of the monitoring interval using the reference biokinetic parameters provided by ICRP [ICRP 1997, 2015b, 2016b, 2017] (e.g. an AMAD of 5 µm in workplaces) unless clear indication of another route of intake (e.g. wound). Following this first basic assessment, additional information may be used to improve the dose assessment (see **Chapter E**). ISO and ICRP provide tables with retention and excretion functions that may be used for both types of calculations [ICRP 2015b; ISO 2011]. Several software packages that may be used for the calculations are commercially available, see **Chapter E**. If the assessed dose exceeds the IL (or another threshold set below this level) a more detailed assessment is required; typically additional measurements (special monitoring) are also performed in these cases.

If a measurement is below the decision threshold (DT), the fact that the measurement has been performed and its detection limit should be documented. It is also recommended that for all data including results below the DT, records of the measurement value, its uncertainty as well as further information required for interpreting the measurement are kept [EURADOS 2013]. Such information includes background and sample count rates, duration of sample and background measurements and calibration factors. This information may be used in the dose assessment, taking account of the uncertainty associated with each measurement result.

The reference assumptions and the calculation procedures applied in the dose assessments should be documented in the definition of the routine monitoring programme, so that these may be accurately reproduced. More details about "standard" dose assessment procedures are given in **Chapter E**. Recommendations for dose recording and reporting in routine monitoring programmes are described in **Chapter G**.

## Other Monitoring

***Q6*** *What requirements should be considered when designing other types of monitoring programmes?*

### Confirmatory monitoring

Confirmatory monitoring is performed to check assumptions made about exposure conditions and to demonstrate that there is no need for routine or task-related individual monitoring (especially if the likely annual doses are below the recording levels). Typically, workplace monitoring and occasional individual monitoring are performed in this case. The latter is useful for radionuclides that are retained in the body for long times, because the absence of a radionuclide in the body could be demonstrated by these occasional measurements. Additionally the effectiveness of protective measures may be tested and demonstrated by confirmatory monitoring [ISO 2006].

### Triage Monitoring

In the context of occupational exposures, triage monitoring consists of frequent individual screening measurements (typically performed at nuclear medicine centres for all staff at risk of exposure), conducted to detect whether an intake of a radionuclide with a short effective half-life has occurred. It should not be confused with radiological triage, which is applied in emergency situations for the purpose of selecting and prioritising individuals for whom significant exposure has occurred. Occupational triage monitoring is typically implemented where workplace monitoring is not sufficient and routine monitoring for all exposed workers is not achievable. These measurements may be performed with standard radiation protection equipment (e.g. dose rate meters, contamination monitors) available at the facility, and results should be compared to a predefined threshold value. Dose assessments should not be performed using the results of these measurements. If the triage monitoring threshold is exceeded, *in vivo* bioassay or sample bioassay measurements should be performed in order to confirm internal contamination and to quantify the intake for the subsequent dose assessment.

### Special Monitoring and Task-related Monitoring

Special and task-related monitoring programmes are performed after a suspected intake, or after a distinct event (for example, a change in working conditions) that could accompany a certain task with an increased risk of intake. In these situations, higher potential exposures warrant additional measurements to provide a more accurate dose assessment. The measurement techniques applied in these kinds of monitoring are the same as in routine monitoring; sometimes, additional measurements (for example, lung measurements after acute intake of $^{226}$Ra or $^{239}$Pu) or screening techniques such as nasal samples are used. In many cases a combination of different techniques is applied and the frequency of the measurements is adapted to the scenario. Since every case is different and needs special consideration, no general recommendations are given here. For several radionuclides, ISO 20553:2006 recommends methods suitable for special individual monitoring [ISO 2006]. In addition, the IDEAS Guidelines [EURADOS 2013] provide tables presenting the minimum number and type of monitoring data required for dose assessment that depend upon the radionuclide and the evaluated dose range. These are reproduced here as Tables C.6 and C.7. The IDEAS Guidelines also point out that "more measurements should be taken the greater the dose estimate" [EURADOS 2013].

A graded approach to the more complex internal dose assessments following special monitoring is presented in ISO 27048:2011 [ISO 2011]. A step-by-step approach to the calculations has also been presented in the IDEAS Guidelines [EURADOS 2013]. One difference with routine monitoring programmes is that, in special monitoring, typically more than one measurement needs to be interpreted and curve fitting techniques are therefore applied. Individual model parameter values may be derived and applied in the dose assessments. In most cases additional information on the scenario (especially a suspected time of intake) is available and may be used in the

dose assessments to reduce uncertainties. Workplace monitoring may provide further information on model parameter values, e.g. for the values of AMAD. ISO and EURADOS provide guidance on using additional information in the dose assessment [ISO 2010b; EURADOS 2013]. Recommendations on the dose assessment procedures used for interpretation of special monitoring data are given in **Chapter E**. All assumptions made for a dose assessment should be documented in order to be able to reproduce the dose assessment at later times.

**Table C.6** Minimum number and type of data required for assessment of dose for some categories of radionuclides
(Table 6.1 of IDEAS Guidelines, reproduced with kind permission of EURADOS)

| Category of Radionuclide | Type of monitoring | Number of required monitoring data | | |
|---|---|---|---|---|
| | | E<1 mSv[a] | 1 mSv<E<6 mSv[b] | E>6 mSv[c] |
| All type of alpha-emitters with significant gamma-component ($^{235}$U, $^{241}$Am etc.) | Urine | - | 2 | 3 |
| | Faeces | 1 | 2 | 3 |
| | Whole Body, critical organ or wound site respectively | - | 2 | 4 |
| All type of alpha-emitters without significant gamma-component ($^{210}$Po, $^{239}$Pu etc.) | Urine | - | 3 | 5 |
| | Faeces | 1 | 3 | 5 |
| All type of beta-emitters with significant gamma-component ($^{60}$Co, $^{131}$I, $^{137}$Cs etc.) | Whole Body, critical organ or wound site respectively | 1 | 2 | 4 |
| | Urine | - | 2 | 4 |
| F-type beta-emitters without significant gamma-component ($^{3}$H, $^{14}$C etc.) | Urine | 1 | 4 | 8 |
| M/S-type beta-emitters without significant gamma-component ($^{90}$Sr etc.) | Urine | 1 | 2 | 4 |
| | Faeces | - | 2 | 4 |
| Pure gamma-emitters ($^{123}$I etc.) | Whole Body or critical organ | 1 | 2 | 4 |
| | Urine | - | 2 | 4 |

a) Minimum requirement
b) The monitoring data should cover a time range of 30 d; if the effective half-life is less than 30 d, the monitoring data should cover a time range corresponding to the effective half-life.
c) The monitoring data should cover a time range of 60 d; if the effective half-life is less than 30 d, the monitoring data should cover a time range corresponding to twice the effective half-life.

Special monitoring is also required following decorporation therapy or medical treatment such as wound excision, because in these cases the modified biokinetic behaviour of the radionuclide needs to be assessed. Here, care needs to be taken in selecting the monitoring methods and the frequency of the measurements because the standard procedures applied for the radionuclide may not be suitable due to the modified biokinetic behaviour. Additional measurement techniques such as wound

monitoring or the measurement of excised tissues could be applied to provide supplementary information for the dose assessments.

**Table C.7** Monitoring method, minimum number and time range of measurements required for assessment of dose for some selected radionuclides
(Table 6.2 of IDEAS Guidelines, reproduced with kind permission of EURADOS)

| Radionuclide | Type of monitoring | Required monitoring data | | | | | |
|---|---|---|---|---|---|---|---|
| | | E<1 mSv[a] | | 1 mSv<E<6 mSv[b] | | E>6 mSv[b] | |
| | | Number | Range (days) | Number | Range (days) | Number | Range (days) |
| $^{3}H$ | Urine | 1 | - | 4 | 10 | 8 | 20 |
| $^{60}Co$ | Whole Body | 1 | - | 2 | 30 | 4 | 60 |
| | Urine | - | - | 2 | 30 | 4 | 60 |
| $^{90}Sr$ | Urine | 1 | - | 2 | 10 | 4 | 20 |
| | Faeces | - | - | 2 | 10 | 4 | 20 |
| $^{131}I$ | Thyroid | 1 | - | 2 | 7 | 4 | 14 |
| | Urine | - | - | 2 | 7 | 4 | 14 |
| $^{137}Cs$ | Whole Body | 1 | | 2 | 30 | 4 | 60 |
| | Urine | | | 2 | 30 | 4 | 60 |
| $^{235}U$ | Urine | - | - | 2 | 30 | 3 | 60 |
| | Faeces | 1 | - | 2 | 30 | 3 | 60 |
| | Lungs | - | - | 2 | 30 | 4 | 60 |
| $^{239}Pu$ | Urine | - | - | 3 | 30 | 5 | 60 |
| | Faeces | 1 | - | 3 | 30 | 5 | 60 |
| $^{241}Am$ | Urine | - | - | 2 | 30 | 3 | 60 |
| | Faeces | 1 | - | 2 | 30 | 3 | 60 |
| | Lungs | - | - | 2 | 30 | 4 | 60 |
| | Skeleton[a] | - | - | 1 | - | 2 | 60 |

[a] Minimum requirement
[b] These measurements are desirable if facilities are available

## Monitoring Programmes for short-lived Radionuclides

***Q7*** *How should potential exposures to short-lived radionuclides (e.g. such as are used for medical applications) be taken into account when designing a monitoring programme?*

Short-lived radionuclides such as $^{99m}Tc$ ($T_{1/2} \approx 6$ h) and $^{18}F$ ($T_{1/2} \approx 2$ h) are typically used in nuclear medical applications and research. If routine monitoring programmes for these radionuclides were to be developed based on the same considerations as for the longer-lived radionuclides discussed earlier, the number of measurements would be unreasonably large due to the short monitoring intervals required. Furthermore, the detection limit needed to detect an exposure at the RL or IL would be unrealistically low. Therefore, for radionuclides with effective half-lives shorter than that of $^{131}I$ ($T_{1/2} \approx 8$ d), triage monitoring performed directly at the facility with the equipment available there may be implemented based upon the result of the likely dose assessment. In this case, triage threshold values should be established using a 1 mSv $y^{-1}$ reference level. The values should be given in terms of the quantities measured using the available equipment. If the triage threshold value is exceeded,

special monitoring by sample bioassay may be employed in order to confirm and assess intake and dose. Otherwise, only the fact that the measurement has been made needs to be documented.

If an assessment of potential exposure indicates that the implementation of a triage programme is not necessary, confirmatory monitoring, which consists of workplace and/or individual monitoring performed at regular intervals, should be performed to check the effectiveness of protection measures.

For the case of internal exposure of nuclear medical staff, [ISO 2016b] provides detailed guidance on implementing these types of monitoring programmes.

## Documentation and Quality Assurance in Monitoring Programmes

***Q8*** *How should a monitoring programme and its implementation be documented?*

The strategy and objectives of the monitoring programmes as well as the methods, techniques, models and assumptions which are applied should be documented. Measurements made should be recorded in sufficient detail to allow reproduction of the exact conditions of the measurement. For the dose assessments, the calculation procedure and the underlying assumptions should be documented. The calculation (if performed manually) or the software identity (if applied) should be recorded [ISO 2006]. All information should be documented clearly and concisely to ensure the traceability of the measurements and the dose assessment, as well as to provide a link with documentation associated with other parts of the radiation protection programme [IAEA 1999a].

Formal procedures for documentation and record keeping should be established. Reports and records should be authenticated by responsible and competent persons and should be stored according to national requirements for record keeping [ISO 2006]. In the case of outside workers, provisions for appropriate data exchange by the parties involved (e.g. employer, undertaking, dosimetry service, Occupational Health Service) should be established.

An effective quality assurance (QA) system (see **Chapter G**) should be implemented to monitor the quality and effectiveness of the programme. The QA system should cover all aspects of the monitoring, ranging from measurement to dose assessment as well as the underlying assumptions. It is recommended that the QA programme should be based on the general laboratory standard ISO/IEC 17025:2005 [ISO/IEC 2005] and the standards for internal dosimetry, ISO 20553:2006, 27048:2011 and 28218:2010 [ISO 2006; 2011; 2010b].

## Recommendations

| R# | G | Text of the recommendation |
|---|---|---|
| | | ***Q1**: What is the overall purpose of an individual monitoring programme in the context of occupational intakes of radionuclides, and how does it relate to general radiation protection programmes?* |
| C01 | I | An individual monitoring programme for workers occupationally exposed to a risk of internal contamination should be designed to verify and document that the worker is adequately protected against the risk and that the protection complies with legal requirements [ISO 2006]. It is an essential component of the general radiation protection programme of the undertaking. |
| | | ***Q2**: What types of information are required in order to make decisions on the need for, and design of, an individual monitoring programme?* |
| C02 | I | The types of information required include [ISO 2006]:<br>• the radionuclide(s) to which workers may be exposed and the radiations emitted by their decay;<br>• the decay rate(s) of the radionuclide(s);<br>• the retention of the radionuclide(s) in the body or excretion from the body as a function of time after an acute intake. |
| C03 | A | Information of the following types should also be collected:<br>• working practices and sources of exposure;<br>• likely route(s) of intake;<br>• potential time patterns of intake;<br>• physical form of the materials involved;<br>• chemical form of these materials. |
| | | ***Q3**: How should workers be identified for whom individual monitoring may be required?* |
| C04 | M | Systematic monitoring is mandatory for workers liable to receive effective doses greater than 6 mSv per year (category A). For other workers (category B), monitoring should be sufficient to demonstrate that the classification is correct [EC 2014]. |
| C05 | I | In general, the assignment of a monitoring programme to an individual should be based on the likelihood that the individual could receive an intake of radioactive material exceeding a predetermined level, as a result of normal operations or in the event of an accident [ICRP 2015b]. |
| C06 | A | The evaluation of the likelihood of intakes for groups of workers should be based on past experience and past and current monitoring data if available. |
| | | ***Q4**: How should the need for an individual monitoring programme be determined and what type of monitoring programme should be selected?* |
| C07 | I | The need for an individual monitoring programme should be determined from a consideration of the following factors [ISO 2006]:<br>• The magnitude of the likely exposures;<br>• The need to recognise and evaluate events resulting in intakes (should they occur);<br>• The need to assess the effectiveness of protective equipment.<br>Evaluation of these factors should take into account all radionuclides and the different scenarios in which a worker could be exposed during routine operations. |
| C08 | A | The basis of the evaluation should be available data from earlier monitoring programmes (individual or workplace monitoring) and/or results of dedicated measurements currently performed at the workplace to characterise radiological conditions. If no such data are available, the decision factor approach [IAEA 1999a] should be employed. |
| C09 | I | The type of monitoring programme should be selected based on comparison of the estimated likely annual dose with predefined reference levels. The recording level as defined by ISO [ISO 2006] should be used as the reference level that indicates the need for a routine monitoring programme. If the need for routine monitoring is not indicated, confirmatory monitoring may be employed to demonstrate that this is the case. |

| R# | G | Text of the recommendation |
|---|---|---|
| C10 | I | Individual monitoring techniques should be applied if the worker is liable to receive doses exceeding the investigation levels defined by ISO [ISO 2006]. |
| C11 | A | Monitoring programmes using individual monitoring techniques are also recommended in situations where the estimated likely annual dose falls between the recording and investigation level. |
| | | ***Q5**: What requirements should be considered when designing a routine monitoring programme?* |
| C12 | I | In routine monitoring, bioassay measurements should be performed on a regular schedule. The monitoring interval and the technique should be chosen in such a way that:<br>• the programme reliably detects intakes resulting in doses at the recording levels, and<br>• the maximum underestimate in the resulting dose due to unknown time of intake is less than a factor of three.<br>For the commonly- encountered radionuclides, the methods and intervals provided by ISO [ISO 2006] or ICRP [ICRP 1997] should be used. |
| C13 | I | If there are no positive measurements during a routine monitoring interval, the fact that the measurement has been performed should be documented [ISO 2011]. |
| C14 | I | Dose assessments should be performed using defined reference assumptions. Documentation and record keeping of measurements and dose assessments should follow formal procedures and should enable later reproduction of the conditions of the measurement and a recalculation of the doses [ISO 2011]. |
| | | ***Q6**: What requirements should be considered when designing other types of monitoring programme?* |
| C15 | I | Non-routine (special, task-related and confirmatory) monitoring programmes should be specified in such a way that sufficient information for the subsequent dose assessment is provided. A combination of several monitoring methods may be specified. The methods and number of measurements required for special monitoring provided by ISO [ISO 2006] or EURADOS [EURADOS 2013] should be used. |
| C16 | I | Information about the specific events triggering non-routine monitoring should be used in the dose assessment procedure [ISO 2011]. |
| | | ***Q7**: How should potential exposures to short-lived radionuclides (e.g. such as are used for medical applications) be taken into account when designing a monitoring programme?* |
| C17 | I | In cases where short-lived radionuclides are encountered, triage monitoring programmes may be employed. They may be performed directly at the facility using available monitors.<br>Triage threshold levels (specified in terms of the quantities measured using the available equipment) should be defined. These levels may be used to trigger special monitoring for confirmation and assessment of the intake. Further information is provided by ISO [ISO 2016b]. |
| | | ***Q8**: How should a monitoring programme and its implementation be documented?* |
| C18 | I | The strategy and the objectives of the monitoring programme as well as the methods, techniques, models and assumptions should be documented [ISO 2006]. |
| C19 | A | A quality assurance (QA) system should be implemented that not only monitors measurement aspects, but also the dose assessment aspects and the quality of the overall programme. The QA system should be based on the general laboratory standard ISO/IEC 17025:2005 [ISO/IEC 2005] and the ISO standards on monitoring and dose assessment [ISO 2006; 2010b; 2011]. |

G = Grade: M = Mandatory, I = International, A = Advisory

# CHAPTER D – Methods of Individual and Workplace Monitoring

***MAIN QUESTION***

***Q1*** *What are the methods that should be used for individual monitoring and workplace monitoring?*

***Subsidiary questions***

***Q2*** *How should in vivo bioassay of the activity (Bq) of radionuclides retained in the body that emit penetrating radiation be performed?*

- ***Q2.1*** *How are in vivo measurement systems designed and applied?*
- ***Q2.2*** *How are in vivo measurement systems calibrated and how is the activity calculated from the measurement?*

***Q3*** *How should the excretion rate (Bq $d^{-1}$) of incorporated radionuclides in biological samples be measured?*

- ***Q3.1*** *Which issues need to be considered in sampling for bioassay monitoring?*
- ***Q3.2*** *Which techniques are applied for the analysis of bioassay samples?*
- ***Q3.3*** *Which calibrations are required for in vitro bioassay techniques and how is the activity concentration calculated?*

***Q4*** *How is the radionuclide concentration in air monitored in a workplace?*

## Special Terms used in this Chapter

*In vivo* monitoring, Direct measurement, *In vitro* analysis, Indirect measurement, *In vivo* bioassay, Sample bioassay, Urine bioassay, Faeces bioassay, Workplace monitoring, Decision Threshold, Detection Limit, Reference Individual, Calibration phantom, Calibration standard, Detection efficiency, Photon emission, Monte Carlo methods, Personal Air Sampler, Static Air Sampler, Voxel phantom.

## Introduction

This chapter describes the monitoring techniques that are appropriate for the determination of radionuclides incorporated into the body.

***Q1****: What are the methods that should be used for individual monitoring and workplace monitoring*

Doses from intakes of radionuclides cannot be measured directly. Rather, they are assessed from monitoring measurements of the activity content in the body, the activity in biological samples, the airborne radionuclide concentration in the workplace or by a combination of these methods.

The choice of monitoring technique mainly depends on the radiation emitted by the radionuclide and its progeny. Other factors which influence the choice of monitoring technique are the decay rate of the radionuclide, the chemical compound, the retention in the body or the excretion rate from the body of the contaminant as a function of the time between intake and measurement, organ deposition and excretion pathway of the contaminant and technical feasibility of measurement.

Internal dosimetry services should be supplied with appropriate equipment for individual or workplace monitoring according to the recommendations summarised in ISO 20553:2006 [ISO 2006] for routine and special monitoring of occupational exposures to radionuclides, taking into account the advantages and limitations (including availability and sensitivity) of different measurement methods.

## *In vivo* monitoring: Direct measurements of radionuclides incorporated into the body

***Q2**: How should in vivo bioassay of the activity (Bq) of radionuclides retained in the body that emit penetrating radiation be performed?*

*In vivo* monitoring of radionuclides incorporated in the human body is usually a rapid technique (typical counting times are in the range of 5-60 minutes) to assess the retention and the deposition of the activity of radionuclides in the body at the time of monitoring. Lung counting can take longer depending on the desired sensitivity.

These direct methods are useful only for radionuclides emitting penetrating radiation that can be detected outside of the body (X / gamma emitters, positrons detected by measurement of annihilation radiation or energetic beta particles that can be detected by measurement of bremsstrahlung radiation). The International Commission on Radiation Units and measurements [ICRU 2003] and the International Atomic Energy Agency [IAEA 1996a] have given guidance on the direct measurement of body content of radionuclides.

### Detector Systems

***Q2.1**: How are in vivo measurement systems designed and applied?*

The selection of a detector system depends on sensitivity requirements, energies of the photons emitted and environmental background interference. Thallium-activated sodium iodide (NaI(Tl)) scintillation detectors and High Purity Germanium (HPGe) semiconductor detectors are the most common detection systems used in direct measurements.

- NaI(Tl) scintillation detectors have a good efficiency at medium and high energies (above 100 keV) but poor energy resolution comparing with semiconductor detectors.
- High Purity Germanium detectors (HPGe) are now the most commonly used due to their excellent energy resolution, low intrinsic background and good efficiency at low energies. The main inconvenience is that they need to be cooled (e.g. with liquid nitrogen) during operation. Detectors equipped with electric cryostats have been developed to replace liquid nitrogen cooling systems.

Electronic instrumentation processes the signals generated from the interaction of photons with the detector system. The result of a measurement is an energy spectrum that is analysed using gamma spectrometry techniques [ICRU 2003]. The calibrations of the detectors (i.e. energy vs. channel number, Full Width at Half Maximum (FWHM) vs. energy and detection efficiency vs. energy) allow the identification and quantification of the radionuclides present in a contaminated person at the moment of the measurement. Appropriate calibration phantoms simulating the body and/or the organs of interest are filled or labelled with appropriate radioactive sources (e.g. X and gamma emitter radionuclides in the energy range of interest) [ICRU 2003]. The nature of the calibration phantoms and the identity of the radionuclides depend on the requirements of individual monitoring programmes for occupational intakes.

Various international projects and working groups have worked to improve the use of *in vivo* monitoring methods: OMINEX [Etherington 2004], EURADOS-Radiation Dosimetry Network [Pihet 2005], IDEAS [Doerfel 2006], CONRAD [Lopez 2007]. Advances in techniques have improved the measurement accuracy and sensitivity with the widespread application of *in vivo* measurements in fields such as nuclear medicine [Genicot 2011].

Lanthanum bromide ($LaBr_3$:Ce) detectors are a new generation of inorganic scintillators for gamma spectrometry with better energy resolution and stability than NaI(Tl) detectors [Menge 2007; Löher 2012]. New types of semiconductor counting system (Si, CdTe detectors) are being developed to avoid the need for cooling systems [Genicot 2011]. The main advantage is the possibility to operate detectors at room temperature, but a significant disadvantage is the small size (low efficiency) of such devices.

## Shielding

Background reduction is important to improve the sensitivity of the detection system, to reduce the counting time and to avoid interferences with natural radiation. Furthermore, environmental background radiation or human intrinsic radioactivity can interfere in the energy range of the *in vivo* measurements [ICRU 2003] and should be controlled. To reduce the background, the detectors are usually partially shielded and/or placed in a low background shielded room constructed using shielded materials that are free of (or low in) contaminating radionuclides (e.g. a shielded room of pre-nuclear age steel, with walls with a lead (or lead and copper) lining to reduce background from fluorescence X rays from high-Z shield materials [ICRU 2003]). Typical steel wall thicknesses of 100-200 mm and a few mm of lead lining are usually employed.

## Counting Geometries

When the activity of a radionuclide in the whole body is measured, the result should be as independent as possible of the distribution of activity in the organs of the body. Conversely, when a measurement of the activity of a radionuclide in an individual organ or tissue is performed, the result should be as independent as possible of the radionuclide activities in other organs.

### Determination of radionuclides deposited in total body: Whole body monitoring

Whole body monitoring generally employs NaI(Tl) scintillators and/or HPGe semiconductor detectors in an appropriate counting geometry, for the measurement of most of the fission and activation product radionuclides (except for radioiodine, which is mainly absorbed in the thyroid gland, or $^{60}$Co oxide in the lungs). The main advantage of NaI(Tl) detectors is their high counting efficiency, and measurement times that are rapid enough for routine monitoring. In the case of HPGe detectors, the very high energy resolution permits accurate radionuclide identification and analysis of complex gamma spectra. Some facilities utilise both NaI(Tl) and HPGe detectors in order to improve energy resolution and detection efficiency.

### Determination of activity in an organ of the body (thyroid, lungs, skull, knee, liver, others): Partial body monitoring

If the radionuclide deposits preferentially in a single organ such as the thyroid (e.g. $^{125}$I, $^{131}$I), then partial body monitoring of the relevant organ should be employed. In the case of inhalation of materials that are absorbed less rapidly from the respiratory tract, lung monitoring is preferable to whole body monitoring soon after the intake, as it gives a more accurate measurement of lung deposition and retention than a whole body measurement. *In vivo* monitoring of specific organs is also useful for some radionuclides that emit photons (X/gamma rays) at lower energies and/or with lower yields (e.g. $^{241}$Am, $^{226}$Ra, $^{235}$U, $^{210}$Pb).

## Specific radionuclides

### Radioiodine isotopes $^{125}$I and $^{131}$I

Iodine-125 and $^{131}$I are the most important radioiodine isotopes from the point of view of radiological protection. Iodine-131 is an important radionuclide to consider in the context of occupational exposures, which may occur in nuclear power plants or as a result of exposures in the medical field. Because of the preferential uptake of iodine to the thyroid, *in vivo* measurement of the thyroid is the recommended procedure to estimate intakes of these radionuclides. NaI(Tl) scintillation detectors (partially shielded or inside a shielded room) are usually used for this type of *in vivo* measurement, but for complex exposure scenarios (e.g. releases from nuclear power plant accidents) HPGe semiconductor detectors can improve qualitative and quantitative evaluation of intakes, due to their excellent energy resolution (detector cooling is required so liquid nitrogen or an electricity supply must be guaranteed). In the case of nuclear or radiological accidents resulting in occupational exposures, other devices (e.g. simple hand-held NaI(Tl) detectors, lanthanum bromide detectors) can be used for measurements of radioiodine in the thyroid, at least for triage purposes.

### Actinides (plutonium, americium, uranium)

Radionuclides of these elements generally have high radiotoxicity and the sensitivity of detectors should allow measurements to be made of their low energy X-rays or/and gamma photon emissions, with adequate sensitivity for radiation protection purposes.

However, because of the low photon emission energies and low photon yields, attenuation by overlying tissues significantly reduces the detection efficiency. In the case of lung monitoring for actinide radionuclides, the individual's chest wall thickness should therefore be estimated and calibrations performed that take account of this factor [Griffith 1986].

- Direct measurement of plutonium in lungs is based on the detection of the X-ray emissions at 13.6 keV, 17.1 keV and 20.3 keV. Determination of plutonium activities in the lungs depends on the isotopic composition of the intake expressed in terms of the relative activities of $^{238}$Pu, $^{239}$Pu and $^{240}$Pu. The low energy photons are highly attenuated by soft tissue and muscle tissue in the body, and are almost completed absorbed in bone. This high attenuation and the low photon yield results in detection limits for activities in the lungs that correspond to large intakes and committed effective doses that are well above annual dose limits.
- Many plutonium sources contain $^{241}$Am, which is present because of the decay of the pure beta-emitting radionuclide $^{241}$Pu. The activity ratio of $^{239/240}$Pu to $^{241}$Am is often well-known, in which case it may be used to infer the Pu activity in the lungs. (Measurements of the activity of alpha-emitting Pu radio-isotopes are often presented as the sum of the $^{239}$Pu and $^{240}$Pu activities because their alpha spectra are almost indistinguishable). The main gamma ray emission energy of $^{241}$Am is 59.5 keV (36% yield). Photons of this energy are less attenuated in the body than the low-energy X-rays from plutonium, and thus are easier to detect in lungs, bone (skull, knee) and liver. The assessment of plutonium exposures on the basis of $^{241}$Am requires good knowledge of the Pu:Am ratio.
- Uranium compounds generally contain a mixture of the major isotopes $^{234}$U, $^{235}$U and $^{238}$U; in certain cases, $^{233}$U and $^{232}$U are also present. In enriched and depleted uranium, the $^{235}$U content is elevated or reduced respectively, compared to its natural value. The main $^{235}$U photon emission has an energy of 185.7 keV (yield 57.2 %). Uranium-238 can be measured using the 63.3 keV and 92.5 keV photon emissions of its daughter $^{234}$Th; in the absence of physical or chemical separation, secular equilibrium is frequently assumed and isotopic composition of the uranium radio-isotopes is usually known. Uranium miners are occupationally exposed to natural uranium, for which the full decay chains (Figures D.1 and D.2) are present. Conversely, when considering uranium

compounds that have been chemically purified, the $^{238}U$ and $^{235}U$ decay chains terminate at $^{234}U$ and $^{231}Th$.

## Naturally occurring radionuclides

NORM (naturally occurring radioactive materials) are found naturally in the environment. NORM can be monitored *in vivo* for the evaluation of exposures to radionuclides in the decay chains of uranium (Figures D.1 and D.2) and thorium (Figure D.3), or to radon and its progeny. Since chemical separation can occur either naturally or by industrial processing, the relative proportions of progeny with the parent radionuclide is an important factor in the interpretation of monitoring data for effective dose assessments. Furthermore, the members of a decay chain can have important differences in their biokinetic behaviour. The contribution of NORM to the measurement background of the counting laboratory should be taken into consideration, as well as background levels of NORM in the body arising from non-occupational exposures resulting from dietary intake.

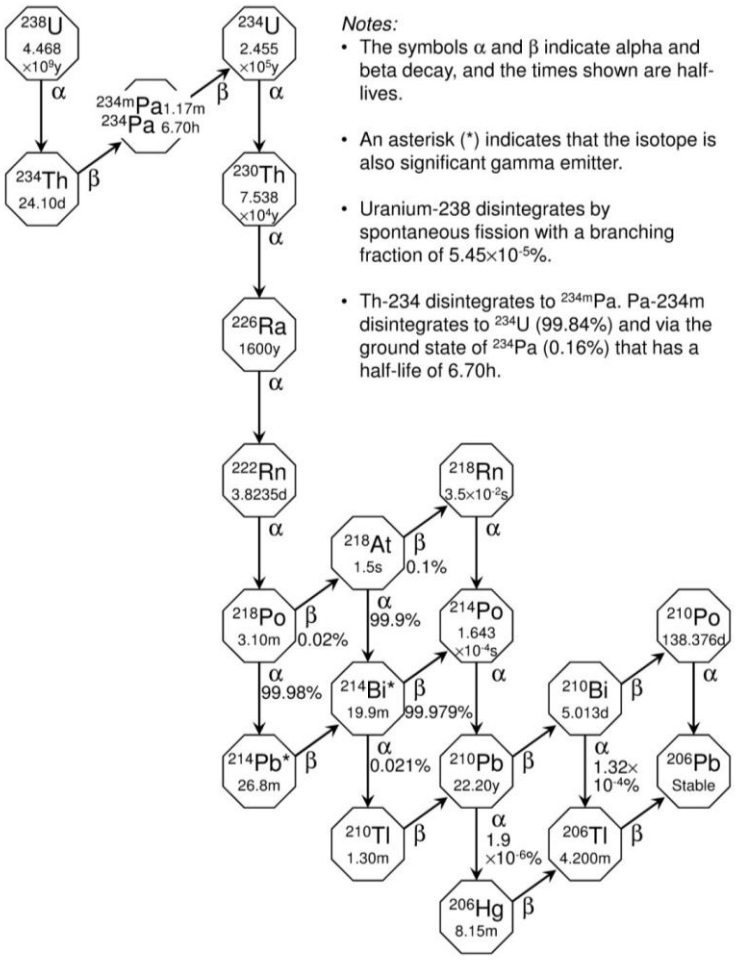



**Figure D.1** Decay chain of $^{238}U$ (from OIR report series, Part 1, Annex A [ICRP 2015b], reproduced with kind permission of ICRP)

Regarding uranium exposures, $^{235}U$ and $^{238}U$ occur naturally and are also encountered in operations and facilities related to the nuclear fuel cycle (see "Specific radionuclides" above, for individual monitoring of uranium compounds). The presence of uranium and/or its radioactive progeny in building materials as well as in radon decay products is a significant potential source of background.

Radium-226 is part of the $^{238}U$ decay chain but it is readily separated from the preceding members of the series and is distributed differently in the environment. Radium-226 was used in the past in medical and industrial applications (such as luminous paint) and is currently encountered as a waste product in the gas and petroleum industry.

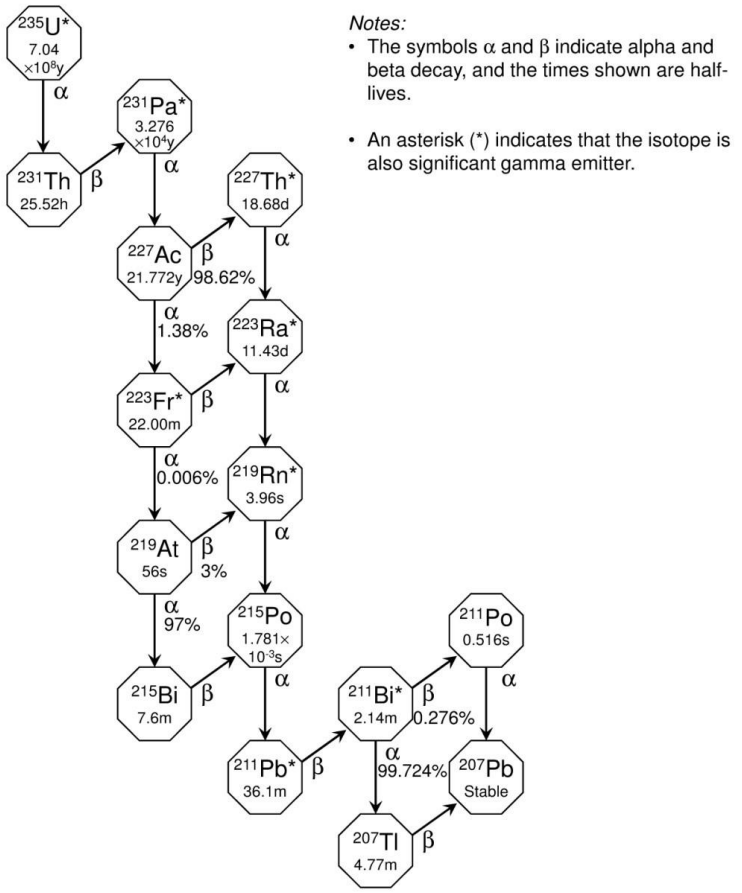



**Figure D.2** Decay chain of $^{235}U$ (from OIR report series, Part 1, Annex A [ICRP 2015b], reproduced with kind permission of ICRP)

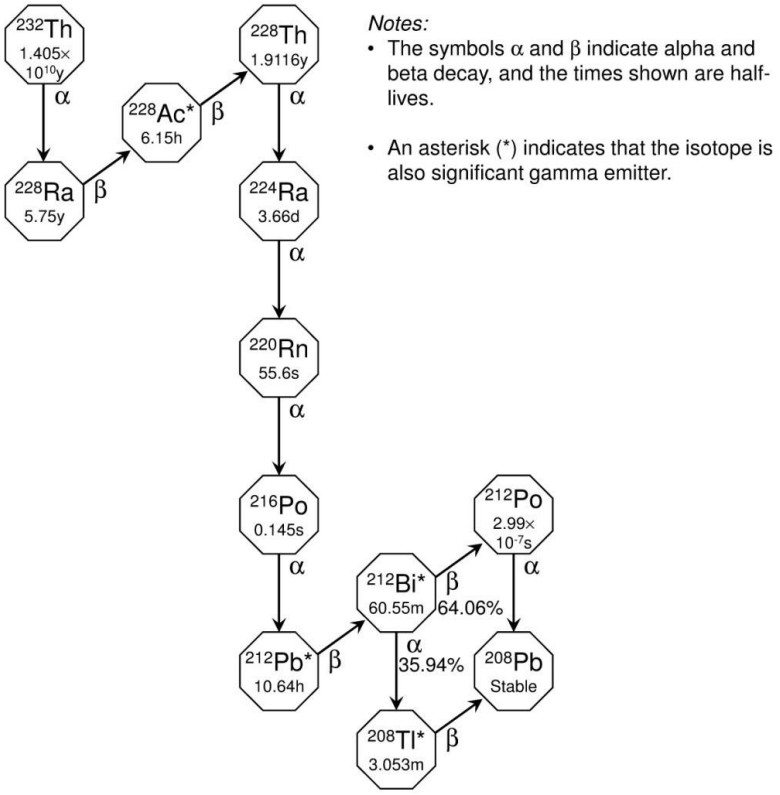



**Figure D.3** Decay chain of $^{232}Th$ (from OIR report series, Part 1, Annex A [ICRP 2015b], reproduced with kind permission of ICRP)

*In vivo* monitoring of $^{226}$Ra involves either the measurement of the main $^{226}$Ra gamma ray emission (186.2 keV; 4% yield) or the detection of gamma ray emissions from its progeny (specifically, $^{214}$Pb and $^{214}$Bi). Underestimates of $^{226}$Ra activity may arise in the latter method because the immediate decay product of $^{226}$Ra is a gas ($^{222}$Rn), some of which is exhaled from the body (radon is soluble in blood and can thus pass to the lungs, pass the lung/blood interface, and exit the body through exhalation [ORAU 2005; Srivastava 1986]).

The $^{235}$U 185.7 keV gamma-ray and the $^{226}$Ra 186.2 keV gamma-ray tend to overlap in measured spectra even with semiconductor detectors; this complicates determination of the contributions from the two radionuclides when they are both present in a gamma spectrum.

Lead-210 (46.5 keV photons; 4.6% yield) is the first long-lived progeny radionuclide in the decay-chain of $^{222}$Rn (also a member of the $^{238}$U decay chain), and can act as an indicator of exposure to radon gas. Lead-210 is deposited in the skeleton, where a small fraction is retained with a long biological half-time. *In vivo* measurement of $^{210}$Pb in bone [Dantas 2007; Johnston 2005; Laurer 1999] is useful for assessing the cumulative exposure of uranium miners to radon progeny.

Exposure to thorium can occur in a number of industries (e.g. mining and processing of mineral sands, manufacture of gas mantles and welding rods). Thorium levels can be quantified by measuring $^{232}$Th decay products, making the assumption of equilibrium between progeny [Genicot 2001]. The direct measurement (by gamma spectrometry) of thorium uses the gamma ray emissions of $^{232}$Th progeny radionuclides such as $^{228}$Ac (911 keV, 26.2% yield) or the gamma ray emissions of the $^{228}$Th decay products $^{224}$Ra, $^{212}$Bi, $^{212}$Pb and $^{208}$Tl retained in the body. Exhalation measurements of progeny radionuclides of $^{232}$Th and air sample monitoring are also available methods for intake estimation [Chen 2008; Sathyabama 2006; Youngman 1994]. Uncertainties in interpretation arise because the state of equilibrium between $^{232}$Th and its progeny at the time of intake may not be known, and also because the decay products do not exhibit the same biokinetic behaviour as their parents. Thus, it cannot necessarily be assumed that thorium and its decay products are present in the body in equilibrium proportions, nor can it be assumed that their relative distribution within the body remains unchanged over time.

NaI(Tl) scintillation detectors and HPGe detectors can be used to assess thorium intakes by measuring $^{208}$Tl in the body provided equilibrium between $^{232}$Th and $^{228}$Th is confirmed and the loss of thoron ($^{220}$Rn) gas by exhalation is taken into account. An alternative sensitive method is the use of HPGe semiconductor detectors placed in a lung monitoring geometry in order to evaluate $^{228}$Ac (a progeny radionuclide of $^{232}$Th). Lung monitoring should be used with caution: the progeny radionuclides are cleared from the lungs at different rates than the parent. Another problem arises from the origin of the $^{232}$Th and $^{228}$Th radioisotopes. Sometimes the source of thorium has undergone chemical separation from the progeny radionuclides, in order to obtain purified thorium, and the separation steps may be repeated more than once, so that the activity of inhaled $^{228}$Ac is much smaller than that of $^{232}$Th. Thus it is sometimes better to measure the progeny radionuclides of $^{228}$Th, as they reach equilibrium much faster.

Although direct measurements for *in vivo* monitoring of $^{232}$Th and $^{238}$U are rarely used for NORM and *in vitro* monitoring of excreta samples is the technique usually selected, *in vivo* monitoring can still provide relevant information.

Potassium-40 ($^{40}$K) is a naturally occurring radionuclide of potassium with an isotopic abundance of 0.0117%. It emits a 1.46 MeV gamma ray (yield 0.6%). Potassium is present in all living things, being physiologically necessary for their function. The human body generally contains between 2 and 5 kBq of $^{40}$K (closer to 5 kBq in young males), distributed throughout the body. Potassium-40 is detected by most *in vivo* measurements of workers and members of the public, and its presence is clearly identified in the resulting gamma spectrum.

### Radiopharmaceuticals in Nuclear Medicine

ISO 16637:2016 [ISO 2016b] addresses monitoring and internal dosimetry for staff exposed to medical radionuclides as unsealed sources. Individual monitoring as part of confirmatory monitoring is used to confirm the adequacy of protective measures and of assumptions made regarding the level of exposures. Individual monitoring can be performed via periodic *in vivo* measurements or urine bioassay analysis. However, due to the short half-lives of radionuclides in use for diagnostic or therapeutic administration in nuclear medicine, *in vivo* measurements of radionuclides in the body are recommended, particularly for common radionuclides such as $^{99m}$Tc or $^{18}$F. The *in vivo* measurements may be performed in whole body monitoring facilities located near the nuclear medicine department. For departments located far away from such facilities, mobile body counter laboratories may be used to perform on-site measurements. Iodine-131 presents a high risk of intake and is the largest cause of internal dose to nuclear medicine workers. Due to the cost associated with transporting workers or bioassay samples to laboratory, nuclear medicine centres may use their own devices to perform the monitoring of the workers involved in a radioiodine handling procedure. For instance, measurements may be performed using gamma cameras or thyroid probes [Rodriguez 2010].

### Beta emitters

Detection of pure beta emitters may be carried out using NaI(Tl) detectors and semiconductor HPGe detectors to measure the bremsstrahlung radiation produced, which forms a continuous photon spectrum that depends on the beta particle energy and atomic number of any absorbing material. In the human body, bremsstrahlung radiation is produced as a result of deceleration of beta particles in the tissues. The highest intensity bremsstrahlung radiation is in the low energy photon range up to 250 keV. Quantification of these spectra is complicated because there is no distinct peak which can be evaluated.

Strontium-90 is a pure beta emitter that is usually in a secular equilibrium with its progeny radionuclide $^{90}$Y. Strontium is a bone-seeker element. *In vivo* determination of $^{90}$Sr/$^{90}$Y is feasible from the evaluation of the bremsstrahlung in the gamma spectrum, using appropriate calibration phantoms simulating strontium in the body. *In vivo* determination of other beta emitters such as $^{32}$P is also possible.

However, because of the relatively high limits of detection for bremsstrahlung counting and the difficulty in discriminating bremsstrahlung radiation from the background spectrum, the usefulness of *in vivo* measurement is limited.

## Calibration of *in vivo* monitoring systems. Detection systems and calibration phantoms

***Q2.2**: How are in vivo measurement systems calibrated and how is the activity calculated from the measurement?*

*In vivo* monitoring measurements assess radionuclide content in the body by means of gamma ray spectrometry. The detection system therefore requires an appropriate quality assurance programme, with detectors regularly calibrated for energy, efficiency and resolution (FWHM) using sealed point sources traceable to a national standard.

To calibrate *in vivo* monitoring systems for measurements of radionuclides distributed in all or part of the body, laboratories generally use active physical phantoms simulating internal contamination of organs or total body (e.g. the ANSI N13 thyroid phantom [ANSI 2014; Mallet 2015], the BOMAB phantom [ANSI 2009], the Brick phantom (often named 'Igor' or the St Petersburg phantom) [Thieme 1998], the Lawrence Livermore National Laboratory (LLNL) thorax phantom [Griffith 1986] or the Japanese Atomic Energy Research Institute (JAERI) thorax phantom [Shirotani 1987], the latter both used for lung monitoring). The development of realistic body phantoms is strongly dependent on the availability of comprehensive human anatomical data [ICRU 1992]. The size of the calibration phantom and the distribution of the radionuclides should match that expected in the human subject (although the simplifying assumption of a homogeneous radionuclide distribution is usually made).

When calibrating detection systems for the measurement of low energy photon emitters in the lungs (radioisotopes of americium, uranium, plutonium and others) it is necessary to use more realistic anthropomorphic phantoms with different thoracic plates to simulate different chest wall thicknesses.

For calibration purposes, due to the short half-life of radioiodine ($^{131}$I, $^{125}$I), other radionuclides (e.g. $^{133}$Ba, $^{129}$I) may be used as mock sources for calibration because of their long half-life and very similar gamma emissions [ANSI 2014].

Numerical calibration techniques may be used as an alternative tool for *in vivo* measurement calibrations. The method consists of simulating transport of photons from a numeric phantom to a mathematical, three-dimensional model of the detectors to be calibrated. Monte Carlo methods are used to simulate photon transport, using radionuclide decay data describing photon energies and yields. In principle, numerical techniques allow generation of calibration factors for a wide range of scenarios. Flexible computational models of human bodies varying in gender, body height and mass have been used to study the morphology-induced variation of the detector counting efficiency. Measurements can be accurately simulated for both sexes, for adults and children of different ages, for different statures (including different chest wall thicknesses), for any radionuclide distribution within the body, and for any detector type and arrangement that can be described using a mathematical model.

Several codes for Monte Carlo simulations of radiation transport are available and have been applied to *in vivo* monitoring (e.g. EGSnrc, GEANT4, VMC and MCNP). The codes differ in the level of flexibility and the programming needed to generate the simulation scenario, although ease of use is being improved with the development of multi-platform graphic user interfaces (GUI). A number of recent publications [Hunt 2000; Borissov 2002; Franck 2003; Gómez Ros 2007; Marzocchi 2009; Farah 2010; Broggio 2011; Vrba 2013; Ferreira Fonseca 2014a; 2014b; 2015c] discuss the practical implementation of the method.

However, a higher degree of computational competence is required of the user. This could explain why, currently, numerical techniques are rarely used for routine calibrations of *in vivo* measurements, although a significant amount of work is being carried out, and the use of the method is becoming more widespread. Furthermore, for the technique to be used in routine applications, adequate validation procedures should be implemented which could be complex and need to be verified after any change of detectors. Validation of the method can be achieved by (i) validation of the modelling of the detector (counting geometry, materials, dead layer) and (ii) performing appropriate intercomparisons with physical phantom measurements using traceable radionuclide sources.

## Types and Sources of Nuclear Data required for Calibration

While performing calibration or assessment of measurements, nuclear data are required for some calculations. Basic radionuclide data, such as the half-life and modes of decay, as well as more detailed information on the emissions (type and energy of radiation and its yields) are required. Nuclear data (e.g. charts of the nuclides or tables) are available – in printed or electronic form – from different sources e.g. ICRP Publication 107 [ICRP 2008]. The data from different sources may show differences in terms of format, accuracy (e.g. number of significant digits) but also in numerical values. The latter could become a source of error in radionuclide activity measurements and corresponding intake and dose assessments. Available decay data have been evaluated by the international Decay Data Evaluation Project (DDEP) and recommended data are published on the website of the Laboratoire National Henri Becquerel [LNHB 2015].

## Identification and Quantification of Radionuclides

The energy calibration of *in vivo* monitoring systems in the energy range of interest, covering all the emissions of the radionuclides to be evaluated, permits the appropriate identification of the peaks present in the measured spectrum, that

correspond to the photons emitted by the radionuclides inside the body of the contaminated person.

The determination of efficiency ε (c $\gamma^{-1}$ = counts/gamma photon) versus energy E (keV), and efficiency versus chest wall thickness (cwt, cm) in the case of lung monitoring of low energy photon emitting radionuclides, allows the calculation of the activity (Bq) of the radionuclides incorporated in the body (Eq. D.1) assuming the activity distribution of the subject and phantom are the same:

$$A_{R,E} = \frac{N_E}{t_{live} \cdot \varepsilon(E) \cdot I_{R,E}} \qquad \text{(Eq. D.1)}$$

where

| | |
|---|---|
| $A_{R,E}$ | activity of radionuclide R, evaluated at energy E [Bq] |
| $N_E$ | net peak area at energy E [counts] |
| $t_{live}$ | live time of the measurement [s] |
| $\varepsilon(E)$ | efficiency at energy E [counts photon$^{-1}$] |
| $I_{R,E}$ | photon yield [photon disintegration$^{-1}$]. |

It is recommended to measure the background before an individual monitoring measurement and to proceed with background subtraction when appropriate [ICRU 2003].

## Sensitivity of *in vivo* monitoring: Detection Limit, Decision Threshold

One of the main challenges in *in vivo* monitoring is to determine whether a peak in the measured spectrum indicates the presence of a radionuclide in the body or is associated only with background radiation from the environment. Furthermore, the presence of natural radioactive elements in the person being measured could introduce additional uncertainty in this determination. According to ISO 28218:2010 [ISO 2010b], the value of the "detection limit" is the smallest true value of the measurand that is detectable by a measuring method. The value of the detection limit indicates the ability of the laboratory to detect a radionuclide in a sample (urine, faeces) or in a person (in the case of *in vivo* measurements). The "decision threshold" is a fixed value of the measurand by which, when exceeded by the result of an actual measurement of a measurand quantifying a physical effect, it is decided that the physical effect is present [ISO 2010b]. The decision threshold provides a way of distinguishing the difference between the count rate from the measurement under analysis and the background count rate from the appropriate blank. The detection limit is mainly dependent on the person (e.g. attenuation due to tissue thickness), the radionuclide, the detectors (counting efficiency and source-detector distance) and the counting time. Detection limits may be used to estimate the sensitivity of the detection systems in a specific geometry of measurement taking into account routine conditions.

## Uncertainties

Measurement uncertainties arise from counting statistics, characterised with a Poisson or Gaussian distribution (Type A uncertainties), and Type B uncertainties which contain all uncertainties other than Type A. Type B uncertainties cannot be determined empirically but rather are evaluated assuming a single lognormal distribution.

For *in vivo* measurements, common sources of Type B uncertainty include variations of (1) detector/person positioning, (2) background signals, (3) body dimensions, (4) overlying structures and (5) activity distribution. Other Type B uncertainties arise from the calibration process and the spectrum evaluation.

The IDEAS Guidelines [EURADOS 2013] and ISO 27048:2011 [ISO 2011] describe and analyse the components of uncertainties in *in vivo* (Tables B.1 and B.2, ISO 27048:2011) and sample bioassay measurements (Table B.3, ISO 27048:2011) and propose a method for quantification of measurement uncertainties by applying a

"scattering factor" (*SF*, the geometric standard deviation of the lognormal distribution). See **Chapter F**.

In cases where the Type A uncertainties are relatively small (less than 30%), both Type A and Type B uncertainties can be approximated by lognormal distributions. The total *SF* for the lognormal distribution describing the overall uncertainty for measurement M is given by Equation D.2:

$$SF = \exp\sqrt{[\ln(SF_A)]^2 + [\ln(SF_B)]^2} \qquad \text{(Eq. D.2)}$$

where $SF_A$ and $SF_B$ are the scattering factors for Type A and B uncertainties, respectively.

## *In vitro* Monitoring: Determination of the Activity of Radionuclides in Biological Samples

***Q3**: How should the excretion rate (Bq $d^{-1}$) of incorporated radionuclides in biological samples be measured?*

*In vitro* monitoring consists of the determination of activity concentrations of radioactive materials in the excreta or in other biological materials removed from the body. The majority of sample bioassay monitoring programmes require analysis of urine samples, although faeces analysis may be required if the radionuclide is in a relatively insoluble form, or when an element is preferentially excreted via faeces, or the purpose is to assess clearance of Type S (slow absorption) material from the respiratory tract. Nose blow or nasal swab analysis may also be used after a suspected incident to identify radionuclide intakes. Other samples may also be analysed, such as blood, hair and teeth in special circumstances, but this is very unusual. The choice of biological sample depends not only on the major route of excretion, according to the biokinetic model for the element and the physico-chemical form of the intake, but also on factors such as ease of collection, type of analysis, availability and sensitivity of the analytical technique [IAEA 2000].

In some cases, excreta monitoring may be the only measurement technique available for those radionuclides which have no gamma ray emission or which have only low energy photon emissions. In general, *in vitro* bioassay is the measurement technique of choice to quantify internal contamination of pure alpha and beta emitters.

Regarding measurement techniques, alpha spectrometry is most commonly used for the monitoring of alpha emitting radionuclides. This requires radiochemical separation of the sample prior to the measurement. Inductively Coupled Plasma Mass Spectrometry (ICP-MS) allows direct analysis of long-lived radionuclides such as uranium, thorium and neptunium. Kinetic Phosphorescence Analysis (KPA) is also used to determine uranium concentration, with higher detection limits. The majority of beta emitters are monitored by liquid scintillation counting and do not need a very complex sample treatment prior to measurement (e.g. comparing with actinides), except for $^{90}$Sr analysis which requires radiochemical separation. Gamma emitting radionuclides may be determined by direct measurement by gamma spectrometry using scintillation or semiconductor-based detectors. Measurement of gross alpha and gross beta activities may be useful as a simple screening technique. Total activity measurements may be useful following a known contamination event or to identify those samples that merit early attention.

Principal *in vitro* methods used for dose assessment based on type of biological sample are shown in Table D.1.

### Collection of biological samples

***Q3.1**: Which issues need to be considered in sampling for bioassay monitoring?*

The collection of appropriate biological samples is an essential step in monitoring radionuclides incorporated in the body. Consideration should be given to the time of sample collection. A sample collected at the end of the work shift is the most sensitive indicator of exposure. On the other hand, analysis of a sample taken before starting

work (e.g. on a Monday morning) is a better indicator of retained or accumulated material. A sample taken after a period of no exposure or after a vacation will indicate the presence of a radionuclide in the body that is slowly excreted.

**Table D.1** Typical methods for *in vitro* monitoring of incorporated radionuclides

| Type of biological samples | Type of emission | Sample preparation | Method of detection and measurement | Examples |
|---|---|---|---|---|
| Urine | Alpha emitters | Radiochemical separation of the elements from the matrix | Alpha Spectrometry<br>Gross alpha counting<br>ICP-MS, TIMS | Am(1), Cm(1), Pu, U, Th, $^{226}$Ra, Np… |
| | Beta emitters | None, or concentration only | Liquid scintillation counting | $^{3}$H, $^{14}$C, $^{35}$S, $^{32}$P… |
| | | Radiochemical separation of the elements from the matrix | Liquid scintillation counting<br>Proportional counter<br>Gross beta counting | $^{90}$Sr, $^{228}$Ra, $^{210}$Pb… |
| | Gamma emitters | None | Gamma spectrometry<br>Gross gamma counting | gamma-emitting radionuclides |
| | All(2) | None, or separation of the elements | ICP-MS, TIMS<br>KPA<br>Fluorimetry | U, Th, Pu… |
| Faeces or biological samples | Alpha emitters | Radiochemical separation of the elements from the matrix | Alpha spectrometry<br>Gross alpha counting | Pu, Am, Cm, U, Th, $^{226}$Ra, Np… |
| | Beta emitters | Radiochemical separation of the elements from the matrix | Liquid scintillation counting<br>Proportional counter<br>Gross beta counting | $^{90}$Sr, $^{228}$Ra, $^{210}$Pb… |
| | Gamma emitters | Sample preparation such as calcination and mineralisation | Gamma spectrometry | gamma-emitting radionuclides |
| Nose blow | Alpha emitters | Acid treatment and evaporation | [Alpha spectrometry]<br>Gross alpha counting | Pu, Am, U, Th and other alpha emitting radionuclides |
| | Beta emitters | None | Liquid scintillation counting<br>Proportional counter<br>Gross beta counting | beta emitting radionuclides |
| | Gamma emitters | None | Gamma spectrometry | gamma-emitting radionuclides |

(1) not measured by ICP-MS
(2) non-radiometric methods

The collection of biological samples should be made in non-contaminated areas to avoid accidental contamination of the sample. Single-use containers should be used for collection and storage. All biological samples are subject to deterioration by

bacteriological action that may interfere with subsequent analysis. Prompt analysis following collection will avoid these complications. Preservatives (acid reagents or other chemical compounds) may need to be added to the sample containers to minimise precipitation and to prevent bacterial growth; alternatively, the samples may be stored at reduced temperature. All biological samples should be handled with care due to the possible presence of bacteria, viruses or other biological hazards. Refrigeration or freezing should be employed where appropriate.

The collection of urine samples is relatively simple. For most routine analyses, a 24-hour collection is recommended. Spot samples may also be collected for direct analysis of actinides using ICP-MS or KPA and for *in vitro* monitoring of beta emitters such as tritium ($^{3}H$), $^{14}C$, $^{32}P$ and $^{35}S$. However, as normalisation by volume or creatinine content (see below) brings about further uncertainty, 24-hour urine collection is preferable, except for $^{3}H$. Spot sampling is sufficient for the monitoring of intakes of tritiated water because it is considered to be uniformly distributed in the body fluids. Spot sampling of urine for soluble uranium exposures is commonplace.

It is important to establish procedures for sample handling which describe:

(i) appropriate identification of the samples,

(ii) need for pre-treatment of the samples,

(iii) appropriate packaging and labelling of containers,

(iv) prevention of biological or radionuclide contamination, and

(v) specification of chain of custody requirements.

The reference value for the volume of daily urinary excretion for a Reference Man is 1.6 l $d^{-1}$ and for a Reference Female is 1.2 l $d^{-1}$ [ICRP 2002]. Samples should not be rejected on the basis of volume as this is subject to large variation. Actually there are significant daily variations in the excretions of some materials, so in general total daily output should be collected to estimate accurately the daily excretion rate; this is particularly important for samples taken shortly after a suspected acute exposure. When 24-hour samples are not collected, the first void in the morning is the preferable spot sample for analysis. It should be taken into account that spot samples may not be representative after normalisation by volume or creatinine content. As the daily excretion of creatinine is produced as a metabolic product in muscle metabolism, it is recommended to use creatinine measurements to estimate 24-hour excretion from urine samples collected over part of a day. This estimation is based on the fact that creatinine is excreted at an average rate of 1.7 g $d^{-1}$ for men and 1.0 g $d^{-1}$ for women [ICRP 2002]. The ratio of this reference value to the measured creatinine content in the sample provides a correction to normalise the radionuclide amount measured in the sample to the equivalent of a true 24-hour collection. Other methods of obtaining an estimate of 24-hour excretion include normalisation by volume (with or without a correction for specific gravity) and normalisation by the length of the sampling interval [ICRP 2002].

The analysis of faecal samples for routine monitoring involves uncertainty in interpretation due to daily fluctuations in faecal excretion. The transit time through the gastro-intestinal (or alimentary) tract is subject to large inter- and intra-subject variations. Therefore, in order to average these variations, sampling for routine monitoring should be performed over a three day period. For special monitoring, sampling may be performed over the three days following an intake event. The uncertainty associated with cumulative excretion is lower compared with the uncertainty associated with daily excretion, especially in the case of the excretion over the first three days after intake. Workers should be well informed on this matter to ensure samples collected are total voidage over the sampling period. The reference faeces wet weights for males and females are 150 g and 120 g respectively [ICRP 2002].

Faecal monitoring is often used in special investigations, especially when an intake of a Type M or Type S material has occurred. Faecal samples are particularly subject to

biodegradation; therefore they should be analysed promptly, ashed and stored, or preserved by deep freezing.

The use of nose blow sampling as a semi-quantitative monitoring method following a suspected inhalation incident requires samples to be collected soon after the exposure and preferably also at regular intervals during the following 24 hours [Smith 2012]. This technique is very dependent on whether the individual is a dominant mouth breather, and on the level of physical activity during the potential exposure period. A positive result of the measurement (above the detection limit) gives an indication that an unexpected exposure may have occurred. Excreta measurements or *in vivo* monitoring should follow, to confirm the intake and to provide a quantitative assessment. Further discussion of the interpretation of nasal swab and nose blow sampling is given in **Chapter E**.

## *In vitro* radiobioassay techniques

***Q3.2**: Which techniques are applied for the analysis of bioassay samples?*

Decisions about the appropriate method of measurement and the need, if any, for the pre-treatment of the sample prior to counting, are very important. These decisions should be based on information on the radionuclides involved, the chemical and physical forms, the possible presence of interfering radionuclides, the necessary sensitivity to meet monitoring requirements, the availability of instrumentation and technical expertise in the laboratory.

Analysis of biological samples involves the detection and quantification of emissions from the radionuclides present. Sometimes, the radionuclides must first be separated from the matrix to allow sensitive and reproducible detection. In some cases, limitations of the detectors prevent discrimination between radionuclides that have emissions of similar energy; in these cases, radiochemical separation of the samples is required before counting.

Instrumentation for radiometric assessment can be divided into three classes depending on the emission type: alpha particles, beta particles and photon emissions.

### Alpha emitters

Alpha particles can be detected by a variety of techniques, each having advantages and disadvantages.

- Alpha spectrometry: Alpha spectrometry can be used when the identity of the radionuclide is known and chemical separation of the element is possible. After radiochemical separation, alpha spectrometry methods using semiconductor detectors or gridded ionisation chambers can quantify individual radionuclides, provided that their energies are sufficiently different. Alpha spectrometers have low backgrounds, but when very low levels of activity (mBq/sample) must be measured, long counting times may be required to achieve acceptable sensitivity.
- Mass Spectrometry: Inductively Coupled Plasma Mass Spectrometry (ICP-MS) and Thermal Ionisation Mass Spectrometry (TIMS). ICP-MS may be used for measuring plutonium, uranium, thorium and other long-lived radionuclides in biological samples. The analytical method is based only on the mass of the radionuclide, so chemical separation of elements with isotopes of the same mass number is needed. If uranium or thorium isotopes are present in urine, then, acidification and dilution is required prior to measurement. ICP-MS offers much shorter sample turnaround time (in relation to alpha spectrometry) although the quantification of shorter-lived isotopes (e.g. $^{238}$Pu, $^{228}$Th or $^{241}$Am) is difficult. Mass spectrometric techniques provides information on isotopic composition. TIMS is often used to perform uranium and plutonium isotopic measurements on a variety of sample types, to provide analytical support for nuclear material processing as well as for the low-level analysis of plutonium and uranium in urine [Maxwell 2001; Chamberlin, 1998]. TIMS has been used

for over 20 years as part of the Pu internal dosimetry programme at Los Alamos National Laboratory (USA).

- Kinetic Phosphorescence Analysis (KPA): KPA is used to quantify the total concentration of uranium in urine samples. The urine sample is wet and dry ashed to remove organic materials and finally dissolved. The uranium solution is mixed with a complexing agent. KPA analysis is a simple and rapid method which can be applied as an alternative to alpha spectrometry for screening.
- Fluorometry: This method quantifies total uranium in urine. It is faster than alpha spectrometric methods, and is useful when rapid assessment is important, but the detection limit of fluorometry is higher than that of KPA.
- Other techniques: When identification of the radionuclide is unnecessary, gross alpha counts may be performed with gas flow proportional counters or scintillation counters. Gas flow counters usually use a counting gas of 90% argon and 10% methane, and typically have detection efficiencies of around 45%. Scintillation counters employ a thin, transparent membrane coated with a scintillator such as zinc sulphide (ZnS) that is placed in proximity to the sample. These methods are efficient, but do not discriminate between alpha particles of different energies and cannot identify or quantify individual radionuclides in a mixture.

### Beta emitters

Beta particles are most commonly detected using Liquid Scintillation Counting (LSC), especially for low energy beta emitters. LSC is an analytical technique that measures activity of radionuclides using the rate of light photons emitted by a liquid sample. The radionuclide is contained in a scintillation cocktail liquid that fluoresces when exposed to alpha or beta radiation. The number of photons emitted is proportional to the energy deposited in the solvent. The photons are detected by two (or three) photomultiplier tubes working in coincidence to reduce background.

Counting efficiency is strongly dependent on quenching of the detection process, especially in the case of low energy beta emitters. The quenching effect results in the reduction of the number of emitted photons from the sample. As a result, the energy spectrum detected appears to shift toward lower energies.

Different techniques are used to address this quenching effect including: (i) the use of internal standards, (ii) the use of a physico-chemical procedure, such as distillation (for organically bound tritium) or the addition of activated charcoal (for free tritium) to remove any quenching agents, (iii) external standardisation, where scintillation in the samples induced by an external source are compared with those induced in an unquenched sample. Calibrations should be done using identical conditions to the analysis.

Beta LSC measurements have limited capacity to identify radionuclides, especially for the simultaneous determination of multiple radionuclides in samples, since the high energy emitters mask the contribution of the low energy emitters. Provided that the multiple radionuclides have quite different beta energies, it is possible to perform simultaneous determinations. For instance, it is possible to measure mixtures of $^{3}H$, $^{14}C$ and $^{99}Tc$, but it is not possible to measure $^{14}C$ and $^{35}S$ simultaneously as they have similar energies.

Gross measurements of high energy beta emitters deposited on planchettes or filters can be obtained using proportional detectors.

### Gamma Emitters

Radionuclides that emit gamma or X-rays may be determined by direct measurement with scintillation or semiconductor detectors (gamma spectrometry). Only a minimum amount of chemical preparation (i.e. concentration) may be required, but self-absorption of photons in the sample should be considered. Samples should be contained in appropriate containers that have the same geometrical configuration as

the reference source used for the efficiency calibration. Counting time is chosen according to the desired detection limit.

## Radiochemistry: Preparation of the Samples and Chemical Procedures

Written procedures should include all steps from the receipt of the sample at the laboratory facility to the preparation of the sample for analysis [IAEA 2000].

Taking an aliquot of a homogeneous sample to determine the activity present in the total sample is an acceptable procedure.

The usual aim of sample preparation is to reduce the sample to its inorganic constituents, eliminating the organic matter which can interfere in the radiochemical procedure or in the measurement. In some cases, a pre-concentration is needed in order to separate the radionuclides of interest from other inorganic materials (using co-precipitation techniques). Addition of isotopic tracers or/and carriers (for any kind of radiochemical analyses) is commonly used in order to calculate the chemical yield of the process. The tracers should be certified standards, have chemical behaviour similar to the radionuclides to be quantified and not have any interference in the analytical process nor in the measurement. Biological samples are mineralised by successive dry and wet ashing, finally obtaining a white residue. Dry ashing is performed in a muffle furnace or microwave oven; wet ashing requires strong acidic reagents. Care should be taken to prevent the loss of volatile elements such as caesium and polonium during the ashing process.

Radiochemical separation is carried out to isolate the radionuclide of interest. The separation may be performed by solvent extraction, ion exchange separation, extraction chromatography or co-precipitation. Depending on the matrix, it could be necessary to perform two or more consecutive separations.

The final step of the sample treatment is the preparation of the source for the measurement. The source preparation depends on the type of measurement and the radionuclide emissions. For alpha spectrometry, the most commonly used source preparation techniques are electrodeposition of the isolated radionuclides onto polished stainless steel discs, or the co-precipitation of the element with lanthanum, cerium or neodymium fluoride and collection onto a small filter paper [IAEA 2000]. For gross alpha and beta counting, the purified solution can be evaporated directly onto a filter paper or stainless steel planchette. Source preparation for beta emitters can be achieved by precipitation of different anions (hydroxide, oxalate, sulphate, carbonate and phosphate), whilst LSC sources are prepared by mixing the separated or partially separated analyte with an appropriate scintillation cocktail. ICP-MS and KPA measurements require the reconstitution of the volume of the sample after its treatment is completed.

Gamma emitters require minimal sample treatment prior to the measurement. When preparing a sample in a standard counting geometry it is necessary to consider the following factors: solid samples need to be packed to a standard density and volume; volume of liquid samples needs to accurately correspond to that of the standard geometry; liquid samples need to be sealed to prevent both spillage and evaporation; special care should be taken with any sample containing either a chemically volatile radionuclide (e.g. iodine) or a gaseous radionuclide (radon); settling and separation of samples into solid and liquid phases or into separate immiscible liquid phases containing different radionuclide fractions will affect detection efficiency and hence may bias results.

## Equipment Calibration

***Q3.3**: Which calibrations are required for in vitro techniques and how is the activity concentration calculated?*

Calibration standards should be traceable to national standards. Calibration of measurement equipment should be done at pre-determined intervals. Measurement equipment should be calibrated prior to any sample measurements. Calibration should

cover the range of energies and geometries required for the specific radionuclides and samples being measured.

There are two types of calibration in alpha spectrometry: an energy calibration (which includes energy and FWHM calibrations) and an efficiency calibration. The efficiency calibration is necessary if tracerless analyses of samples are performed or if accurate chemical recoveries for tracer analysis are required. An energy/FWHM calibration should be done before the efficiency calibration.

Calibration standards share some very particular characteristics: the standard typically contains a mixture of alpha emitting radionuclides, emitting at several distinct energies distributed across the useful energy range of the spectrometer. The radioactive material is presented as an extremely thin layer deposited on a solid substrate, yielding spectra with narrow, well resolved peaks. The sample is prepared in a way that makes it durable and chemically stable over long periods of time. If the standard is to be used for performing efficiency calibrations, the activity of each radionuclide in the sample should be precisely known. A usual mixture contains natural uranium, plutonium and americium radionuclides electroplated on a stainless steel disk.

An efficiency calibration should be performed for every detector and for each geometry used.

Gamma ray spectrometers are calibrated for energy, FWHM and efficiency. Efficiency calibration is carried out using a series of standard sources prepared at the laboratory from a certified solution of a common mixture of gamma emitting radionuclides that covers the energy range of interest.

Gas flow, Geiger-Müller and proportional counters are commonly used for the measurement of beta emissions of samples deposited on planchettes with energies above 100 keV. The counter should be calibrated for the energy of interest. The possible effect of self-absorption on the counting efficiency should be taken into account.

Verification of equipment calibrations should be performed periodically.

## Identification and Quantification of Radionuclides

The chemical procedures should allow identification and quantification of the radionuclides present in the sample, subject to the detection limits for each radionuclide.

The method used for identification and quantification of radionuclides depends on the type of measurement. ISO 28218:2010 [ISO 2010b] provides in its Annex II three examples of methods for activity quantification of radionuclides measured by alpha spectrometry, ICP-MS and liquid scintillation counting.

## Naturally Occurring Radionuclides. Natural Background

Typically, radiobioassay for NORM comprises urine and faeces monitoring for uranium and thorium isotopes. Background levels of NORM in excreta samples resulting from dietary intake should be taken into consideration when the contribution from natural background could have a significant effect on the assessed dose.

*In vitro* measurements performed before the start of the occupational exposure of a particular individual are highly recommended in order to quantify the individual background; if natural background levels are not taken into account, it should be demonstrated that their contribution to assessed dose is not significant. ISO 16638-1:2015 [ISO 2015d] and the IDEAS Guidelines [EURADOS 2013] present advice on how to handle monitoring data taking into account the contribution from dietary intake.

According to ISO 16638-1:2015 [ISO 2015d], where the occupational exposure is to natural uranium, a range of reference values must be set to distinguish between occupational exposures and natural background. Tests to determine whether an

occupational exposure has occurred should include a test to determine whether such a reference value is exceeded.

Where the occupational exposure is to either depleted or enriched uranium, measurement of the isotopic content of a bioassay sample allows the contribution from the natural uranium background to be determined and subtracted.

The reference value for an individual worker should be determined by one or more measurements of blank bioassay samples taken before work with uranium starts. If this is not feasible or not reliable, information on bioassay samples provided by a representative population of unexposed workers may be used to set background ranges and reference values. If this is not feasible, measurements of the uranium content in representative samples of drinking water may be used to establish reference values. Lastly, published data may be used, particularly those reported in IDEAS Guidelines, section 4.1.3 [EURADOS 2013]. Whichever method is used, ISO 16638-1:2015 states that it must be demonstrated that the reference value is representative of the natural background level for the worker to whom it is applied [ISO 2015d].

## Uncertainties

All procedures used to quantify the activity of a radionuclide can give rise to both Type A and Type B uncertainties. Uncertainties in measurements are mainly due to counting uncertainties, the validity of the calibration procedures, possible contamination of the source or the measurement system, and random fluctuations in the background.

For *in vitro* measurements, common sources of Type B uncertainty include: the quantification of the sample volume or weight; error in dilution and pipetting; evaporation of the solution in storage; stability and activity of standards used for calibration; chemical recovery; blank corrections; background contributions and fluctuations; electronic stability; environmental conditions; spectroscopy resolution and peak overlap; contamination of the sample and impurities; source positioning for counting; density and shape variation from the calibration mode; decay corrections; and assumptions about homogeneity in calibration.

The IDEAS Guidelines and ISO 27048:2011 [ISO 2011] describe and analyse the components of uncertainties in indirect measurements (Table B.3, ISO 27048:2011) and propose quantification of measurement uncertainties by applying scattering factors (geometric standard deviation of the distribution). See **Chapter F**.

## Detection Limit and Decision Threshold for *in vitro* Techniques

Tables D.2 and D.3 present typical and achievable detection limit values for different radionuclides and methods of measurements for *in vitro* assays [Hurtgen 2012]. The reported values have not been derived using the methods described in the most recent ISO 28218:2010 standard [ISO 2010b], but they provide a basis for assessing the sensitivity of a detection method developed by a specific laboratory, and for comparing it to the state-of-the-art sensitivity, internationally recognised for the type of bioassay measurement under consideration.

**Table D.2** Detection limit values for urine bioassay [Hurtgen 2012; Zoriy 2015]

| Isotope | Method of measurement | Typical DL | Achievable DL | Units |
|---|---|---|---|---|
| $^{226}$Ra | ICP-MS | 0.3 | | mBq $L^{-1}$ |
| $^{234}$U | Alpha spectrometry | 0.3 | 0.05 | mBq $L^{-1}$ |
| | ICP-MS | 0.3 | 0.1 | mBq $L^{-1}$ |
| $^{235}$U | Alpha spectrometry | 0.3 | 0.05 | mBq $L^{-1}$ |
| | ICP-MS | 0.01 | | µg $L^{-1}$ |
| | | 0.08 | | mBq $L^{-1}$ |
| $^{238}$U | Alpha spectrometry | 0.3 | 0.05 | mBq $L^{-1}$ |
| | ICP-MS | 0.0015 | | µg $L^{-1}$ |
| | | 0.02 | | mBq $L^{-1}$ |
| | Tr-KPA | 0.1 | 0.06 | µg $L^{-1}$ |
| | Fluorimetry | 1 | | µg $L^{-1}$ |
| $^{237}$Np | Alpha spectrometry | 1 | 0.1 | mBq $L^{-1}$ |
| | ICP-MS | 0.1 | | mBq $L^{-1}$ |
| $^{238}$Pu | Alpha spectrometry | 0.3 | 0.05 | mBq $L^{-1}$ |
| $^{239}$Pu | Alpha spectrometry | 0.3 | 0.05 | mBq $L^{-1}$ |
| | TIMS | 0.01 | 0.004 | mBq $L^{-1}$ |
| | ICP-MS | 1 | 0.1 | mBq $L^{-1}$ |
| $^{241}$Pu | LSC | 30^ | 0.03# | Bq $L^{-1}$ |
| $^{241}$Am | Alpha spectrometry | 0.3 | 0.05 | mBq $L^{-1}$ |
| $^{244}$Cm | Alpha spectrometry | 0.3 | 0.05 | mBq $L^{-1}$ |

^ Direct measurement

# After chemical separation and redissolution of the tray from alpha spectrometry

**Table D.3** Detection limit values for faeces bioassay [Hurtgen 2012]

| Isotope | Method of measurement | Typical DL | Achievable DL | Units |
|---|---|---|---|---|
| $^{226}$Ra | Proportional counting | 16 | | mBq d$^{-1}$ |
| $^{234}$U | Alpha spectrometry | 2 | 0.2 | mBq d$^{-1}$ |
| $^{235}$U | Alpha spectrometry | 2 | 0.2 | mBq d$^{-1}$ |
| $^{238}$U | Alpha spectrometry | 2 | 0.2 | mBq d$^{-1}$ |
| $^{228}$Th | Alpha spectrometry | 2 | 0.2 | mBq d$^{-1}$ |
| $^{230}$Th | Alpha spectrometry | 2 | 0.2 | mBq d$^{-1}$ |
| $^{232}$Th | Alpha spectrometry | 2 | 0.2 | mBq d$^{-1}$ |
| $^{237}$Np | Alpha spectrometry | 2 | 0.2 | mBq d$^{-1}$ |
| $^{238}$Pu | Alpha spectrometry | 2 | 0.2 | mBq d$^{-1}$ |
| $^{239}$Pu | Alpha spectrometry | 2 | 0.2 | mBq d$^{-1}$ |
| $^{241}$Am | Alpha spectrometry | 2 | 0.5 | mBq d$^{-1}$ |
| $^{244}$Cm | Alpha spectrometry | 2 | 0.5 | mBq d$^{-1}$ |

***Q4**: How is the radionuclide concentration in air monitored in a workplace?*

## Workplace Monitoring: Determination of Airborne Radionuclide Concentration

Workplace monitoring of exposures to radionuclides consists of measurements made in the working environment. Personal air samplers (PAS) and static air samplers (SAS) may be used for workplace monitoring of individual exposures. PAS and SAS can be particularly useful in cases where available *in vivo* and *in vitro* techniques can only quantify exposures reliably above 6 mSv, as is the case for monitoring of exposures to some actinides (ISO 20553:2006 [ISO 2006]).

Workplace monitoring of exposure to airborne naturally occurring radionuclides is also required in some circumstances.

### Sampling Methods

#### Personal Air Sampler (PAS)

The PAS is a portable device used to collect a sample representative of the activity concentration in the air inhaled by the worker; this allows the estimation of occupational intakes of some radionuclides. Personal air sampling (also often abbreviated to PAS) is most commonly used for the estimation of actinide exposures. A sampling head containing a filter is worn on the upper torso within the breathing zone. This is normally assumed to be within 30 cm of nose and mouth. Ideally sampling rates should be the same as typical breathing rates for a worker (~1.2 m$^3$ h$^{-1}$), but current devices often provide only about one fifth of this value. The activity on the filter at the end of the sampling period can give a warning of unexpected high exposures. Intakes can be simply estimated using the ratio of sampling rate to typical breathing rate, and doses can then be estimated using reference dose coefficients. PAS can be fitted with aerosol size-selecting sampling

heads. Aerosol particles of different aerodynamic diameters are deposited on separate regions of the collection filter, allowing for some degree of aerosol size analysis.

PAS is sometimes used to estimate intakes by inhalation of actinide radionuclides such as the radioisotopes of plutonium and uranium. For those actinides with relativity high dose coefficients and higher specific activities (such as $^{239}Pu$), the main source of uncertainty in estimated intakes is generally considered to arise from the statistical variation in the radionuclide activity collected by the sampler during a defined sampling period [Birchall 1991]. Uncertainties arise from two main sources: (i) statistical variation of the number of particles in any randomly sampled volume; (ii) variability in the activity associated with each particle due to the variation of sizes of particles in the aerosol.

With respect to the sampling uncertainties related to use of the PAS, the propensity for the sampler to pick up non respirable particles can give false positive doses. Uncertainties become increasingly significant when low aerosol number concentrations are sampled at low rates. An example is provided by the hypothetical case of an aerosol of pure $PuO_2$ (Type S) present in a workplace in a constant concentration. If the aerosol concentration is such that continuous exposure for a working year (2000 h) would result in a committed effective dose of 20 mSv, then a PAS sampling at a rate of 2 litres/min would collect only about 15 particles during an 8 hour working day, on average. Because of the low number of particles, the actual number of particles sampled on any one day is subject to a high degree of variability [Birchall 1988].

### Static Air Sampler (SAS)

The SAS is commonly used to monitor workplace conditions, but can underestimate concentrations in air in the breathing zone of the worker; in extreme cases underestimates can be several orders of magnitude [Whicker 2004].

Where PAS is used in conjunction with static air sampling (SAS), PAS:SAS air concentration ratios are found to vary from less than 1 up to 100, depending on the nature of the work; where air activity concentrations are believed to be reasonably homogenous in the work place and multiple sample measurements are taken then ratios tend to be in the range of 1 to 10. Variability in the ratio arises principally from the spatial variation of aerosol concentration in the workplace, and depends on the relative positions of the SAS, the PAS, the source(s) of airborne contamination and the localised air flow patterns. Where aerosol concentrations are spatially and temporally uniform then the ratio of PAS measurements and SAS measurements, averaged over a number of measurements, is expected to converge to a consistent and reproducible value, which can be considered to be a characteristic of the workplace and sampling programme. Where the source is closer to the SAS than a worker wearing a PAS, then the PAS:SAS ratio may be less than one. The more usual case when PAS is employed is that the source is closer to the worker than the SAS. This would be the case for workers engaged on glove box operations, for example. The PAS:SAS ratio may then be greater than one.

SAS devices can also provide useful information on radionuclide composition, and on particle size [Meisenberg 2015], for example if used with a size analyser such as a cascade impactor. SAS may also be used to estimate intakes and doses for workers; this is most typically applied when expected doses are either low (ISO 20553:2006 [ISO 2006]), or for confirmation that workplace conditions do not require individual monitoring programmes. In this case the estimated intakes will need to account for potential underestimates of the SAS measurement by the application of correction factors (sometimes known as Dilution Factors, Breathing Zone Factors or PAS Factors). The laboratory should consider at what level the use of correction factors becomes unreliable: a correction factor exceeding a factor of 10 is recommended as a suitable level for reviewing the reliability of intakes estimated in this manner. Further corrections are required to account for potential differences in the occupancy time of a worker in the area being monitored by SAS, the SAS sample time, and the aerosol retention characteristics within the local area.

### Continuous Air Monitors (CAM)

CAMs are essentially an enhanced version of SAS which incorporate a detector facing the collection filter connected to a real time activity monitor and alarm unit. The primary function is to provide a real time response in order to detect unexpected airborne releases which would prompt evacuation of the area and remedial actions. These units can also be used like SAS for assessing chronic exposure levels within a workplace; however, it should be noted that alarm thresholds are typically set to detect acute events, and that these thresholds might not be appropriate for monitoring chronic levels of air activity to sufficiently low levels, particularly for alpha activity. In this case it would be appropriate to treat CAMs as SAS and remove filter samples periodically for more sensitive radiometric analysis.

Detailed information about sampling methods is presented in the Appendix of this chapter.

### Radon Exposure Monitoring

The topic of Radon Measurement and Dosimetry for Workers is presented in **Chapter H**. Radon is an inert noble gas that is encountered in elemental form as a gas or dissolved in water. Three isotopes of radon are usually considered: $^{222}$Rn, $^{220}$Rn and $^{219}$Rn, as progeny radionuclides of radium isotopes ($^{226}$Ra, $^{224}$Ra and $^{223}$Ra), which are members of the three natural radioactive decay series (with the parent radionuclides $^{238}$U, $^{232}$Th and $^{235}$U respectively). However, $^{219}$Rn is usually not monitored. The isotopes $^{222}$Rn, $^{220}$Rn, $^{219}$Rn are known as radon, thoron and actinon respectively. Radon-222 and $^{220}$Rn are the radon radioisotopes of main concern for radiation protection. High concentrations of radon in air have been found in workplaces such as mines, waterworks, caves, underground stores and others. High levels of radon may also be encountered in U/Th handling facilities.

## Uncertainty, Detection Levels and Decision Thresholds

General requirements are discussed in **Chapter F**. This section focusses on specific issues relevant for air sample measurements. In some cases air sample measurements may be used for monitoring well-defined and unique hazards; however, in many operational circumstances these measurements are used for monitoring a range of hazards and workplace conditions. Also, air sampling measurements are typically used when the magnitude and risks of exposures to airborne radionuclides are relatively low (corresponding to doses that are usually much less than dose limits). For these two reasons it is not normally considered appropriate nor proportionate to evaluate and report uncertainty estimates for every individual measurement. It is normally sufficient to provide systemic estimates of uncertainty and sensitivity for the overall process in a defined but idealised set of conditions (e.g. for a defined mix of radionuclides). The set of conditions should be chosen to be reasonably representative of the actual expected operational conditions. For poorly-defined or very variable operational conditions it would be necessary to provide a sensitivity analysis for a range of conditions and potential magnitudes of exposure. These analyses should be recorded as part of the QA programme and subject to periodic review.

## Recommendations

| R# | G | Text of the recommendation |
|---|---|---|
| | | ***Q1**: What are the methods that should be used for individual monitoring and workplace monitoring?* |
| D01 | I | The requirements presented in ISO 20553:2006 [ISO 2006] for individual monitoring methods and workplace monitoring methods should be adopted, taking into account the advantages and limitations (including sensitivity and availability) of the different measurement methods. |
| | | ***Q2**: How should in vivo bioassay of the activity of radionuclides retained in the body that emit penetrating radiation be performed?* |
| D02 | I | In vivo measurement of radionuclides in the body should be employed for radionuclides emitting penetrating radiation that can be detected outside of the body (mainly high energy X-ray and gamma emitting radionuclides) wherever feasible [ICRU 2003; IAEA 1996]. Methods should satisfy the performance criteria for radiobioassay set by ISO 28218:2010 [ISO 2010b]. |
| D03 | I | For radionuclides that are X/gamma emitters (>100 keV) and are rapidly absorbed from the respiratory tract into the body (e.g. $^{137}$Cs, $^{60}$Co), whole body monitoring using NaI(Tl) scintillation detectors and/or HPGe semiconductor detectors should be performed [ICRU 2003; IAEA 1996] |
| D04 | I | Monitoring of specific organs using NaI(Tl) scintillation detectors and/or HPGe semiconductor detectors should be performed for X/gamma emitting radionuclides that concentrate in particular organs or tissues (e.g. $^{131}$I in the thyroid) [ICRU 2003; IAEA 1996] |
| D05 | I | <u>Whole body counters</u><br>HPGe detectors should be used for *in vivo* measurements of low energy X-ray and gamma emitters (< 100 keV). The design should allow easy and reproducible placement of detectors close to the organ of interest.<br>Where available, HPGe detectors should be used for *in vivo* measurements of complex mixtures of radionuclides, for uranium, for measurements of transuranic radionuclides and for $^{131}$I/$^{125}$I.<br><u>Partial body counters</u><br>If the radionuclide deposits preferentially in a single organ such as the thyroid (e.g. $^{125}$I, $^{131}$I), then partial body monitoring of the relevant organ should be chosen. [ICRU 2003; IAEA 1996]<br>If the intake is chronic, or where intakes occurred in the past, measurements of X/gamma emitting radionuclides in specific organs should be performed. For bone seeking radionuclides, measurements on the knee or skull are recommended. Calibrations should be performed using phantoms that simulate the organ of interest. |
| D06 | I | In the case of radiological or nuclear (RN) emergencies, NaI(Tl) scintillation detectors may be used in the early days after the accident especially for triage based on the level of contamination. To achieve better capabilities (in terms of both qualitative and quantitative information) it is recommended that whole body and organ monitoring based on HPGe detectors or a combination of both types are used. [ICRU 2003; IAEA 1996] |
| D07 | I | *In vivo* measurement laboratories should estimate their own uncertainties. The IDEAS Guidelines, ISO 27048:2011 and NCRP Report No. 164 (Appendix D) provide general information about how to calculate the uncertainties in different *in vivo* monitoring geometries. |
| D08 | I | To calibrate in vivo monitoring systems for measurements of radionuclides distributed in all or part of the body, laboratories should use active physical phantoms simulating internal contamination of organs or total body [ICRU 2003; IAEA 1996]. |
| D09 | I | It is recommended to document the sources of nuclear data used in the laboratory. It is recommended to use only a reference library (e.g. the DDEP data) throughout all procedures. This aids the accreditation process by guaranteeing traceability of results. |
| D10 | I | Calibrations should be performed using phantoms that simulate the organ of interest. The size of the calibration phantom and the distribution of the radionuclides should match that expected in the human subject [ICRU 2003; IAEA 1996]. |

| R# | G | Text of the recommendation |
|---|---|---|
| D11 | I | When calibrating detection systems for the measurements of low energy photon emitters in the lungs (radioisotopes of americium, uranium, plutonium and others) more realistic anthropomorphic phantoms (e.g. the Lawrence Livermore phantom) should be used [ICRU 1992; IAEA 1996]. |
| D12 | A | Numerical calibration techniques may be used as an alternative tool for *in vivo* measurement calibrations. It is recommended that national competent authorities consider adapting approval protocols of *in vivo* monitoring laboratories to allow the use of numerical calibration techniques, subject to the implementation of an appropriate quality assurance programme that includes appropriate validation procedures. |
| D13 | A | *In vivo* measurements of $^{232}$Th and $^{238}$U can be carried out with much better detection limits when its progeny are measured. However, the extrapolation to parent radionuclide activities may have significant associated uncertainties. In this case, *in vitro* measurements of the parent radionuclide are recommended in order to avoid large uncertainties and inconsistencies in the results. |
| D14 | A | The measurement of exhaled radon/thoron may be used for the assessment of the uranium/thorium content of the human body. |
| | | ***Q3**: How should the excretion rate (Bq d$^{-1}$) of incorporated radionuclides in biological samples be measured?* |
| D15 | I | The worker should be made responsible for collecting bioassay samples according to clearly written instructions using sample containment provided by the bioassay laboratory.<br>Hand washing before provision of samples should be required as it is important to reduce possibility of additional cross contamination of samples. [ISO 2012a] |
| D16 | I | Sample collection should be made in non-contaminated areas to avoid accidental contamination of the sample. [ISO 2012a] |
| D17 | I | A 24-hour urine sample is preferred, as no correction for sample duration is then needed. [ISO 2011] |
| D18 | I | When 24-hour collection cannot be achieved, it is recommended that either creatinine normalisation or volume normalisation should be used to estimate 24-hour excretion [ISO 2011]. It may be assumed that creatinine is excreted at an average rate of 1.7 g d$^{-1}$ for men and 1.0 g d$^{-1}$ for women. Regarding volume correction, an excretion rate of 1.6 l d$^{-1}$ may be assumed for male adults and 1.2 l d$^{-1}$ for woman excretion [ICRP 2002]. |
| D19 | I | Faeces bioassay should be used to assess inhalation intakes of insoluble radionuclides where urine bioassay does not provide adequate sensitivity; the representativeness of reference values for daily faecal mass excretion is an important source of uncertainty. Collection of 3-day total voids should be made to reduce such uncertainty, especially just after the time of the intake. [ISO 2015d] |
| D20 | I | Each radionuclide-specific procedure should specify its own requirements for sample preparation depending on the radionuclide, the requirements of the detection system, the characteristics of the sample matrix and the level of sensitivity that is required. [ISO 2012a] |
| D21 | I | Sample collection, sample preparation, analyte concentration, and measurement should be specified in every analysis to be performed, regardless of the sample or analyte. [ISO 2012a] |
| D22 | I | When urine samples are not promptly analysed or must be stored, they should be refrigerated, acidified to minimise precipitation and/or add a preservative to prevent bacterial growth. It is usual to stabilise samples with concentrated nitric acid. [ISO 2012a] |
| D23 | I | Faeces samples should be analysed promptly, ashed or preserved by deep freezing because of their biodegradation. [ISO 2012a] |
| D24 | I | The method used for monitoring should have adequate sensitivity to detect the activity levels of interest. [ISO 2010b] |
| D25 | I | Analysis of excreta samples should be used to assess intakes of radionuclides that do not emit energetic photons (e.g. $^{3}$H), as it is the only available bioassay method. [ISO |

| R# | G | Text of the recommendation |
|---|---|---|
| | | 2010b] |
| D26 | I | The selection of a specific in vitro method depends on the level of activity in the samples and the availability of instrumentation and technical expertise in the laboratory. Methods should satisfy the performance criteria for radiobioassay set by ISO 28218:2010 [ISO 2010b]. |
| D27 | I | In vitro measurement laboratories should characterise the sensitivity of their techniques by calculating the DL (detection limit) and the DT (decision threshold) according to ISO 28218:2010 [ISO 2010b], by measuring blank samples under routine conditions. |
| D28 | I | In vitro measurement laboratories should estimate their own sources of uncertainty. The IDEAS Guidelines, ISO 27048:2011, and NCRP report No. 164 (Appendix F) provide general information about how to calculate the uncertainties. |
| D29 | A | Fluorometry, KPA, alpha spectrometry and ICP-MS analytical methods may be employed for measurement of natural uranium in urine (ISO 16638-1:20015, Annex C) [ISO 2015d]. However, alpha spectrometry is the established method for the measurement of enriched uranium. |
| D30 | A | The use of ICP-MS or TIMS should be considered for the measurement of long-lived radionuclides. The main advantage is the short time (minutes) needed to perform the measurement and the sample preparation. The methods can be particularly useful in the event of accidental exposures involving uranium. However the methods are not sensitive enough for short-lived radionuclides (e.g. $^{241}$Am). In this case alpha spectrometry is recommended. |
| D31 | A | Alpha spectrometry is nevertheless recommended as the default method for measurements of alpha emitters in bioassay samples, on the basis of cost, versatility, throughput and availability. |
| D32 | A | Beta emitters may be quantified by liquid scintillation counting through direct measurement. Special attention should be given to reduction of the quenching processes. |
| D33 | A | Gamma spectrometry is recommended for the determination of radionuclides that emit gamma rays in biological samples, by direct and non-destructive measurement using scintillation (NaI(Tl)) or semiconductor (HPGe) detectors. Faeces samples require sample preparation before gamma spectrometric analysis. |
| D34 | I | When an occupational exposure to NORM materials has been detected, the mean natural background level in bioassay samples should be determined using the procedure set down in [ISO 2015d]. |
| D35 | A | Due to the relatively high detection limits of direct measurements and the problems with interpretation of monitoring data arising from lack of knowledge of the parent-daughter equilibrium state, *in vitro* bioassay measurements (urine and faeces) of all radionuclides are recommended for individual monitoring of exposed workers to NORM. |
| | | ***Q4**: How is the radionuclide concentration in air monitored in a workplace?* |
| D36 | A | Workplace monitoring (PAS/SAS monitoring) may be used for the assessment of occupational exposures to airborne radionuclides, but it is important to establish realistic assumptions about exposure conditions. |
| D37 | A | Exposure to some alpha, beta or gamma-emitters can be evaluated by PAS/SAS measurements, particularly $^{131}$I and uranium, thorium and plutonium isotopes, although the results are not always used for individual dose evaluation. |
| D38 | A | PAS can be particularly useful for assessing exposures in cases where *in vivo* and *in vitro* measurements do not have sufficient sensitivity to quantify exposures above 6 mSv reliably, as is the case for monitoring of exposures to some airborne actinide radionuclides. |
| D39 | A | PAS may be used to obtain satisfactory estimates of intake for groups of workers. However, for individuals, lack of correlation between assessments using PAS and *in vitro* analysis of bioassay samples can occur. |

G= Grade: M = Mandatory, I = International, A = Advisory

# Appendix to Chapter D

## Workplace Monitoring - Sampling Methods

### Sample Collection and Filter Media

Various filter media are available (ISO 2889 [ISO 2010c]), the most commonly used for PAS, SAS and CAM being glass-fibre media. The primary considerations for choice of an appropriate medium are:

- Collection efficiency: this should be greater than 95% for the aerosols of interest, otherwise specific correction factors should be evaluated and validated.
- Low pressure drop across the filter: if the pressure drop is too high then this could place excessive demands on the sampling pump, especially for the battery-powered pumps used for PAS. It could also incur excessive uncertainties in the sample collection flow-rates.
- General environmental conditions: for example, high relative humidity, could affect the performance and robustness of some filter media.

Preferably, the exposed face of the sample collection medium should directly sample the air in the workplace, and lie in the vertical plane to avoid the effects of gravitational settling of larger aerosols. In some cases this might not be feasible, for example as a result of a need to take air samples remotely from an area via the use of tubing or ducting, without access to the area. In this case the particle loss rates within the sampling tubing, before collection on the filter media, should be evaluated and validated. If loss rates exceed 10% then correction factors should be established and validated.

Where aerosol size-selective attachments (e.g. impactors) are employed, then particle loss-rates within the sample head should be established, as above.

### Analysis Systems

This section describes the measurement systems and methods used for radiometric analyses of the sample collection filters but excludes radio-chemical analyses that might be employed for full destructive assay. These measurement systems should be located and operated within a laboratory designed for this purpose and which complies with the standard laboratory quality management requirements of ISO/IEC 17025:2005 [ISO/IEC 2005].

#### Types of Systems

Various measurement systems are available; for the measurement of alpha and beta activity the most common systems use either proportional counter detectors or solid state (silicon) detectors. When only a low throughput of samples is required then simple single-detector manual counters are sufficient; for higher levels of throughput then multiple-detector arrays and/or automated sample-changer counting systems are normally used.

#### System Performance

Measurement systems should be operated according to a clearly defined QA programme to assure reliability of performance and output [ISO/IEC 2005]. It is recommended that such a programme should include the following technical features [NPL 2006]:

- *Type Test*: this test defines the characteristics and expected performance of a system to enable the most appropriate choice of system for a particular application. Currently there are no IEC Standards specifically for laboratory counting systems (although IEC 61172 [IEC 1992] is applied for radioactive particular monitors in the environment); however, manufacturers will usually supply technical performance data for a specific system.

- *Test before First Use*: this test provides assurance that the performance of a particular system conforms to the specified *Type Test* specification; this enables any defects or non-conformities to be identified and addressed before bringing the system into use.
- *Periodic Tests:* these routine periodic tests should be established to provide continuing assurance that the system is still performing according to the *Type Test* specification. These tests should consider various factors in addition to detector performance: e.g. mechanical reliability, data management and reliability of output reports. The frequency of tests is dependent on local factors such as frequency and intensity of use, the nature and variability of environmental conditions, established track record of reliability. It is recommended that tests should be no less frequent than annually. It is recommended that the QA programme for the laboratory should define and document the specific tests, together with the 'pass/fail' quality control criteria for each test.
- *Function check:* this is a minimal check to provide assurance that a system is still functional; for air sample counters this check normally comprises the measurement of a radioactive standard source and a background measurement; the results of these checks are compared to the Quality Control criteria defined in the laboratory's QA programme. The frequency of function checks is dependent on how the system is used; as a default it is recommended that at least one function check is performed on each day that the system is used for sample measurements.

## Calibration

The term 'calibration' refers to the means for determining how the system performs according to its defined *Type Test* specification. The result is the calculation of a correction factor(s) which is to be applied to the measured quantity to calculate the required output quantity: e.g. for the conversion of measured counts to activity. It is important to note that the output quantity is only valid within the idealised context of the systems *Type Test* specification and cannot be automatically assumed to be a reliable estimator of the required recording/reporting quantity: e.g. air activity concentrations in the workplace. It is recommended that the laboratory should establish and document how reliably the systems' 'calibration' is characterised with respect to the specific operational features for which it is to be used [NPL 2006]: this could include detector efficiency measurements to standard radioactive sources; identification of the radionuclides the system is expected to measure; differential energy responses; potential cross-over between alpha and beta responses in the detector; sensitivity to gamma background levels; levels of localised radon levels within the laboratory as well as in the sampled workplaces; potential self-absorption of radiation particles within filter media. This characterisation process should be included within the laboratory's QA programme, which should also define which of these processes need to be included within the different levels of System Performance tests: e.g. detector efficiency tests might need to be included in *Periodic Tests*, whereas energy response tests might need only be included in the *Test Before First Use.*

## Sample Measurement

A variety of factors can affect the reliability of the sample measurement; the laboratory QA programme is required to identify which of these factors might have significance, and how these factors should be monitored and accounted for: this could be within the System Performance and Calibration processes (as above), included within the laboratory's operational methods, or applied to specific samples measurements as determined by Quality Control criteria [ISO/IEC 2005]. Influencing factors could include:

- *Particulate radon-daughters collected on the sample*: this can be mitigated by using radiometric compensation methods or by delaying measurement for at least five days to allow for radioactive decay.

- *Radon gas within the laboratory*: specific environmental controls (e.g. effective ventilation) might be required.
- *Differential energy response in detector*: this might be an issue where the sampled radionuclides have significantly different radiation emission energies to the radiation standard source as used for calibration; correction factors might need to be considered, or the calibration process might need to be reviewed.
- *Radiation emission characteristics*: factors that will need to be considered are the number and/or probability of emission particles, and also the presence of short-lived daughter radionuclides (e.g. $^{90}Sr/^{90}Y$). This might need to be considered for both sample and calibration measurements.
- *Differential media substrates*: radioactive standard sources are typically produced onto a metal substrate, as opposed to the glass-fibre media typically used for sample collection; this can be a significant factor for calibrating beta response due to the back-scatter of beta particles from the metal substrate, which isn't replicated for beta sample measurements.
- *Calibration source construction*: if the radioactive element of a radiation standard source is too deep within the source then there is a risk of self-collimation of emitted particles (particularly for beta); this might provide a forward bias for particle emissions which would not be replicated for sample measurements, where emissions are more likely to be semi-(2π)-isotropic.
- *Differential edge effects*: radioactive standard sources are typically constructed to have a homogenous distribution of the activity over most of the surface area; sampled particulates are likely to have discrete deposition patterns. This issue can be overcome by employing detectors which have a surface area greater than that of both sources and samples; otherwise this factor might need to be evaluated as part of uncertainty estimations.
- *Self-absorption*: it is feasible that sampled aerosol particulates might penetrate into the filter media, or be obscured by later accumulations of particulates. This is not generally considered a significant issue in practice for environments with low dust loading in the workplace air; however, this will require to be monitored. It is recommended that, periodically, samples should be subject to independent assessment as part of the overall validation of the process; if feasible full-destructive assay of the sample and analysis by radio-chemistry techniques should be considered. This will provide an indication of whether self-absorption is a significant problem. In dusty workplaces it may be worthwhile to conduct studies to establish the relationship between deposited mass and self-absorption (i.e. to avoid the need to dissolve every sample thereafter).
- *Background corrections*: all detector systems are subject to 'background'. In practice it can be difficult to ascertain the source of this 'background' and it is normally just considered to be un-defined 'noise'. Regular measurements from blank samples should be undertaken to establish the magnitude and consistency of background levels, which are then used to determine correction factors. If the magnitude or variability of these measurements exceed pre-defined quality control criteria, then an investigation should be instigated; if background levels cannot be suppressed then it might be necessary to amend laboratory procedures (e.g. extend sample measurement counting periods), or to consider additional controls to the laboratory environment (e.g. improved ventilation; use of mains-power filters).
- *Sampling handling*: sample measurements for alpha-emitting radionuclides are especially sensitive to careful handling, due to the low detection levels which are typically required. In addition to normal sampling handling requirements the laboratory should also be aware that samples collected on glass-fibre filters could be sensitive to risks of exposure to static electricity (e.g. from use of polythene bags).

It should be ensured that there is no excess contribution to the background from filter cards. Some treatments of cards, particularly glazes, can include naturally occurring radioactive material.

# CHAPTER E – Routine and Special Dose Assessment

Chapter E is divided into six sections, and addresses the following topics:

E1. Interpretation of monitoring data
E2. Dose assessment and interpretation: Routine monitoring
E3. Dose assessment and interpretation: Special monitoring
E4. Monitoring and dosimetry for wound cases and cutaneous contamination
E5. Monitoring and dose assessment in the event of decorporation therapy
E6. Radiation protection for pregnant and breastfeeding workers

## E1 - Interpretation of Monitoring Data

***Issues addressed by section E1***

***MAIN QUESTION***

***Q1*** *How should information on exposure conditions be collected from the workplace and interpreted, and what can be learned from an inspection of the results of individual monitoring?*

***Subsidiary questions***

***Q2*** *What additional information and data is required in order to interpret individual monitoring data?*

***Q3*** *Where can this information be found?*

***Q4*** *What information can workplace monitoring provide?*

***Q5*** *How can the results of individual monitoring be used to guide and inform the formal dose assessment procedure?*

***Q6*** *How much emphasis should be placed on information derived from data fitting procedures on exposure conditions and material-specific model parameter values?*

***Q7*** *What are the issues that might prevent a straightforward interpretation of individual monitoring data?*

### Special Terms used in this Section

Absorption Type, Acute intake, Aerosol, AMAD, Blocking agent, Cascade impactor, Chronic intake, Contamination monitor, Creatinine, Cyclone, Data fitting, Decorporation agent, Exposure conditions, Intake route, Material-specific parameter value, Monte Carlo method, NORM material, Particle size distribution, Pattern of intake, Personal air sampler, Personal air sampling, Personal protective equipment, Prospective dose assessment, Radiation Protection Supervisor, Radioactive progeny, Respiratory protective equipment, Retrospective dose assessment, Wound contamination.

### Introduction

Interpretation of individual monitoring data requires information on such factors as the time and/or period of potential exposure, the radionuclides and chemical compounds

involved, the particle size distribution of the aerosol to which the worker was exposed, and so on. These types of information act as the input data for the dose assessment, providing the required model parameter values. **Section E1** discusses in detail the collection and interpretation of this information.

The formal process of internal dose assessment is explained and discussed in the later sections of **Chapter E**.

Judgements must be made on the extent of the information that is required for the assessment of any particular exposure case, and on the effort that should be expended on examining it in advance of the formal dose assessment process. The principle of proportionality should be applied. Interpretation of the results of special monitoring is likely to require more information, and more expenditure of effort, than the results of routine monitoring. More information and greater expenditure of effort are likely to be needed for assessments where the potential dose for an individual worker could approach or exceed the annual dose limit.

## Information on Exposure Conditions

***Q2**: What additional information and data is required in order to interpret individual monitoring data?*

Information on exposure conditions is an essential input to any assessment of radionuclide intake and resulting dose, and will improve the reliability and accuracy of the dose assessment.

The term "exposure conditions" includes qualitative information (e.g. the identity of the main route of intake) as well as quantitative information (e.g. concentrations of a radionuclide in air). Information available in advance about a particular work area could be used for a prospective dose assessment. Information collected during or after a particular exposure event would be used in any retrospective assessment. The types of information that should be sought are detailed below:

### Prospective information on conditions within a particular work area

- The identity of the radionuclide or radionuclides to which workers may be exposed
- Descriptions of working practices in the work area, including identification of the time periods of work associated with potential exposure to radionuclides, whether work is carried out in respiratory protective equipment or using glove boxes or fume hoods
- Whether inhalation is the main route of intake (as is the case in most instances of occupational exposure)
- Whether exposures to airborne radionuclides are continuous, or characterised as discrete events
- The time pattern of the concentrations in air of airborne radionuclides containing the radionuclides present in the workplace
- Whether airborne radionuclides are in particulate (aerosol) form, or in vapour form
- If particulate, the distribution of airborne particle sizes
- If vapour, its solubility and reactivity
- The identity of the chemical compounds (or elements) in which the radionuclides are present
- Whether ingestion is a possible intake route
- Whether intake by absorption through intact skin is a possible intake route
- Whether intake via a wound site is a possible intake route

- Information from any additional workplace monitoring, such as static air sampling, continuous air monitoring, contamination monitoring, surveys

### Retrospective Information on a particular Exposure Incident

- All of the types of information listed above, for the specific exposure incident
- The location of the event
- The nature of the event (fire, explosion, etc.)
- Data on the activities of radionuclides released
- The time and period of exposure
- Descriptions of the work activities being carried out at the time of exposure
- Descriptions of any use of Personal Protective Equipment (PPE)
- Descriptions of any treatment with blocking or decorporation agents

For routine exposures where no particular exposure event has been identified, an assessment is likely to be based on the items listed under the heading of "prospective information". On the other hand, for exposures resulting from a particular exposure incident, an assessment will place more weight on the items listed under the heading of "retrospective information".

Judgements must be made on the extent of information on exposure conditions that is required for the assessment of any particular exposure case. Not all of the information listed will be required in all cases. The effort that should be expended on collection of such information depends on the likelihood of exposure and the likely magnitude of resulting doses (**Sections E2 and E3**).

***Q3**: Where can this information be found?*

A number of sources of information will need to be interrogated or investigated. These include information sources within the workplace on working practices and work activities, information from workplace monitoring, and information from the results of individual monitoring.

## Collection and Interpretation of Information from the Workplace

***Q4**: What information can workplace monitoring provide?*

### Sources of Exposure

The starting point is a determination of the work location where the intake under investigation could have taken place. The degree of precision with which this location is known is likely to be highly variable. The location could be as general as "any location at {a specified industrial site}", or as specific as "in close proximity to {an item of equipment containing radioactive material}", or it could be specified with intermediate levels of precision (e.g. "within {a particular building}", or "within {a specified laboratory}"). Information is likely to be more precise for exposures resulting from a particular incident compared with that for routine, continuous, low-level exposures where no particular exposure event has been identified. The required information could be gathered from a radiation protection supervisor, supervisory staff, or local management staff, depending on local management structures.

When the work location has been specified, working activities and working practices at that location should be reviewed. A review of the history of contamination incidents associated with the work location may prove to be useful, as may a review of the history of contamination incidents associated with the individual. These reviews should seek to provide information on:

- Ubiquitous levels of contamination on workplace surfaces and identification of the time periods of exposure of the worker (in the case of continuous exposures that are likely to be at a low level)

- Resulting airborne concentration levels due to radionuclide resuspension
- The likelihood of discrete releases of airborne material to the workplace environment as a result of unplanned incidents or accidents
- The particle size distribution of an airborne aerosol, from a consideration of aerosol generation processes at the work location. For example, vaporisation/condensation processes produce smaller aerosol particles than mechanical processes such as milling and grinding.
- The solubility and reactivity of airborne vapours, from a consideration of the chemical processes and chemical reactions that are in use at the work location.

***Q3**: Where can this information be found?*

Some of this information may be available in workplace records, while some may be available in the results of contemporaneous workplace monitoring (see below).

## Radionuclides, radioactive Progeny and Chemical Compounds

These workplace information reviews should also seek to provide information on:

- the identity of the radionuclides to which the worker was exposed, from a consideration of the radioactive sources, radiochemical processes and radiochemical reactions that are in use at the work location
- The identity of chemical compounds associated with these radionuclides, from a consideration of the chemical processes and chemical reactions that are in use at the work location
- The absorption characteristics ("lung solubility") of these chemical compounds

For some elements, exposures may well involve a number of radio-isotopes. Examples include uranium (where $^{234}$U, $^{235}$U and $^{238}$U are usually present in varying ratios depending on enrichment or depletion of the source material, and are sometimes accompanied by $^{232}$U, $^{233}$U and $^{236}$U), and plutonium (where $^{240}$Pu and $^{241}$Pu usually accompany $^{239}$Pu). For uranium, knowledge of the isotopic ratios in the source material is essential for the correct interpretation of bioassay monitoring data.

Radionuclides of one element are sometimes accompanied by radionuclides of other elements. Examples include $^{241}$Am, which often accompanies $^{239}$Pu because of the radioactive decay of $^{241}$Pu; $^{90}$Y, which always accompanies $^{90}$Sr due to its in-growth from the radioactive decay of $^{90}$Sr; and $^{132}$Te, $^{132}$I, $^{133}$I and $^{135}$I, which may accompany $^{131}$I in the event of an exposure at a nuclear reactor.

Collection of information on the identity of radionuclides to which the worker was exposed will also provide information on exposure to radioactive progeny. For some parent radionuclides, monitoring involves the measurement of radioactive progeny. An example is $^{232}$Th, for which *in vivo* monitoring (typically over the chest to determine activities in the lungs) can be performed, but it is the gamma-emitting progeny radionuclides ($^{228}$Ac, $^{212}$Pb, $^{212}$Bi and $^{208}$Tl) that are actually detected. Correct interpretation requires information on the equilibrium conditions of the progeny radionuclides. For example, assuming secular equilibrium can result in underestimation of the intake of the parent radionuclide when intake is assessed from measurements of progeny radionuclides in the lungs and the progeny elements are more soluble in the lungs.

Experimental studies may have been conducted to determine site-specific and/or material-specific absorption characteristics (absorption Types or absorption parameter values to be used with the HRTM). Results of such studies may be used for internal dose assessments (**Sections E2, E3**) provided the studies were conducted to a standard appropriate for peer review publication, and results have been accepted by the national competent authority.

### Intake Route

Information on working practices and work activities will provide information on the likely intake route, as well as on the time, period or pattern of intake.

Inhalation is the most likely intake route for occupational exposures, but intakes by ingestion, by uptake through intact skin, of *via* wounds are also possible. Direct intake by ingestion should not normally occur in the workplace, because eating or drinking in controlled areas in workplaces is not permitted, and inadvertent ingestion is limited by the use of personal protective equipment (PPE). However, when contamination levels in the workplace environment are significant (such as may arise as a result of mining and milling of NORM materials), ingestion may occur as a result of contamination of the mouth or lips by deposition of airborne material, or transfer to the mouth from the hands. Intake via intact skin is possible for those radionuclides present at the work location in chemical forms that can be absorbed in this way, tritiated water being the best known example.

Information on unplanned incidents or accidents at a work location should make it clear whether a worker has received an injury that has resulted in a wound while handling radioactive material. Monitoring of the wound site, and bioassay monitoring, are needed to determine whether the wound site is contaminated, and whether any uptake has taken place.

### Time, Period or Pattern of Intake

For special monitoring in response to a specific exposure event (**Chapter C**), collection of all available information on the time of an acute exposure resulting from an unplanned incident or accident, or the time period and pattern of a protracted exposure due to such an incident, is of prime importance. Such information should be available in records of operations at the work location.

Routine monitoring (**Chapter C**) is conducted on the basis that intakes could occur at any point in the monitoring period. Workplace information, e.g. reviews of surveys, air sampling data and incident reports may provide information on whether an acute or chronic intake is more likely. In addition, even if the information available is limited, it may be used to determine whether any systematic bias could be introduced as a result of the timing of any intakes. For instance, in the extreme case, doses will be consistently underestimated if working practices mean that exposure to radioactive materials can only occur at the beginning of monitoring period. Conversely, doses will be overestimated if exposures can only occur at the end of the monitoring period.

***Q3**: Where can this information be found?*

This information should be available in workplace records.

## Information provided by Workplace Monitoring

Information from reviews of working activities and working practices may be supplemented by information derived from the results of workplace monitoring (**Chapter C**). Such monitoring includes measurement of the activity of airborne radionuclides and measurement of surface contamination by radionuclides. The latter may be performed using contamination monitors, or by measurements of surface wipes. It may also include measurement of physical properties of radioactive materials, such as particle size distribution. Individual monitoring of selected groups of workers is also usually considered to be workplace monitoring, since its purpose is to characterise exposure conditions within the workplace, rather than to assess dose of record for an individual.

### Radionuclide Identification

Gamma-spectrometric measurements on air filters or surface wipes can be carried out rapidly to identify gamma-emitting radionuclides. For pure beta-emitting radionuclides (e.g. $^{90}Sr/^{90}Y$) and most alpha-emitting radionuclides, radio-chemical separation

followed by beta-counting or alpha-spectrometry is required, which is more time-consuming.

### Characterisation of Airborne Particle Size Distribution

Aerodynamic particle sizers, including cascade impactors and cyclones, may provide particle size information, although their use in the workplace is not routine. If this information is absent, but found to be critical for individual dose assessments required as a result of exposures at a particular work location, then the use of these types of instruments may be recommended to the site operator (e.g. by the Radiation Protection Expert, RPE).

### Time, Period or Pattern of Intake

Temporal analysis of monitoring data from continuous air monitors situated at relevant locations in the workplace may be capable of providing information on the time of an acute intake, or on the period and pattern of a protracted (chronic) intake. When used with information on operations at the work location retrieved from workplace records, it may be possible to define with high precision the time, period and pattern of intake.

***Q3**: Where can this information be found?*

This information should be available in the results of contemporaneous workplace monitoring.

## Information provided by Individual Monitoring

***Q5**: How can the results of individual monitoring be used to guide and inform the formal dose assessment procedure?*

Individual monitoring methods are described in **Chapter D**. The results of individual monitoring measurements should be inspected before applying the formal dose assessment methods described later in **Chapter E**. These checks can provide valuable information that will aid and direct the dose assessment process. The effort that should be expended on such investigations depends on the likelihood of exposure and the magnitude of assessed doses.

Three simple approaches are available to evaluate the significance of a single bioassay measurement. These are the critical value ($M_C$) method for judging the significance of a monitoring result, as described in section 5 of ISO 27048:2011 [ISO 2011] and in the IDEAS Guidelines [EURADOS 2013], the dose per unit content data of the type provided by ICRP in [ICRP 2015b; 2016b; 2017], and the graphical method for making comparisons with dose limits, as described in Section 7, Step 6 of ISO 27048:2011. These methods all provide simple ways of making a rapid evaluation, and are described in more detail in **Sections E2** and **E3**.

For more complex, higher exposure cases where a sequence of monitoring measurements has been made, the methods described above can be applied to each measurement in turn. Extended sets of monitoring data can also be used to make judgements on whether the expected biokinetic behaviour is observed, by plotting each monitoring dataset together with the corresponding model predictions (**Annex I**) determined using appropriate model parameter values. These parameter values may be either default values or specific values determined from a consideration of exposure conditions (see above).

### Nose Blow/Nasal Swab Sampling

Measurements of radionuclides deposited on nose blow or nasal swab samples (see also **Chapter D**) may be used to indicate whether a significant intake by inhalation has occurred. Investigations of workplace exposures have often shown little correlation between assessed intake and radionuclide activities measured on nose blow/nasal swabs [Hounam 1983]. As a result, it is generally used only as a screening technique, to indicate whether or not a substantial intake has taken place, and is not generally used to provide quantitative estimates of intake. However, a more recent study [Guilmette 2007] analysed a large database of workplace nasal swab monitoring

data and showed a correlation between measured $^{239}$Pu activities and assessments of effective dose based on urine bioassay, albeit with uncertainties of plus or minus a factor of five. This study indicates that nasal swab monitoring could be used for early dose assessment (i.e. within about two hours of an intake). In an experimental investigation, [Smith 2012] showed that the correlation can be improved using nasal mucus stimulants. These two studies offer the possibility of a semi-quantitative rapid intake assessment technique.

Gamma spectrometric measurements of nose blow or nasal swab samples can also provide rapid information on radionuclide composition of the intake and isotopic ratios.

### Personal Air Sampling

Personal air sampling (PAS) (**Chapter D**) is another monitoring method that may be used to indicate whether a significant intake by inhalation may have taken place. In addition, PAS has been shown to provide adequate intake estimates for groups of workers [Britcher 1994] and is commonly used for individual monitoring of exposures to actinide radionuclides and to radon and its progeny.

### *In vivo* Monitoring Data

*In vivo* monitoring data may take the form of whole body retention data, lung retention data and organ retention data (**Chapter D**). As noted above, comparisons with model predictions can be informative about the biokinetic behaviour of the radionuclide and can help to inform and guide the dose assessment. Where monitoring data and biokinetic model predictions differ significantly, and where assessed doses could potentially exceed dose limits, consideration may need to be given to the application of non-default material-specific model parameter values in the subsequent dose assessment (see **Sections E2, E3**). Some examples follow:

- If the radionuclide activity remaining in the chest at later times (after a few tens of days) remains higher than expected from model predictions, this could indicate that absorption to blood is proceeding at a slower rate than expected (e.g. Type S rather than Type M behaviour). This could be corroborated by comparison of measured urine excretion with model predictions.
- If the radionuclide activity measured in the chest is similar to the measured whole body activity, this indicates that the material could be highly insoluble in the lungs, and that little uptake is taking place. This behaviour may or may not be predicted from biokinetic modelling, depending on the assumed absorption Type.
- Measurements of radionuclide activity in the head might be made in the course of a detailed examination of a specific exposure case. If calibrated head measurements are made and the activity of an insoluble aerosol measured in the head during the first 24 hours after inhalation is higher than expected from model predictions, relative to the activity measured in the chest, this may indicate a larger than expected AMAD value (e.g. 10 μm rather than 5 μm). The reason for this is that, for AMAD values above about 0.1 μm, aerosol deposition in the extra-thoracic airways (nose, pharynx and larynx) increases with increasing AMAD. Conversely, a lower than expected activity in the head may indicate a lower than expected AMAD value (e.g. 1 μm rather than 5 μm). Potential confounding factors need to be taken into account, including possible interference from surface contamination on or near the head, and possible contributions to the measured count from activity in organs near to the head (see "The effect of confounding Factors on Individual Monitoring Data" in this section (**E1**)). Workplace data on airborne particle size distribution should be reviewed to check for supporting evidence. If an "effective AMAD" is to be estimated, this is better done by means of a comparison of faecal excretion with measurements of activity in the chest (see following section on "Bioassay Sample Monitoring Data").
- If the activity measured in the chest is similar to that expected in the chest when uptake to systemic organs is complete, this could indicate that the

material is highly soluble in the lungs, and uptake from the lungs is complete with no deposited material remaining in the lungs in particulate form. This could be corroborated by comparison of measured urine excretion with model predictions. This behaviour may or may not be predicted from biokinetic modelling, depending on the assumed absorption Type.

- If the activity measured in whole body or an organ is increasing with time, this may indicate that intakes are protracted and are still continuing.
- Gamma spectrometric *in vivo* measurements of gamma-emitting radioactive progeny should help to establish whether their predicted biokinetic behaviour is similar to, or independent of, the parent radionuclide (see "The Effect of confounding Factors on Individual Monitoring Data" in this section (**E1**)). This type of investigation may need to be performed at a specialist facility.

## Bioassay Sample Monitoring Data

Bioassay sample (or *in vitro*) monitoring data may take the form of urinary excretion or faecal excretion data (**Chapter D**). As noted above, comparisons with model predictions can be informative about the biokinetic behaviour of the radionuclide and can help to inform and guide the dose assessment. Where monitoring data and biokinetic model predictions differ significantly, consideration may need to be given to the application of non-default parameter values in the subsequent dose assessment. With respect to the use of faecal data, information should be sought from the individual to determine whether faecal excretion may be abnormal due to alimentary tract disorders.

Some examples follow:

- Comparison of the time dependence of faecal excretion measurements with model predictions in the 3-5 day period after acute intake can help to confirm that intake has occurred by inhalation (rather than another route). The reason is that a large fraction of moderately soluble or insoluble (Type M or S) particulate material deposited in the respiratory tract (in both thoracic and extra-thoracic regions) is cleared to the gastro-intestinal (or alimentary) tract within this time period and then excreted in faeces. If ingested rather than inhaled, the material clears to faeces more rapidly. This technique cannot be used for inhaled soluble (Type F) materials because they are rapidly absorbed into blood and therefore their clearance via faecal excretion is very low. If the AMAD is known, then it may be possible to determine the fraction inhaled from the early lung retention and faecal data, as described in the IDEAS Guidelines, Chapter 10 (Stage 7B) [EURADOS 2013].
- Inspection of the time dependence of faecal excretion measurements during the first few days after an acute intake may help identify the time of the acute intake if this is not well-known from other sources. The reason is that faecal excretion shows a well-defined increase, peak value and decrease in the 3-5 day period after acute intake by inhalation. This technique can be used if measurements are made within about 10 days of the intake, but it cannot be used for inhaled soluble (Type F) materials because clearance of the radionuclide via faecal excretion is then very low. Thus, this technique can be used to identify the time of intake if the intake occurred close to the time range of the measurements.
- The relative activities of a radionuclide measured in lungs and in faecal samples in the first few days following acute intake or commencement of a chronic intake can inform the selection of an appropriate "effective AMAD" value. This may be useful if monitoring data are inconsistent with the default value of 5 μm. This technique cannot be used for inhaled soluble (Type F) materials. The method is described in the IDEAS Guidelines, Chapter 8 (Stage 5B) [EURADOS 2013].
- After an intake by ingestion, the ratio of the cumulative faecal excretion to the activity measured contemporaneously in the whole body (or in a systemic

organ such as the liver or thyroid), can be compared with the corresponding biokinetic modelling predictions, so informing the selection of an appropriate $f_1$ (or $f_A$) value. This may be useful if monitoring data are inconsistent with the default $f_1$ (or $f_A$) value for the element or compound.

- Systemic uptake is one of the most important factors determining assessed equivalent doses to organs, and the activity of a radionuclide measured in urinary samples is a measure of uptake to systemic organs. The activity measured in urinary samples relative to the activity measured contemporaneously in whole body (or in a systemic organ such as the liver or thyroid) provides a quantitative measure that can be compared with biokinetic model predictions to test whether systemic uptake of the radionuclide is at the expected level.
- The ratio of the radionuclide activities measured in urinary and faecal samples at early to moderate times when compared with model predictions gives information on the respiratory tract absorption charactistics of the inhaled material. These measurements should be made while the material remains in the lungs.
- The ratios between radionuclide activities measured in urinary and faecal samples at later times, and the ratios of these activities with whole body or systemic organ activities, when compared with biokinetic model predictions, provide information on whether measured and expected biokinetic behaviour are consistent. These measurements should be made when systemic uptake from the respiratory tract is close to completion, as indicated by biokinetic modelling.
- The volume and the creatinine content of a urine sample, and the weight of an ashed faecal sample, can provide indications about whether the stated sampling time period is likely to be correct.

## Wound Monitoring

Dose assessments for cases involving wound contamination usually have to be conducted on a case-by-case basis. The biokinetic behaviour of a radionuclide contaminating a wound site is usually not well-known in advance of an incident, and, frequently, the biokinetic behaviour observed is unique to the contamination case under investigation. As a result, predictive biokinetic modelling using a wound model (e.g. [NCRP 2007] with reference or default model parameters may be of limited value. Results of a sequence of monitoring measurements made using external detectors at the wound site (**Chapter D**) give important information on rate of uptake, although other routes of clearance (e.g. by irrigation of the wound site) should be taken into account. Comparison between the activity of a radionuclide measured at the wound site, and the activity of a radionuclide taken up systemically by the body, as indicated by *in vivo* measurements or urinary excretion measurements, provides important information on the biokinetic behaviour of the contaminating material. Wound, *in vivo* and *in vitro* monitoring should ideally be conducted for a sufficiently extended period of time so that the biokinetic behaviour can be adequately characterised, without recourse to predictive modelling.

***Q3**: Where can this information be found?*

This information, where it exists, should be available in dosimetry service records.

***Q6**: How much emphasis should be placed on information derived from data fitting procedures on exposure conditions and material-specific model parameter values?*

After having obtained information provided by workplace and individual monitoring, the structured approach for performing internal dose assessments as explained and discussed in **Sections E2 and E3** should be used. These sections describe the interpretation of bioassay monitoring results originating from individual routine or special monitoring respectively. However, it is important that internal dose assessment is not considered as a completely automatic, "black box" process. In

considering how to interpret monitoring data obtained for a particular worker, much can be learnt from an examination of information on working practices and the general circumstances that resulted in the exposure, as discussed above. In addition, an informed examination of the individual monitoring data for the worker will provide a better understanding of the exposure, and will aid and direct the formal dose assessment process.

The use of iterative data fitting methods with the available monitoring data can provide useful information on the model parameter values to be used in the final dose assessment and on the route of intake. However, a cautious approach must be adopted, and these derived model parameter values must be viewed in the context of information collected from the workplace. For example, data fitting methods, when used alone, may indicate an inhaled particle size distribution that does not (or could not) occur in the particular work location, or may indicate an absorption Type that is inconsistent with the known biokinetic behaviour of the chemical compound to which the worker was exposed.

## The Effect of confounding Factors on Individual Monitoring Data

***Q7**: What are the issues that might prevent a straightforward interpretation of individual monitoring data?*

There are many confounding factors arising from the practical aspects of individual monitoring that can result in misleading findings and erroneous dose assessments. Dose assessors should be aware of such factors, and should ensure that they have been avoided, or their potential effect considered and minimised. The more common confounding factors are described below.

### External Contamination of the Body

In the absence of effective decontamination of skin and clothing after an incident and before a measurement, external contamination may be mis-interpreted as internal contamination. Consideration of the relative magnitudes of measured gamma emissions at low (< 100 keV) and high (>100 keV) energies (if both are present) can often reveal this effect because of the differential attenuation of low energy photons arising from external and internal contamination. Apparently uneven distribution of activity (e.g. large differences between left and right lung measurements; unexpectedly high measurements of activity in the head or on the hands) may also indicate the presence of external contamination. Standard procedures for removing external contamination before *in vivo* monitoring should always be employed.

### Treatment with Medical Radioisotopes

On rare occasions, individuals being monitored may have received an intake of a radionuclide as a result of medical treatment unrelated to any occupational exposure. Nuclear medicine treatments may have been performed for either diagnostic or therapeutic purposes. It should not be assumed that an individual is aware that their medical treatment has resulted in an intake of a radionuclide.

### Contamination of Bioassay Samples

Samples provided by individual workers may be contaminated if reliable sampling protocols have not been established, validated and rigorously adhered to. This can be a particularly significant issue in cases of intake of relatively insoluble materials that are subject to long-term retention, because urine sample activities are then likely to be very low, since they are a very small fraction of the intake. Standard procedures for avoiding contamination of bioassay samples should always be employed, and their correct use by the worker monitored.

### Errors in the Bioassay Sample Collection Period

For urine sampling, assessments are generally based on daily excretion, and so 24-hour samples are preferred as discussed in **Chapter D**. However, practical considerations mean that it is often not possible to obtain a 24-hour sample and so a

normalisation must be applied, either using the actual collection period, or the volume of urine collected, or the creatinine content (**Chapter D**). Where 24-hour samples are requested, or the radionuclide activity is normalised according to the actual collection, it is possible that the actual sample collection period differs from that recorded by the worker. This results in a scaling error in a dose assessment based on that sample. Comparisons may be made with reference values of sample volume or creatinine content [ICRP 2002]; a decision is then required on whether re-normalisation of the measured radionuclide activity is appropriate.

A similar problem arises for faeces samples, but the problem is compounded by the discrete nature of faecal excretion. In this case, comparisons may be made with reference values of sample mass, and a decision then made on whether to apply re-normalisation. Collection of samples over several days rather than a single day helps to alleviate this problem.

The IDEAS Guidelines [EURADOS 2013] recommend that normalisation should be considered when a urine sample is less than 500 mL or a faeces sample is less than 60 g.

## Background Radiation in *in vivo* Monitoring

Background radiation levels, or background radionuclide levels in air or in construction materials used in the *in vivo* monitoring system, may cause erroneous identification or quantification of radionuclides in the body. These problems can be severe for radionuclides with gamma ray emissions below 100 keV, and for naturally-occurring radionuclides with which workers may be contaminated (e.g. uranium, thorium or radium isotopes). Background levels in *in vivo* monitor enclosures should be adequately controlled (**Chapter D**).

## Contribution to measured Counts from Activity in other Organs (e.g. Skeleton for Chest Measurements)

*In vivo* measurements are conducted with detectors positioned externally to the body, so measurements of radionuclide activities in specific organs can be subject to interference arising from the presence of radionuclides in nearby organs. One example is the measurement of the activity of an actinide radionuclide (e.g. $^{241}$Am) in the lungs after inhalation of the material in insoluble form, where uptake to bone in the thorax (i.e. the ribcage) is a potential source of interference. Appropriate corrections may need to be applied. In this example, the skeletal activity in the thorax could be predicted for a specified intake using an appropriate biokinetic model (**Chapter B**). *In vivo* calibrations could then be made using an appropriate thorax phantom to predict the contribution from the activity in the skeleton to a measurement made using detectors positioned for a measurement of the activity in the lungs. Active calibration sources would need to be placed within the thorax phantom to simulate the distribution of skeletal activity. Alternatively, Monte Carlo calibration methods with mathematical phantoms could be applied (**Chapter D**).

## Dietary Intakes (NORM)

Measurements of uranium and thorium isotopes and their radioactive progeny in the body resulting from workplace exposures may include contributions from dietary intakes received away from the workplace. Typically, monitoring for these materials will comprise urinary and faecal monitoring. ISO 16638-1:2015 [ISO 2015d] presents advice on how to establish an appropriate correction or reference value for the contribution from dietary intake.

## Independent Biokinetic Behaviour of Radioactive Progeny used to Monitor for Intake of the Parent

Individual monitoring for internal contamination with radionuclides with decay chains may involve measurement of a radioactive progeny radionuclide rather than the parent. While *in vitro* measurements normally involve the measurement of the parent radionuclide, *in vivo* measurements often involve measurement of a progeny

radionuclide. An example is the *in vivo* measurement of $^{214}$Pb and $^{214}$Bi for monitoring a $^{238}$U intake. The *in vivo* measurement of the progeny is then used to assess the intake of the parent, but in some circumstances (**Chapter D**), the biokinetic behaviour of parent and progeny are quite different, and secular equilibrium between them cannot be assumed. With some exceptions (i.e. tellurium, lead, radium, thorium, uranium), ICRP's recommended systemic models published before 2016 did not allow for independent biokinetic behaviour of the progeny formed within the body. With the publication of the OIR report series [ICRP 2015b; 2016b; 2017], independent biokinetic behaviour of progeny is now included. When interpreting *in vivo* measurements, the biokinetic behaviour of the progeny radionuclide relative to the parent radionuclide should be predicted using biokinetic models that implement independent biokinetics. Alternatively, experimental studies of material-specific absorption characteristics in the published literature may provide a description of the differences in biokinetic behaviour. Assumptions made about equilibrium between a parent radionuclide and its progeny should always be evidence-based.

A related issue is the ingrowth of a radioactive progeny radionuclide following intake of a parent, where the progeny radionuclide is the main contributor to dose. An example is the ingrowth of $^{241}$Am in the body after an intake of $^{241}$Pu. Interpretation of monitoring data should take account of the fact that the presence of the progeny radionuclide arises from ingrowth, and not direct intake.

## Independent Biokinetic Behaviour of Mixtures of Radionuclides

The activity of a particular radionuclide in a body organ may be inferred from a measurement of the activity of another radionuclide that is more easily detected, if the ratio of their activities in body organs is known. The best known example is the use of measurements of $^{241}$Am in the lungs to infer the activity of $^{239}$Pu. Confirmation should be sought that the biokinetic behaviour of both radionuclides in the body organ is similar.

## Presence of Large Particles in the Respiratory Tract or GI Tract

If a radionuclide is present as a small number of relatively large (> 10 μm), discrete radioactive particles rather than a larger number of smaller aerosol particles, clearance behaviour may be quite different to that predicted by conventional modelling. Such particles could potentially be deposited in the extra-thoracic or upper thoracic airways of the respiratory tract, or in the GI tract. Some high activity ("hot") particles may be classified as large particles in this sense. Significant differences in retention times and residence times may be found. For example, a single large insoluble particle may deposit in the upper thoracic airways, giving rise to a positive *in vivo* lung measurement immediately after intake. It may then be cleared by particle transport to the GI tract within a few hours, resulting in a positive *in vivo* measurement over the abdomen and a (well-collimated) *in vivo* lung measurement below the decision level. Case-specific modelling, possibly using Monte Carlo methods, may be required in such situations.

## Radionuclides in Unusual Chemical Forms

Comparisons between monitoring data and biokinetic behaviour predicted by biokinetic modelling may reveal significant differences. One possible source of such differences could arise because the chemical form may be different to that of the chemical compounds on which the model was based, or model parameter values selected. In such cases, material-specific model parameter values may be required.

This could be the case when the radionuclide is attached to biological macromolecules (e.g. $^{3}$H-DNA bases, $^{18}$F-glucose, etc.), or in the case of radiopharmaceuticals where the radionuclides are attached to complicated labelled molecules, or when the radionuclide is present in cells labelled with radiopharmaceuticals. The radionuclides in these various labelled compounds have a systemic biokinetic behaviour different from that of the ionic form of the radionuclide. When available, specific biokinetic models should be used [ICRP 2015a].

Another example is naturally occurring radioactive materials (NORM). One of the main sources of uncertainty associated with assessing doses from NORM inhalation is the chemical nature of the airborne particle matrix. In most cases, the material inhaled is a mineral dust matrix in which the radionuclides are contained, rather than a chemical compound of uranium, thorium, or the corresponding progeny. Absorption behaviour is then determined by the solubility of the matrix rather than that of the radionuclide. Comparison of biokinetic model predictions with radionuclide-specific *in vivo* and/or *in vitro* monitoring data collected over an extended period after intake is an important step towards understanding the biokinetic behaviour of the inhaled material.

# E2 - Dose Assessment and Interpretation: Routine Monitoring

***Issues addressed by section E2***

***Dose assessment for routine monitoring cases***

***MAIN QUESTION***

***Q8*** *How should dose assessments after routine monitoring be performed in practice?*

***Subsidiary question***

***Q9*** *How does the recommended approach for routine monitoring compare with the ISO 27048:2011 and the IDEAS Guidelines methodologies?*

## Special Terms related to Routine Monitoring

Annual dose, Critical Value, Scattering factor, Contribution from earlier intakes, Structured approach to dose assessment, Data fitting, Monitoring interval.

## Introduction

The remaining sections of **Chapter E** address the activity of retrospective dose assessment after having set up the monitoring programme (**Chapter C**) and having collected the results of the bioassay measurements (**Chapter D**). Special aspects of data handling such as identification of outliers and handling data below the detection limit are described in the IDEAS Guidelines [EURADOS 2013] and in ISO 27048:2011 [ISO 2011] and are not repeated here.

Section E2 presents recommendations for internal dose assessment after routine monitoring. Routine monitoring is the set of actions related to the normal surveillance of workers who are subjected to a risk of internal contamination in the workplace. It is conducted during routine working operations, at predefined time intervals, when the conditions present in the workplace determine the possibility of internal contamination (**Chapter C**). The main purpose of dose assessment in a routine monitoring programme is to evaluate committed effective dose ($E(50)$) in order to determine compliance with dose limits.

In the Appendix to this chapter, a description of the origins, structure and contents of the two main reference documents, namely the IDEAS Guidelines and ISO 27048:2011, is presented.

Both documents present structured approaches for performing internal dose assessments and both aim to ensure that the level of effort applied in the evaluation is commensurate with the magnitude of the exposure.

The main method of ISO 27048:2011 is summarised in Figure 2 of the standard and is reproduced here as Figure E.1. It is structured in eight sequential steps for interpretation of routine monitoring data and six steps for evaluation of special monitoring data. Special monitoring may be introduced either in Step 1 (when the monitoring interval is inconsistent with accepted routine monitoring intervals) or in Step 5 (when unexpected exposure cannot be excluded).

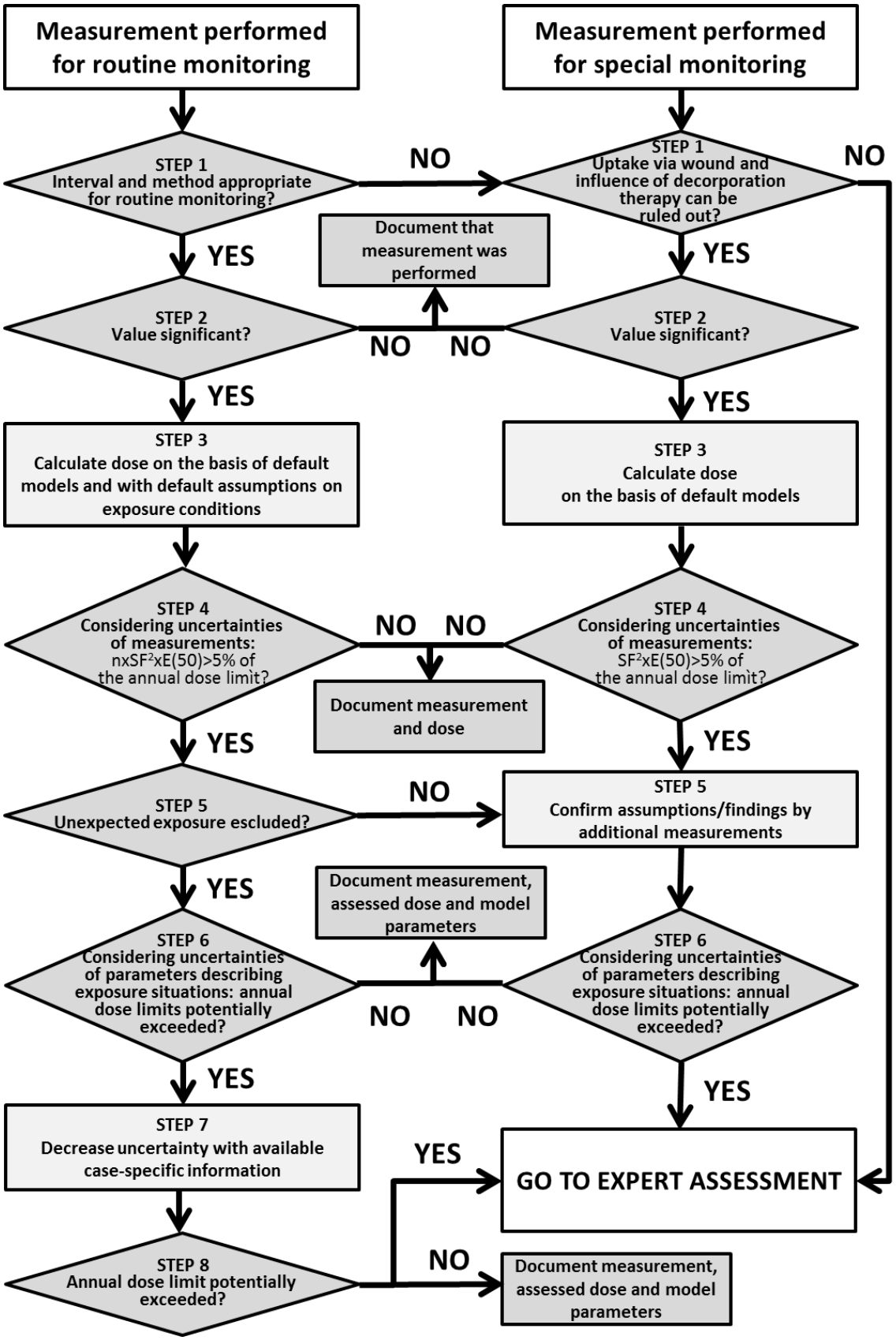



**Figure E.1**: Procedure for assessment of doses on the basis of individual measurements (adapted from ISO 27048:2011, with kind permission)

In the IDEAS Guidelines the level of effort to be applied in the evaluation is determined by the level of the assessed dose (from Level 0 to Level 3). For Level 0 a test on the need for dose assessment is performed using a comparison of bioassay results with critical levels; if the test is satisfied no dosimetric evaluation is needed.

Level 1 requires simple dose assessment, Level 2 requires sophisticated evaluation while Level 3 requires advanced (more sophisticated) evaluation. In practice each level corresponds to one or more stages, each one composed of several steps (see **Appendix to Chapter E**).

Article 13 of the 2013 Directive [EC 2014] states that "standard values and relationships" should be used for the estimation of effective and equivalent doses (see **Chapter A**). However, Article 4, paragraph 96 states that:

> *Member State may approve the use of specific methods in specified cases relating to the physico-chemical properties of the radionuclide or other features of the exposure situation or of the exposed individual*

This means that specific biokinetic and dosimetric models could be used in retrospective dose assessment in special circumstances if approved by the competent authority of the Member State. Examples could include the use of biokinetic models for specific $^{14}C$ compounds, or dose assessments in cases where comprehensive bioassay data are inconsistent with standard model predictions.

## Dose Assessment for Routine Monitoring Cases

***Q8**: How should dose assessments after routine monitoring be performed in practice?*

***Q9**: How does the recommended approach for routine monitoring compare with the ISO 27048:2011 and the IDEAS Guidelines methodologies?*

It is recommended that the methodology described in ISO 27048:2011 [ISO 2011] should be used for routine monitoring cases where it can be concluded that the annual dose limit would not be exceeded. This is the expected situation during normal operations without accidents or incidents. ISO 27048:2011 employs a highly standardised method and presents the minimum requirements for the evaluation of data from an internal monitoring programme to determine committed effective dose.

Section 7.1.8 of ISO 27048:2011 states that a more sophisticated analysis must be applied when the dose assessment indicates that the annual dose limit could potentially be exceeded. It further states that this analysis must be performed by experts, and references the IDEAS Guidelines as a source document. It is recommended here that this more sophisticated analysis should follow the IDEAS Guidelines [EURADOS 2013].

In this procedure, it is only the internal dose that is compared with the annual dose limit when deciding if a more sophisticated analysis is needed. However, to demonstrate compliance with annual dose limits it is the sum of the internal and the external doses that should be considered.

The IDEAS Guidelines are intended to be comprehensive, and so they also include guidelines for internal dose assessment for cases where the annual dose limit has not been exceeded. In most cases, the outcomes of the two methods are likely to be broadly similar. The recommendation made here to follow the ISO 27048:2011 method should be adopted by newly established dosimetry services and by services that have not yet adopted a systematic approach. However, it is recognised that some established dosimetry services may have made a considerable investment in adopting the IDEAS Guidelines for all dose assessments irrespective of the assessed dose. Use of the IDEAS Guidelines for cases where it can be concluded that the annual dose limit would not be exceeded is not excluded by these technical recommendations.

ISO 27048:2011 describes the criteria for determining the significance of the monitoring results, taking into consideration uncertainties arising from sampling, measurement techniques and working conditions.

The eight-step procedure for interpreting single monitoring results is described in the principal flow chart of Figure E.1 and is summarised in Table E.1.

**Table E.1** Summary of ISO 27048:2011 procedure for Routine Monitoring

| Step | Indication | Action or test | If test is verified | If test is NOT verified |
|---|---|---|---|---|
| 1 | Check if the method used and the monitoring interval are appropriate for routine monitoring | Verify that the monitoring method and interval are consistent with those indicated in ISO 20553:2006. | Go to Step 2 | Go to Special Monitoring, Table E.2 – Step 1 |
| 2 | Check if the monitoring value is significant | Check if the measured value exceeds both the decision threshold and the critical value for the type and interval of measurement. Test the significance of contribution(s) from earlier intake(s). | Go to Step 3 | Document the measurement. No further dose assessment is needed. |
| 3 | Standard dose assessment | Perform standard dose assessment with default parameter values. | Go to Step 4 | |
| 4 | Check if the 97.5% confidence level of the assessed projected annual dose is greater than 5% of the annual dose limit | Check if $E(50) > 1/(n \cdot SF^2)$ mSv | Go to Step 5 | Document the intake for the monitoring interval and the related committed effective dose. |
| 5 | Check if unexpected exposures can be excluded (i.e. if the exposure is expected) | Check if the measurement is consistent with earlier experience; (site-specific quantitative criteria should be defined in advance). | Go to Step 6 | Go to Special Monitoring, Table E.2 – Step 5 |
| 6 | Check whether dose *potentially* exceeds annual dose limit | Plot the measurement value on the band figures of Annex A, to check whether the annual dose limit may be *potentially* exceeded. | Go to Step 7 | Document the intake for the monitoring interval, the related committed effective dose and the model parameter values. |
| 7 | Application of case specific information | Apply specific information to decrease the uncertainty of the assessment. | Go to Step 8 | |
| 8 | Second check whether dose *potentially* exceeds annual dose limit | After having applied case-specific information, check again if the annual dose limit may potentially be exceeded. | Go to Stage 4 of IDEAS Guidelines | Document the intake for the monitoring interval, the related committed effective dose and the model parameter values. Go to Step 1. |

Instructions for following the procedure are as follows:

- STEP 1: Check if the monitoring interval and the monitoring method are appropriate for routine monitoring in relation to the intervals indicated by ISO 20553:2006 [ISO 2006].
- STEP 2: Check if the measured value *M* is significant i.e. if it exceeds the decision threshold of the measurement method [ISO 2010b] and the *Critical value*. The *Critical value* is the value of the result of the bioassay measurement which, if repeated during all the routine monitoring periods during the accounting year, results in an assessed committed effective dose of 0.1 mSv, assuming that the intakes occur at the mid-point of the monitoring period. If the value is not significant, document that the measurement was performed. No further dose assessment is needed. The evaluation then ends. If the measurement is significant, test the significance of earlier intake contributions.
  For this check, it is required to know the uncertainty of the measured values in terms of a scattering factor (see **Chapter F**). The ISO 27048:2011 approach in clause 7.1.2.2 of the standard is recommended.
  For outside workers, arrangements should be established for appropriate data exchange (mainly relating to previous already-known and documented intake(s)) by the parties involved (mainly the employer and the internal dosimetry service), in order to correctly calculate the contribution(s) from earlier intake(s) to the measured value (see **Chapter C**).
- STEP 3: Standard dose assessment, using default assumptions
  A standard dose assessment is performed using the default assumptions presented in section 7.1.3 of ISO 27048:2011; in particular the time of intake is assumed to be at the mid-point of the monitoring interval. The method to be applied is that indicated in Eq. B.8 and B.10 for evaluation of intake and committed effective dose.
  Values for retention or excretion functions *m(t)* are provided in Annex C of ISO 27048:2011. Dose coefficients for an AMAD of 5 µm are reported in ICRP Publication 78 [ICRP 1997] and are available on the ICRP web site as a CD-ROM [ICRP CD]. ICRP have compiled all dose coefficients for occupational intakes of radionuclides that are derived using the ICRP Publication 60 recommendations in ICRP Publication 119 [ICRP 2012].
  The ICRP database that will be made available in conjunction with the OIR report series [ICRP 2015b] will provide the reference database for *m(t)*, *e(50)* and *z(t)* values to be used for intake and dose estimation when the OIR report series is adopted. The evaluation of committed effective dose using the dose per unit content function *z(t)* is described in Eq. B.11.
  Where site-specific default model parameter values are available and documented, these may be used provided that they are shown to be appropriate for the process in which the individual was engaged.
  Provision is made in ISO 27048:2011 for the assessment of intake after exposure to a mixture of radionuclides, and the method of summation of the contribution to total dose from the different radionuclides is described.
- STEP 4: Criterion for accepting the standard dose assessment
  There is no need for further evaluation if, on the basis of the calculated committed effective dose *E(50)*, the 97.5% confidence level of the assessed projected annual dose (based on measurement uncertainty alone) is less than 5% of the annual dose limit, i.e. the following relation is valid:

$$E(50) \cdot n \cdot SF^2 < 0.05 \cdot E_{\text{limit}} \qquad \text{(Eq. E.1)}$$

where

| | |
|---|---|
| $n = 365/\Delta T$ | number of monitoring periods in a year |
| $\Delta T$ | monitoring interval (in days) |
| $SF$ | total scattering factor related to the measurement used for intake estimation (see Step 2) |
| $E_{\text{limit}}$ | annual dose limit of 20 mSv. |

The relationship therefore becomes:

$$E(50) < \frac{1}{n \cdot SF^2}\ mSv \qquad \text{(Eq. E.2)}$$

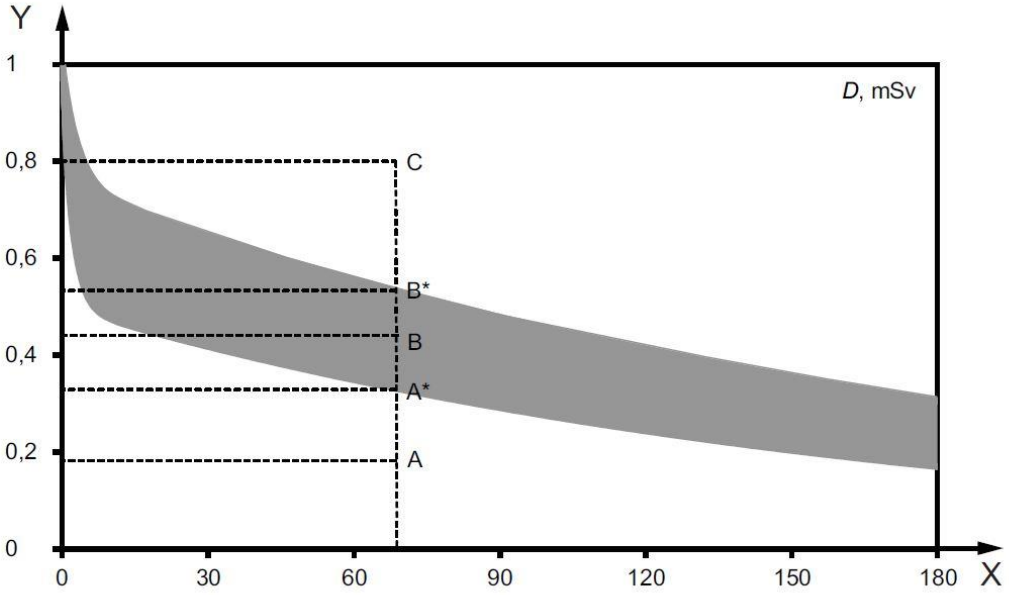
In this case, the result of the measurement, the dose assessment procedure (including the assumptions adopted), the evaluated intake for the monitoring interval and the corresponding committed effective dose should all be documented, following the requirements specified in sections 7.1.4 and 10 of ISO 27048:2011. The evaluation then ends. Otherwise, if the relationship is not satisfied, proceed to the next step.
It is recognised that in many cases this relationship will not be satisfied; however, in most of these cases, STEP 6 will subsequently show with high confidence that E(50) is below the annual dose limit. The procedure will therefore stop at STEP 6, and the assessed dose will be documented. STEP 6 requires little further effort as only a graphical comparison is performed and no further calculations are needed.

- STEP 5: Check on unexpected exposures
  An unusually high measured value could indicate a deviation from the stable workplace conditions that were assumed to prevail when the routine monitoring programme was specified. If this is the case, the worker may have been subject to an unexpected exposure.
  It is therefore recommended to set up adequate quantitative criteria, in advance of performing the monitoring measurements, for the identification of measurements that are not consistent with earlier experience. Comparison of results for different workers with similar exposure situations may also be helpful in identifying unexpected exposure situations.
  The check on unexpected exposure should be performed without delay.
  If an unexpected exposure cannot be excluded, it is recommended to perform additional special monitoring measurements before proceeding with the dose assessment. The procedure for the assessment of special monitoring data presented on the right hand side of Figure E.1 (and summarised in Table E.2) should then be followed (from STEP 5).
  If an unexpected exposure can be excluded, proceed to STEP 6.

- STEP 6: Comparison with dose limits: to check if the annual dose limit may *potentially* be exceeded
  The procedure is aimed at performing a quick test to evaluate the possibility that the annual dose limit may potentially be exceeded, providing a "Yes" or "No" answer. It is separate from the dose assessment procedure.
  The procedure takes into account the measurement uncertainty and the lack of knowledge of those material-specific parameter values that have the greater effect on the assessed dose (mainly absorption Type, gastro-intestinal uptake factor and AMAD) to decide whether the true value of dose may *potentially* exceed the annual dose limit.
  ISO 27048:2011 provides figures of the type shown in Figure E.2 that show the predicted range of the measured bioassay quantity, M, for commonly encountered radionuclides [ISO 2011]. For each time after intake, the upper (B*) and lower (A*) level of a shaded region (band) represent the predicted upper and lower possible values of measurable bioassay quantities corresponding to a specified committed effective dose value, *D* in mSv, taking uncertainties into account.
  In Annex A of ISO 27048:2011, graphs and tables for the lower and upper level are provided, for the different radionuclides and monitoring types, for a committed effective dose of 20 mSv. These were calculated using ICRP Publication 60 methodology and the associated (pre-OIR) biokinetic and dosimetric models. These data are expected to be updated by ISO following the publication of the revised models of the OIR report series.
  Plotting the measurement *M* at its time after intake, it is immediately possible to check if the committed effective dose may potentially exceed the annual

dose limit of 20 mSv. For example, with the graphs and tables of Annex A of ISO 27048:2011 the following statements can be made:

- If $M$ < A* it can be stated, with a high level of confidence, that *E(50)* is below the annual dose limit of 20 mSv.
- If $A^* < M < B^*$, *E(50)* could be below or above the annual dose limit of 20 mSv.
- If M > B* it can be stated, with a high level of confidence, that E(50) is above the annual dose limit of 20 mSv.




**Key**

X days after exposure

Y amount in body (Bq) or excreta (Bq/d)

**Figure E.2**: Predicted range of measured bioassay quantities, normalised to its value at t=1 day for intake resulting in committed effective dose of D mSv [from ISO 27048:2011 with permission]

In all three cases the minimum $[E(50)]_{min}$ and maximum dose $[E(50)]_{max}$ can be estimated from the measurement result $M$ using Eq. E.3 and E.4.:

$$[E(50)]_{min} = \frac{M}{B^*} \cdot 20 \cdot mSv \qquad \text{(Eq. E.3)}$$

$$[E(50)]_{max} = \frac{M}{A^*} \cdot 20 \cdot mSv \qquad \text{(Eq. E.4)}$$

For cases where the likelihood of intake is expected to be similar in each monitoring period, the procedure should be performed with $Mn$ as the value plotted rather than $M$, where $n$ is the number of monitoring periods in a year. In this case the coordinates of the plotted point are ($\Delta T$; $Mn$).

For cases where the measurement uncertainty is large enough, the check is performed using the 97.5% confidence level of the measurement quantity i.e. $M \cdot SF^2$, by comparing it with the corresponding upper limit of the band ($B^*$). In this case the coordinates of the plotted point are ($\Delta T$;$M\ SF^2$). If the value of $M\ SF^2 > B^*$ it can be concluded that *E(50)* may be above the annual dose limit of 20 mSv.

For those radionuclides or monitoring methods for which graphs are not presented in Annex A of ISO 27048:2011, the measured bioassay quantity $M$ should be compared to the derived investigation level, as defined in ISO 20553:2006. Equation E.5 provides the lower level of the derived investigation level $DIL_{min}$. In this equation, the uncertainty in the time of intake is taken into account by calculating $DIL_{min}$ assuming the worst case intake pattern. To do

this, the predicted bioassay quantity $m(\Delta T)$ is used, which implies that the intake takes place at the beginning of the monitoring period. Measurement uncertainty is taken into account by means of the specific scattering factor (*SF*) value.

$$DIL_{\min} = \frac{0.02}{e(50)} \cdot 0.3 \cdot m(\Delta T) \cdot \frac{\Delta T}{365} \cdot \frac{1}{SF^2} \qquad \text{(Eq. E.5)}$$

where 0.02 is the annual dose limit in Sv $y^{-1}$ and the investigation level is 30% of the dose limit. The values of *e(50)* (in Sv $Bq^{-1}$) and *m(t)* (in Bq or Bq $d^{-1}$ per Bq of intake) to be used in Eq. E.5 are those related to the default absorption Type associated with the chemical form of the radionuclide. If the value *M* is less than $DIL_{\min}$ it can be concluded, with a high level of confidence, that the annual dose limit would not be exceeded.
If the above-mentioned method indicates that the annual dose limit has not been exceeded, the assessed intake for the monitoring period under consideration as well as the related committed effective dose (assessed according to STEP 3) should be documented together with all information used in the calculation (including model parameter values and assumptions).

- STEP 7 : Application of case-specific information
  Where the evaluated dose *E(50)* may *potentially* exceed the annual dose limit, further case-specific information, if available, should be obtained and applied in order to decrease the uncertainty of the assessment.
  ISO 27048:2011 provides data to allow evaluation of *E(50)* using a day of intake different from the mid-point of the monitoring interval, or with the assumption of a constant chronic rate of intake during the monitoring period. Values of bioassay functions for chronic intake (Bq retention per Bq $d^{-1}$ intake or Bq $d^{-1}$ excretion per Bq $d^{-1}$ intake) are reported in ISO 27048:2011, Annex C, Part 2.

- STEP 8 : Dose limit potentially exceeded
  After the application of case-specific parameters to reduce the uncertainty of the assessed dose, another comparison with annual dose limits is made, following the approach indicated in Step 6. At this stage, ISO 27048:2011 suggests that additional graphs could be generated, similar to those used in Step 6 but using case-specific information regarding uncertainties on parameter values for AMAD, absorption Type and gastro-intestinal uptake factor.
  If this is not feasible, ISO 27048:2011 recommends that the assessed dose should be compared with the derived investigation level calculated with above mentioned Eq. E.5 but using *e(50)* and *m(t)* calculated on the basis of the assumed case-specific parameter values.
  If the analysis indicates that the annual dose limit may *potentially* be exceeded, it is recommended here that a more sophisticated analysis should be performed with the help of an expert. In such cases, further monitoring measurements should be performed; the minimum number of measurements required is given in the columns of Tables C.6 and C.7 for D > 1 mSv. It is recommended that the procedures described in the IDEAS Guidelines [EURADOS 2013] should then be followed.

It is likely that only a limited number of routine monitoring cases will be assessed using the IDEAS Guidelines methodology since doses are not expected to potentially exceed the annual dose limit of 20 mSv in a year under conditions where routine monitoring is employed. This may not necessarily be the case for intakes of actinides because there is greater potential that the annual dose limit could be exceeded whenever urine bioassay measurements yield positive results, particularly for insoluble forms.

When transferring to the IDEAS Guidelines methodology, it is recommended to start from Stage 4. The primary purpose of this Stage is to allow a decision to be made on the route of intake (pure inhalation, pure ingestion, both inhalation and ingestion or intake via a wound).

Stage 5 of the IDEAS Guidelines (Chapter 8 of [EURADOS 2013]) should be followed for pure inhalation cases. For cases where there is strong evidence of pure ingestion, then Stage 6 of the IDEAS Guidelines (Chapter 9) should be followed. In cases where the pathway could be a combination of inhalation and ingestion, a mixed route of intake may be considered. However, in practice, the fraction of the intake arising from ingestion can only be determined if the aerosol in the workplace has been well characterised and early faecal and lung data are available. It is therefore recommended that pure inhalation should be assumed as a default unless there is available information to justify that a part of the intake is ingestion, in which case Stage 7 of the IDEAS Guidelines (Chapter 10) should be followed. In the case of a contaminated wound, Stage 8 of the IDEAS Guidelines (Chapter 11) should be followed.

The structures of Stages 5, 6, 7 and 8 are similar and are composed of three sub-stages: namely A, B and C. In sub-stage A, the fit to the monitoring data and the subsequent dose assessment are performed using *a priori* model parameter values related to a single default absorption Type, taken from the relevant ICRP publications or evaluated (case- or site-specific parameters are to be used if they are available). If time of intake is unknown or the dose assessed in sub-stage A is greater than 1 mSv, then values of the AMAD, absorption Type and/or time of intake are varied *a posteriori* using data fitting of the measurement data, and the dose assessment is performed using these values (sub-stage B). Finally, if the fit is not acceptable and/or the predicted dose is > 6 mSv, a more sophisticated evaluation with systematic adjustment of model parameter values (*a posteriori*) should be used (sub-stage C). In all sub-stages a specific goodness-of-fit method should be used to check if the predictions of the biokinetic model under the assumed scenario of exposure are consistent with the measurement results.

In the event that assessed doses are above 6 mSv, committed effective dose (and committed equivalent doses to organs if required by national regulations) should be calculated with the same model parameter values that have been used for the assessment of the intake, i.e. the ICRP default dose coefficients should not be used.

When routine monitoring proceeds to the next monitoring period, the evaluation procedure is repeated, commencing at STEP 1 of the ISO 27048:2011 procedure.

# E3 - Dose Assessment and Interpretation: Special Monitoring

***Issues addressed by section E3***

***Dose assessment for special monitoring cases***

***MAIN QUESTION***

***Q10*** *How should dose assessments after special monitoring be performed in practice?*

***Subsidiary question***

***Q11*** *How does the recommended approach for special monitoring compare with the ISO 27048 and the IDEAS Guidelines methodologies?*

***Use of dedicated software tools***

***Q12*** *When selecting dose assessment software, what are the desired capabilities that should be taken into consideration?*

***Q13*** *What issues should be considered when using dedicated software?*

## Special Terms related to Special Monitoring and Software

Observed chi-squared value, Scattering factor, Maximum Likelihood Method.

## Introduction

**Section E3** presents recommendations for internal dose assessment after special monitoring. A special monitoring programme is usually set up after a real or suspected contamination incident. It is performed to quantify significant exposures following actual or suspected abnormal events or in the event of a positive screening during triage or routine monitoring. Therefore, in comparison to routine monitoring programmes, the time of intake is usually much better known and additional information may be available, which helps to reduce the uncertainty of assessment.

When a special monitoring programme is put in place, measurements are usually repeated and extended with different types of bioassay measurements. As a result, more measurement data from different types of monitoring are usually available.

The purposes of dose assessment in such cases include assisting decisions about follow-up actions (e.g. decorporation therapy), compliance with legal regulations and aiding decisions for the improvement of conditions in the workplace.

In most cases, special monitoring programmes are performed for a particular individual. In cases where there is reason to suspect that dose limits could be exceeded, assessment of absorbed doses to organs for that individual may be required, rather than a reference calculation of effective dose or equivalent doses to organs. It may then be appropriate to extend the measurements in order to derive individual retention and excretion functions and individual-specific biokinetic model parameters.

This section addresses the procedure of retrospective dose assessment after having setting up the monitoring programme (**Chapter C**) and having collected the results of the bioassay measurements (**Chapter D**).

## Dose Assessment for Special Monitoring Cases

***Q10**: How should dose assessments after special monitoring be performed in practice?*

***Q11**: How does the recommended approach for special monitoring compare with the ISO 27048:2011 and the IDEAS Guidelines?*

It is recommended that the methodology described in ISO 27048:2011 [ISO 2011] should be used for special monitoring cases where it can be concluded that the annual dose limit would not be exceeded. ISO 27048:2011 employs a highly standardised method and presents the minimum requirements for the evaluation of data from an internal monitoring programme to determine committed effective dose.

The statement made in ISO 27048:2011 that a more sophisticated analysis must be applied when the dose assessment indicates that the annual dose limit could *potentially* be exceeded also applies to special monitoring. ISO 27048:2011 further states that this analysis must be performed by experts, and references the IDEAS Guidelines as a source document. It is recommended here that this more sophisticated analysis should follow the IDEAS Guidelines [EURADOS 2013].

**Table E.2** Summary of ISO 27048:2011 procedure for Special Monitoring

| Step | Indication | Action or test | If test is verified | If test is NOT verified |
|---|---|---|---|---|
| 1 | Check if an intake via wound, intact skin or influenced by decorporation therapy can be ruled out | Test is based on preliminary information. | Go to Step 2 | Go to IDEAS-Guidelines, Stage 4 and follow wound route, or go to expert evaluation. |
| 2 | Check if the measured value is significant | Check if the measured value exceeds the decision threshold. | Go to Step 3 | Document the measurement. No further dose assessment is needed. |
| 3 | Standard dose assessment | Perform standard dose assessment with default parameter values (time of intake is usually known). | Go to Step 4 | |
| 4 | Check if the 97.5% confidence level of the evaluated committed effective dose E(50) is greater than 5% of annual dose limit | Check if $E(50) > 1/SF^2$ mSv | Go to Step 5 | Document the intake and the related committed effective dose. |
| 5 | Confirm assumption and findings related to exposure scenario | Add additional special monitoring measurements. | Go to Step 6 | |
| 6 | Check if the evaluated dose *potentially* exceeds the annual dose limit | Plot the measurement values on the band figures of Annex A of ISO 27048:2011, to check whether the annual dose limit may be potentially exceeded. | Go to IDEAS Guidelines - Stage 4 | Document the intake, the related committed effective dose and the model parameter values. |

The recommendation made here to follow the ISO 27048:2011 method should be adopted by newly established dosimetry services and by services that have not yet

adopted a systematic approach. Use of the IDEAS Guidelines for cases where it can be concluded that the annual dose limit would not be exceeded is not excluded by these recommendations.

The six-step procedure for interpreting single monitoring results is described in the right hand side of the principal flow chart of Figure E.1 and is summarised in Table E.2. Steps 7 and 8 of the procedure for routine monitoring (Figure E.1) relate to acquisition and application of case-specific information and so are not relevant for special monitoring because the available case-specific information has usually already been obtained.

The time schedule for a special monitoring dose assessment is usually more stringent than that for routine monitoring. Given the need to achieve an estimate of the intake and the committed dose as soon as possible, the measurements and activities related to a special monitoring dose assessment are usually carried out according to a shorter timescale. In particular it should be possible to perform the assessment of dose "in real time", i.e. as soon as the results of the bioassay measurements become available. It should be expected that the assessed dose will need to be updated as new bioassay results become available.

Instructions for following the procedure after having performed the first monitoring measurement are as follows (Table E.2):

- STEP 1: Check if an intake via wound or skin, or influenced by decorporation therapy, can be ruled out
  This test is based on preliminary information that may be provided by the Radiation Protection Expert or the Occupational Health Service of the site operator, with regard to the actual mode and progress of the accident and the follow-up actions performed, e.g. the start of chelation therapy.
  If an intake via wound or skin, or influenced by decorporation therapy, cannot be ruled out, all the other steps should be by-passed and an analysis performed by experts. It is recommended here that this more sophisticated analysis should follow the IDEAS Guidelines [EURADOS 2013]. This should be performed, in a first attempt, by following the guidelines related to wound dose assessment (IDEAS Guidelines, Chapter 11, Stage 8), or by following the guidelines on how to treat data influenced by chelation therapy (IDEAS Guidelines, Chapter 6, section 6.4, "Influence of decorporation therapy"). [See also **Section E5**].

- STEP 2: Check if the measured value is significant
  In this step, the measured value *M* is considered to be significant if it exceeds the decision threshold of the measurement method (see ISO 28218:2010).
  If the value is not significant, document that the measurement was performed. No further dose assessment is needed. The evaluation then ends.
  If the measurement is significant, test the significance of earlier intake contributions.
  For outside workers, arrangements should be established for appropriate data exchange (mainly relating to previous already-known and documented intake(s)) by the parties involved (mainly the employer and the internal dosimetry service), in order to correctly calculate the contribution(s) from earlier intake(s) to the measured value (see **Chapter C**).

- STEP 3: Standard dose assessment

  A standard evaluation of intake and committed effective dose is performed using equations B.9 and B.11 or B.12, using all available information on:
  - Actual intake route; pure inhalation should be assumed as a default unless there is clear evidence for pure ingestion (i.e. there is evidence that is well-established and documented);
  - Best estimate of the time (or time interval) of intake;
  - Any information related to the material to which the worker was exposed: chemical composition, AMAD, radioisotope composition of

elements, presence of other radionuclides and their relative isotopic percentages in the mixture.

Values for bioassay functions, *m(t)*, to be applied are reported in Annex C of ISO 27048:2011. Dose coefficients for an AMAD of 5 μm are reported in ICRP Publication 78 [ICRP 1997] and are available as a CD-ROM [ICRP CD]. Publication 119 [ICRP 2012] presents a compilation of all dose coefficients for occupational intakes of radionuclides derived using the ICRP Publication 60 recommendations.

The ICRP database that will be made available in conjunction with the OIR report series [ICRP 2015b] will provide the reference database for *m(t)*, *e(50)* and *z(t)* values to be used for intake and dose estimation when the OIR report series is adopted.

Provision is made in ISO 27048:2011 for exposure to a mixture of radionuclides, and the method of summation of the contribution to total dose from the different radionuclides is described.

- STEP 4: Criterion for accepting the standard dose assessment

  In the event of a single measurement, following ISO 27048:2011, there is no need for further evaluation if the 97.5% confidence level of the calculated committed effective dose *E(50)* is less than 5% of the annual dose limit (i.e. 1 mSv), where the confidence level is determined by considering measurement uncertainties alone and *SF* is the total scattering factor of the measurement used to perform the dose calculation.

  Therefore there is no need for further evaluation if, for the evaluated *E(50)*, the following relation is valid:

  $$E(50) \cdot SF^2 < 0.05 \cdot E_{\text{limit}} \qquad \text{(Eq. E.6)}$$

  where

  | | |
  |---|---|
  | *SF* | total scattering factor related to the measured value |
  | *E(50)* | committed effective dose calculated in Step 3 corresponding to the measured value |
  | $E_{\text{limit}}$ | annual dose limit of 20 mSv. |

  The relationship therefore becomes:

  $$E(50) < \frac{1}{SF^2}\,(mSv) \qquad \text{(Eq. E.7)}$$

  Considering all uncertainties, if the condition of the inequality is fulfilled, there is a reasonable certainty that the expected dose from the event, which determines the implementation of special monitoring, will remain below 1 mSv.

  If $E(50) \cdot SF^2$ in Eq. E.6 is less than 1 mSv, the measurement, the dose assessment procedure including the assumptions adopted, the evaluated intake and the corresponding committed effective dose should be documented, following the requirements specified in sections 7.1.4 and 10 of ISO 27048:2011. The evaluation then ends.

  Otherwise, if $E(50) \cdot SF^2$ in Eq. E.6 is greater than 1 mSv, proceed to the next step.

- STEP 5: Confirm assumptions by additional measurements

  It is recommended to confirm the assumptions/findings already adopted when the single measurement was interpreted, by performing further special monitoring measurements. For example, the same type of measurement could be repeated at short intervals, and/or different type(s) of measurements could be performed.

  After an incident, additional bioassay measurements are usually required to confirm the contamination scenario. The number of measurements required to confirm an unexpected exposure should be evaluated on the basis of the assessed dose *E(50)* using Tables C.6 and C.7 of **Chapter C**.

- STEP 6: Comparison with dose limits: to check if the annual dose limit may *potentially* be exceeded

  As discussed for routine monitoring, the procedure is aimed at performing a quick test to evaluate the possibility that the annual dose limit may potentially

be exceeded, providing a "Yes" or "No" answer. The graphs of Annex A of ISO 27048:2011 can also be used in the case of special monitoring, even though they are intended for the interpretation of a single monitoring measurement, as it is easy to extend the procedure to the case in which more measurements are available and the times of intake are known, as is usually the case [ISO 2011] for special monitoring. If the number of measurements is less than 20 and a single measurement, at time *t*, lies above *A*(t)*, the possibility that the annual dose limit may *potentially* be exceeded cannot be excluded. If the number of measurements is greater or equal to 20 and at least 95% of the measurements $M_i$, at different times $t_i$ , are less than their respective values $A^*(t_i)$, then *E(50)* may be judged to be less than the annual dose limit (see section 7.1.6 of ISO 27048:2011).

For those radionuclides or monitoring methods for which graphs are not presented in Annex A of [ISO 2011], the measured bioassay quantity *M* should be compared to the derived investigation level, as defined in ISO 20553:2006.

Each measured value $M_i$, performed at time $t_i$, is therefore compared with the lower level of the derived investigation level, $DIL_{minSM}(i)$, determined using Eq. E.8. In this equation the measurement uncertainty is taken into account by means of the specific $SF_i$ value:

$$DIL_{minSM}(i) = \frac{0.02}{e(50)} \cdot 0.3 \cdot m(t_i) \cdot \frac{1}{SF_i^2} \qquad \text{(Eq. E.8)}$$

where, as in Eq. E.5, the value of 0.02 is the annual dose limit in Sv $y^{-1}$ and the investigation level is 30% of the dose limit. The values of *e(50)* and $m(t_i)$ to be used in Eq. E.8 are those related to the default absorption Type associated with the chemical form of the radionuclide.

If at least 95% of the measurements $M_i$ are less than $DIL_{minSM}(i)$, *E(50)* can be judged to be less than the dose limit, otherwise the possibility that the dose limit is exceeded cannot be excluded.

If the annual dose limit is not exceeded and when multiple measurements are available, the calculation of the intake and the relative committed effective dose should be performed following sections 9.1 or 9.2 of ISO 27048:2011 using all available measurements simultaneously.

In this case, the intake may be evaluated using Eq. E.9:

$$\ln(I) = \frac{\sum_k \left( \sum_{i_k=1}^{n_k} \frac{\ln(I_{i_k})}{(\ln(SF_{i_k}))^2} \right)}{\sum_k \left( \sum_{i_k=1}^{n_k} \frac{1}{(\ln(SF_{i_k}))^2} \right)} \qquad \text{(Eq. E.9)}$$

where

| | |
|---|---|
| $k$ | index identifying the type of measurement (urine, faeces, whole body, lung…) |
| $n_k$ | number of measurements of type $k$ |
| $i_k$ | index of the i-th measurement of type $k$ |
| $SF_{ik}$ | total scattering factor associated with the i-th measurement of type $k$ |
| $I_{ik} = \frac{M_{ik}}{m_k(t_i))}$ | estimate of intake from the bioassay type $k$ at time $t_i$ |
| $M_{ik}$ | measurement for the bioassay type $k$ at time $t_i$ |
| $m_k(t_i)$ | retention/excretion function for the same bioassay type and time. |

Section 9.2 of ISO 27048:2011 addresses the case where some of the measurements are below the decision threshold.

The value of E(50) can be calculated from the evaluated intake and the corresponding dose coefficient. It is essential that the assumptions used for

selecting the m(t) values (e.g. the AMAD value, absorption Type etc.) are the same as those used to select the dose coefficient.
To test if the fit is inadequate and therefore rejected, or to confirm the consistency of the assumed biokinetic model and scenario of exposure with the observed measurement results, an "observed chi-squared value", $\chi_0^2$, should be calculated and the procedure described in Section 6.3 of the IDEAS Guidelines should be applied [EURADOS 2013]. In the case of multiple datasets of different types, Eq. E.10 should be used:

$$\chi_0^2 = \sum_k \left( \sum_{i_k=1}^{n_k} \left( \frac{\ln\left(M_{i_k}\right) - \ln\left(I \cdot m_k\left(t_i\right)\right)}{\ln\left(SF_{i_k}\right)} \right)^2 \right) \qquad \text{(Eq. E.10)}$$

where the notation is the same as for Eq. E.9.
The use of the maximum likelihood evaluation method with "below detection limit" values to evaluate the goodness of fit is described in section 14.2.2 of the IDEAS Guidelines.
If the fit is rejected by the indicated criteria, it is recommended to follow the recommendations of the IDEAS Guidelines.
If the analysis indicates that the annual dose limit may *potentially* be exceeded, it is recommended here that a more sophisticated analysis should be performed with the help of an expert. It is recommended that this more sophisticated analysis should follow the IDEAS Guidelines. In such cases the minimum number of measurements required is given in the columns of Tables C.6 and C.7 for E > 1 mSv.

As in routine monitoring cases, it is recommended that the assessment should continue at Stage 4 of the IDEAS Guidelines. In this Stage, a decision is made on the route of intake (pure inhalation, pure ingestion, both inhalation and ingestion or via a wound).

Stage 5 of the IDEAS Guidelines should be followed for pure inhalation cases (Chapter 8 of [EURADOS 2013]). Where the possibility of ingestion with simultaneous inhalation cannot be ruled out, a mixed path of intake should be assumed. In this case, Stage 7 of the IDEAS Guidelines (Chapter 10) should be followed. In cases in which there is strong evidence of pure ingestion, Stage 6 of the IDEAS Guidelines (Chapter 9) should be followed. In the case of a contaminated wound, Stage 8 of the IDEAS Guidelines (Chapter 11) should be followed. The IDEAS Guidelines provide a useful tool for dose assessment in the event that wound intake cannot be ruled out or if decorporation therapy has been used. In particular, Chapter 11 of [EURADOS 2013] provides a step-by-step procedure on how to treat wound intakes. In the case of decorporation therapy, section 6.4 of [EURADOS 2013] gives advice on how to treat the data.

The structure of Stages 5, 6, 7 and 8 has been already addressed in **Section E2**.

In the event that assessed doses are above 6 mSv, committed effective dose (and committed equivalent doses to organs if required by national regulations) should be calculated with the same model parameter values that were used for the assessment of the intake, i.e. the ICRP default dose coefficients should not be used.

## Use of dedicated software tools

***Q12**: When selecting dose assessment software, what are the desired capabilities that should be taken into consideration?*

Computational software tools for internal dose assessment (both home-made and commercially-developed) are available.

These software tools can calculate bioassay functions and dose coefficients, and can perform mathematical data fitting to evaluate intake and committed effective dose.

Bioassay functions are calculated by solving first order differential equations that implement the biokinetic models. Dose coefficients are calculated using a database of specific absorbed fraction (SAF) values [Cristy 1987] or radiation-weighted S coefficients [Bolch 2009; ICRP 2015b; ICRP 2016a], together with the total number of transformations in each organ or tissue calculated using the biokinetic models.

Intake may be assessed from multiple bioassay monitoring data obtained using different methods (whole body, chest, urine, faeces, etc) by applying mathematical data fitting to obtain the best agreement between model predictions and bioassay monitoring results. Committed effective doses can then be evaluated by using the appropriate dose coefficient.

Some software tools contain, embedded as a database, the retention/excretion functions and the dose coefficients determined using the reference ICRP models. Others perform the calculation of the bioassay functions and the dose coefficients directly, and can then perform intake fitting and subsequent dose assessment without using default ICRP dose coefficients.

Ansoborlo et al. [Ansoborlo 2003] presented a review of the codes available at that time, following tests of the codes with three intake scenarios. The capabilities of the different codes were described, ranking the capabilities with different levels of importance. Minor criteria are related to the ease of use while the other criteria, indicated as Major, characterise the specific capabilities of the software.

During the IDEAS-IAEA 2005 Intercomparison Exercise on Dose Assessment [Hurtgen 2005; IAEA 2007] different codes were used by participants to implement the procedure, already drafted, of the IDEAS Guidelines. A list of software used is reported for each case study in Annex II of [IAEA 2007].

A review of software was subsequently performed by the French Occupational Health Medicine Society in their Good Practice Recommendations [SFMT 2011], where the different software tools were briefly presented. The desired capabilities of software tools were also classified according to different levels of importance: indispensable, preferable and optional.

On the basis of the work of the French Occupational Health Medicine Society and taking into account the recommendations for internal dose assessment presented in this report, it is here recommended to use those software tools that have the capability to implement both the ISO 27048:2011 approach and the IDEAS Guidelines. As a result, an ability to use the total SF (i.e. $SF_A$ and $SF_B$) for each measurement is an essential capability. It is also advisable to have the capability to calculate the observed chi-squared value (Eq. E.10) and to provide an indication on the rejection of the fit.

In the context of these Technical Recommendations, it is recommended to consider as **essential** for the choice of the software all the capabilities indicated as such in Table E.3.

Quality assurance of commercially available software should be performed as part of the accreditation procedures for internal monitoring services (see **Chapter G**).

***Q13**: What issues should be considered when using dedicated software?*

Software tools may be divided into two main types:

- Software suitable for assessing intake and dose values using ICRP default assumptions and model parameter values (i.e. by selecting one of the fixed values of AMAD, and choosing between the default absorption Types F, M or S or the specific-material absorption parameter values provided in the OIR report series).
- Software suitable for assessing intake and dose values using non-default assumptions and material-specific or site-specific model parameter values, or software suitable for varying parameter values from their default values to optimise the agreement (i.e. to "improve the fit") between model predictions and bioassay data.

In the case of routine monitoring, a software tool using ICRP default assumptions and values should permit implementation of Steps 1 to 3 of the ISO 27048:2011 procedure, allowing recursive assessment of data, while allowing for manual use of the graphical data in Annex A of ISO 27048:2011 (Step 6). In particular, the calculation of the contribution of previous, already assessed, intake(s) (*P*) (see Step 2, section 7.1.2.1 of ISO 27048:2011) is made on the basis of reference ICRP models and default parameter values. Comparison between the measured value *M* and the *P* value (taking *SF* into account) should be possible using this software (see Step 2, section 7.1.2.2 of ISO 27048:2011). The standard evaluation (see Step 3, section 7.1.3 of ISO 27048:2011) requires only the selection of default parameters.

The second type of software is required for the implementation of Step 7 of the ISO 27048:2011 procedure, in which case-specific information is applied. In the application of such software, the need to remain consistent with other ICRP default assumptions and to maintain the use of retention/excretion data accepted by competent authorities and documented to be compatible with ICRP models should be ensured.

The use of software that permits simultaneous evaluation of bioassay data from several monitoring methods is preferred. In this context, the implementation of Eq. E.9 for the evaluation of the intake and of Eq. E.10 for the calculation of the observed chi-squared value when multiple datasets are available, is of primary importance.

**Table E.3** Recommended capabilities of the software tools and relative importance

| Capability | Judgment |
|---|---|
| Implementation of up-to-date ICRP models<br>Ability to implement the ISO 27048:2011 assessment approach and the IDEAS Guidelines<br>Treatment of intake routes: Inhalation, ingestion, mixed<br>Handling of monitoring data with their associated uncertainties (both Type A and B)<br>Effective dose assessment (via intake estimation or via dose per unit content approach)<br>Validation by means of internal dose assessment intercomparison exercises<br>Adaptation to state-of-the-art dosimetric tools (e.g. ICRP OIR publications) and to regulatory developments<br>Documentation in which all assumptions and parameter values adopted are explained | ESSENTIAL |
| Treatment of chronic, acute or mixed intake time patterns<br>Treatment of the wound intake route<br>Handling of large datasets<br>Use of data reported as below a detection limit<br>Intake assessment (if required by national legislation)<br>Evaluation of committed equivalent doses to each organ in the body<br>Use of workplace-specific data<br>Ease of use | ADVISABLE |
| Traceability in the medical file<br>Handling of data influenced by medical treatment<br>Assessment of absorbed dose to organs (if deterministic health effect evaluation is needed) | OPTIONAL |

## Dose Assessment for Nuclear Medicine Staff exposed to short-lived Radionuclides as Unsealed Sources

The recommendations presented here on the topic of the monitoring of internal exposure of nuclear medicine staff exposed to medical radionuclides as unsealed sources are based on ISO 16637:2016 [ISO 2016b].

Individual routine monitoring may not be feasible for radionuclides with a half-life shorter than that of $^{131}$I (i.e. 8 days). In this case, when the likely annual dose is above 1 mSv, implementation of triage monitoring in the nuclear medicine department is one option (see **Chapter C**). Triage monitoring programmes rely on frequent

individual screening measurements performed in the workplace by local staff using standard laboratory instrumentation to detect whether potential intakes have occurred. In contrast to *in vivo* or *in vitro* measurements performed within a routine monitoring programme, screening measurements do not allow determination of doses but they are adequate to verify that a given threshold is not exceeded. If the screening threshold is exceeded, *in vivo* or *in vitro* measurements should be performed in order to confirm internal contamination and to quantify the intake for the subsequent dose assessment.

# E4 - Monitoring and Dosimetry for Cutaneous and Wound Cases

***Issues addressed by section E4***

***CONTAMINATED INTACT SKIN***

***MAIN QUESTION***

***Q14*** *Which dose should be estimated in the event of contamination of the intact skin?*

***Subsidiary questions***

***Q15*** *How should the equivalent dose to the skin be assessed after intact skin contamination?*

***WOUNDS***

***MAIN QUESTION***

***Q16*** *Which doses should be estimated in case of contaminated wounds?*

***Subsidiary questions***

***Q17*** *What relevant exposure indicators may be used to define the initial assessment following exposure via a wound?*

***Q18*** *How should the special case of a contaminated wound be treated?*

## Special Terms used in this Section

Intact skin, Wound, Local doses, Decontamination.

## Introduction

National legislation provides basic rules and regulations to lessen and prevent the absorption of radioactive materials into the body through absorption or passage through the skin. Basic guidelines include the use of gloves and laboratory coats to prevent skin absorption. In occupational scenarios, two types of personal contamination can occur: contamination of the intact skin, or contamination after an incident resulting in a wound. Special procedures, monitoring programmes and dose assessments should be implemented for these cases depending on the circumstances of the event. **Section E4** presents generic tools and recommendations.

## Monitoring and Dosimetry for Cutaneous Contamination on Intact Skin

### General Considerations

Intact skin is a barrier against entry of substances into the body. Generally radionuclides do not cross the intact skin to any significant extent, but a few elements may be transferred rapidly. There is no general model of entry of radionuclides through the intact skin because of the large variability of situations that may occur. Contamination of the skin leads to external exposure and sometimes even to internal exposure, depending on the radionuclide(s) involved, the chemical form(s) present and the activity concentration.

The use of routine hygienic measures such as wearing gloves and a laboratory coat will limit skin contamination.

### Monitoring of Skin Contamination

***Q14**: Which dose should be estimated in the event of contamination of the intact skin?*

Contamination on the skin can result in an intake of the radionuclide into the body. The most important factors to be taken into account are the physical and chemical form of the compound, the location and the surface of the contaminated area, and the physiological state of the skin. These factors are especially important for contamination by tritium, iodine, caesium and some organic compounds. The most important example of significant transfer is tritiated water (HTO); ICRP estimates that absorption through the skin contributes approximately one-third of the total HTO intake for an atmospheric exposure [ICRP 1994a].

Exposure indicators are based on radiation measurements on the skin made using monitors or local detectors at the exit of a controlled area. To evaluate the contribution of skin contamination to the skin dose, an on-site contamination investigation should be performed to identify, localise and quantify the contamination [Covens 2013].

Therefore, for radionuclides for which contamination is directly measurable, a level of skin contamination should be defined above which a special monitoring programme is required [ISO 2016c]. The type of contamination monitor required is discussed in IEC standards 60325 and 61098 [IEC 2002; 2003]. The calibration of surface contamination monitors is discussed in the ISO 7503 series [ISO 1988a; 1988b; 1998].

### Decontamination Processes

The objectives of skin decontamination are to remove the contaminant as soon and as effectively as possible by washing with water in association with decontaminating products, while preserving the integrity of the skin. As the skin is not an absolute barrier, some substances may pass through it. Medical management of people with external contamination requires particular attention in order to prevent the spread of contamination, limit intakes, and reduce external exposure [Bérard 2010].

### Skin Dose Assessments

***Q15**: How should the equivalent dose to the skin be assessed after intact skin contamination?*

ICRU and ICRP have defined $H_{Skin}$ as the equivalent dose to the skin on a surface of 1 cm² and at a 0.07 mm nominal depth [ICRP 2010b; ICRU 1997]. The sensitive basal cells of the skin for stochastic effects are considered to be between 0.02 and 0.1 mm below the skin surface, and therefore 0.07 mm is used to estimate the equivalent dose to small areas of the skin. To assess this skin dose, the activity spread over the skin, the contaminated skin area, and the contamination duration *(t)* should be determined, in addition to the composition of the radionuclides involved. Since the contamination is generally distributed non-uniformly over the skin, and the skin dose limits are defined

taking into account the value the highest local skin dose, the activity must be determined at the location of the highest level of contamination.

In the case of skin surface contamination, the skin dose, $H_{skin}$, is calculated using the formula E.11 defined in ISO 15382:2016 [ISO 2016c]:

$$H_{skin} = A_{F,0} \cdot I_C \cdot \lambda^{-1} \cdot (1 - e^{-\lambda t}) \qquad \text{(Eq. E.11)}$$

where

$\lambda = \frac{\ln(2)}{T_{1/2}}$ radioactive decay constant of the radionuclide ($d^{-1}$)

$T_{1/2}$ half-life of the radionuclide (d)

$A_{F,0}$ activity per unit area at the beginning of the contamination event (Bq $cm^{-2}$)

$I_C$ equivalent dose rate factor (μSv (h Bq $cm^{-2}$)$^{-1}$).

If the half-life is very long compared to the contamination period, it is not necessary to take into account any diminution of contamination due to radioactive decay, and the formula above can be reduced to:

$$H_{skin} = A_{F,0} \cdot I_C \cdot t \qquad \text{(Eq. E.12)}$$

Tables of $I_C$ values for the most frequently encountered radionuclides are given in ISO 15382:2016 [ISO 2016c] and in NCRP Publication 156 [NCRP 2007]. The equivalent dose limit for the skin of 500 mSv in a year applies to the average dose over 1 $cm^2$ of the most highly contaminated area of the skin, regardless of the area actually exposed [EC 2013].

### Summary

Skin monitoring should be considered in workplaces where skin can become contaminated, for instance in the handling of unsealed sources. In cases of external contamination, the Occupational Health Service or the Radiation Protection Expert should use a standardised method based on repeated measurements made using appropriate probes after each decontamination action. To be sure that no absorption takes place, a special monitoring programme using *in vivo* or *in vitro* measurements should be initiated. Where quantitative results of bioassay measurements are obtained, both the equivalent dose to the area of skin contaminated and the committed effective dose should be assessed.

The steps for monitoring cutaneous contamination on intact skin should be:

1. Detect and quantify the highest contamination on the surface of the skin over an area of 1 $cm^2$;
2. Conduct the decontamination (start, end);
3. Determine its effectiveness;
4. Assess the equivalent dose to the skin;
5. In the event that absorption is found to have taken place, evaluate the corresponding committed effective dose or equivalent dose to the target organs using the approach recommended below for wound contamination cases.

## Monitoring and Dosimetry for Wound Cases

Wound events are variable in their nature. They can be cuts, grazes or puncture wounds. They may allow radioactive material to penetrate the subcutaneous tissue and then infiltrate into the rest of the body. NCRP has developed a biokinetic model for radionuclide-contaminated wounds [NCRP 2007], described in **Annex I**. Special attention should be given to this route of intake. The medical management of wounds is case-specific.

## General Considerations

***Q16**: Which doses should be estimated in case of contaminated wounds?*

Medical treatment of injuries involving radioactive material takes precedence over radiological considerations. Emergency medical care should be administered immediately. Also, decontamination efforts should commence without delay to prevent uptake of soluble radionuclides into the blood.

Many radionuclides may be retained at the wound site. A soluble component may be transferred to the blood and hence to other organs and tissues of the body, while the insoluble component will be slowly translocated to regional lymphatic tissue or retained at the wound site.

## Monitoring of Wound Cases

***Q17**: What relevant exposure indicators may be used to define the initial assessment following exposure via a wound?*

The occupational physician in charge has to carry out medical examinations, to take decisions on surgical action and the therapeutic approach, to assess the level of detriment, to follow the removal of radionuclides from wounds and to give clearance for a return at work.

The relevant exposure indicators are the activity of the sharp object, the activity of the local radionuclide deposit, the residual local activity in case of surgical intervention and the activities of the dressings and compresses, together with the results of the other measurements described in Table E.4.

Depending on the radionuclides and the quantity of material, a medical examination and a special monitoring programme may be conducted, first to quantify the radionuclide activity at the site of the wound and second to assess the intake using *in vivo* or *in vitro* monitoring.

**Table E.4** Exposure indicators in the event of a wound, and levels of estimated risk of exposure defined as in [SFMT 2011]

| Exposure indicator | Source of data | Collection | Level by default |
|---|---|---|---|
| Activity measured in a sharp object | Radiation Protection Officer | Recommended | Significant |
| Measurements at the wound site | Occupational Health Service or Measurement Laboratory | | |
| Measurements on dressings and compresses supplemented by measurements on excised tissue (if surgery is performed) | | | |

| Measurement results | Level of estimated risk of exposure | | |
|---|---|---|---|
| | "negligible" | "intermediate" | "significant" |
| All measurements on the individual | < Detection Limit | - | > Detection Limit |
| All measurements on sharp object | < Detection Limit | - | > Detection Limit |

### Monitoring of local radionuclide activities around the wound site

***Q18**: How should the special case of a contaminated wound be treated?*

The activity of the radionuclide or the mixture of radionuclides at the site of the wound should be quantified, taking into account attenuation of the radiation by foreign matter and tissues in order to assess the dose to local tissues and to decide whether or not excision is required. If the decision is taken to attempt to remove the material from the wound, the activity removed and the activity remaining around the wound should be measured to obtain an activity balance.

### Monitoring of systemic uptake and retentions

Measurements should be made to determine the uptake of activity to the rest of the body. *In vivo* measurements and *in vitro* analyses should be performed. If *in vivo* measurements are made, the activity remaining around the wound may have to be shielded to avoid interference. To assess the committed effective dose, allowance should be made for the effect of any treatment administered to increase the excretion of systemic activity.

### Decontamination, surgical and decorporation processes

The use of interventional techniques such as decontamination, surgical intervention at the wound site, decorporation by enhancing excretion or blocking radionuclide uptake should be considered. Various therapeutic drugs can be administered, including diuretics, blocking or chelating agents. An IAEA Guide "Generic procedures for medical response during a nuclear or radiological emergency" provides advice for physicians on medical management in the event of wounds [IAEA 2005]. These techniques influence and modify the biokinetic behaviour of the incorporated radionuclides, and so their use requires special attention to be given to assessment of dose from the bioassay measurements.

### Local dose assessments

The absorbed dose at the wound site and in the regional lymph nodes can be assessed from the activity remaining after excision, radionuclide decay data for the radionuclides involved, the mass of tissue irradiated and the time since exposure [Piechowski 2004].

Radiochemical analysis of excised tissue can provide information on the radionuclides and their relative concentrations, and may assist in assessing the uptake to blood and in determining the course of further actions.

The assessment of dose resulting from a wound needs specific information about the time and location of intake, about the physicochemical form of the radionuclides and about the characteristics of the individual (e.g. body mass).

### Systemic dose assessments

For a skin wound, specific routes of intake should be considered. To a first order of magnitude, the assessment may be made assuming a direct injection into blood [SFMT 2011].

Depending on circumstances, a more precise wound model may be used, in which different assumptions about material characteristics may be made. For instance, the NCRP wound model defines several "categories" of materials – soluble, with low, moderate, strong or avid retention; colloids; particles and fragments. The IDEAS Guidelines [EURADOS 2013] advise to retain a default model category known a priori; Stage 8B considers the systematic search of a default wound category that best fits the excretion data, and considers a mixture of two default retention categories which fits the data. Relevant guidelines may be found in Chapter 11 of the IDEAS Guidelines.

Dose coefficients for incorporation through wounds have been calculated for at least 38 radionuclides using a wound model combined with systemic models used to calculate dose coefficients for workers [Ishigure 2003; Toohey 2011].

## Summary

Wounds should be treated on a case-by-case basis. An indication of the dose can be obtained by applying the ICRP injection model [SFMT 2011] and, for a more accurate assessment, by applying the most appropriate default NCRP wound category [EURADOS 2013]. Interpretation of the data necessitates various consistency comparisons between the available results and the calculated intake. Where quantitative results of bioassay measurements are obtained, both the absorbed dose and the committed effective dose should be quantified.

The recommended steps for monitoring wounds are:

1. Replication of the measurements of the activity retained at the wound site and assessment of the absorbed dose at the wound site.
2. Quantification of the activity in excised tissues.
3. Assessment of the activity transferred to the lymph nodes.
4. Quantification of the activity transferred to the blood and to the systemic circulation by means of *in vivo* measurements and *in vitro* analyses, and assessment of the committed effective dose.
5. Continued clinical monitoring to identify any local tissues detriment.

# E5 - Monitoring and Dose Assessment in the Event of Decorporation Therapy

***Issues addressed by section E5***

***MAIN QUESTION***

***Q19*** *How and why is decorporation therapy applied?*

***Subsidiary questions***

***Q20*** *What monitoring is required in the event of decorporation therapy?*

***Q21*** *How is dose assessed in the event of decorporation therapy?*

## Special Terms used in this Section

Decorporation Therapy, DTPA (diethylene triamine pentaacetic acid), Prussian Blue

## Introduction – Decorporation Therapy

**Section E5** discusses the influence of decorporation therapy on monitoring and dose assessment. However, guidance is not given on the advantages and disadvantages of decorporation therapy, or on medical issues such as dosage and treatment. For such guidance, the reader should refer to other sources, including [HPA 2010; IAEA 2005; Ménétrier 2005; NCRP 2008a; 2008b; 2010b; REAC/TS 2015].

***Q19:*** *How and why is decorporation therapy applied?*

Strictly speaking, decorporation therapy is used to remove or release a radionuclide from tissues and cells (and ultimately from the human body). In this report, all methods used to avert doses after intakes of radionuclides are considered as decorporation therapy. The therapies are conducted using pharmaceuticals that:

- form stable complexes (chelates) with the radionuclide, that are rapidly excreted; or
- reduce and/or inhibit the absorption of the radionuclide from the gastro-intestinal tract into the blood (the systemic circulation); or
- block the uptake to organs or blood.

Examples of the three techniques are:

- the use of salts of DTPA (diethylene triamine pentaacetic acid), for decorporation of actinides;
- the use of Prussian Blue (iron hexacyanoferrate, commercially available as Radiogardase®, [Radiogardase® 2008]), to block absorption of caesium from the gastro-intestinal tract; and
- the use of potassium iodide (stable iodine), to block thyroid uptake of radioisotopes of iodine.

Several decorporation agents have been in use since the 1950s but only a few, such as Prussian Blue and DTPA, have been officially approved as drugs [FDA 2015; ANSM 2015]. The main aim of the different decorporation techniques is the reduction of the resulting committed dose to the individual. Since the application of these pharmaceuticals (purposely) alters the biokinetic behaviour of the radionuclide, the

standard methods and procedures for monitoring and dose assessment cannot be applied in a straightforward way.

The application of decorporation therapy must be balanced against the toxicological risks imposed by the drugs used. Therefore, decorporation is mainly applied in cases where significant doses are expected, such as significant wound contamination events. Another scenario in which decorporation therapy could be applied is after malevolent use of radionuclides (e.g. after explosion of a "dirty bomb") or large scale accidents in nuclear installations. The latter scenarios, which have very different implications, are not considered in this report.

## Monitoring and Dose Assessment in the Event of Decorporation Therapy

***Q20:*** *What monitoring is required in the event of decorporation therapy?*

Decorporation therapies are applied after known accidents, and so there are no general rules for monitoring in these cases and special monitoring programmes, which need to be case-specific, should be applied [ISO 2006]. Information for dose assessment needs to be collected, and the effect and the efficacy of the therapy should be evaluated. The techniques (e.g. *in vivo* monitoring or sample bioassay) to be applied are the same as for cases without therapy. The monitoring scheme, i.e. the number and timing of the measurements or samples, should be adapted to the situation.

For example, in the case of DTPA therapy after a plutonium intake, faecal analyses and urinalysis of 24-hour samples should be performed. The effect of DTPA therapy is an enhancement of the urinary excretion after administration, and the urine collection periods should be aligned to the DTPA administrations, i.e. the monitoring should be conducted on the days before and after each administration [Ménétrier 2005], except before the first administration which should be performed as soon as possible after intake for best efficiency of the treatment. The results of the monitoring conducted in combination with the DTPA administrations ("aligned" data) allow estimation of an enhancement factor that describes the increase in urinary excretion.

To establish baseline excretion values (i.e. in the absence of decorporation), it is preferable to have bioassay measurements that are not influenced by the therapy, i.e. measurements before the start of the therapy or at least 3 weeks after the last treatment [SFMT 2011]. Bioassay investigations may need to continue for a long period, and the need for continuing investigation should be assessed on a case-by-case basis.

***Q21:*** *How is dose assessed in the event of decorporation therapy?*

Decorporation therapy cases require expert assessment – following ISO 27048:2011 [ISO 2011] terminology – because reference models cannot be applied due to the altered biokinetic behaviour of the radionuclide. Unfortunately no generic biokinetic models yet include the effect of decorporation therapy, and so no excretion or retention functions that could be used for intake or dose assessment are available. If it is possible to establish bioassay functions that can be used to estimate altered parameter values, these parameter values could be used for the dose assessment.

The dose that is calculated taking into account the effect of any therapy should be used for the dose of record. The efficacy of the therapy should also be assessed, although this might not always be possible given the available data. The publication of the description of the dose assessment, its data and the interpretation/implications in a scientific journal should be considered as there is a need to increase the database of monitoring data and information on such cases.

### Dose Assessments after Administration of Prussian Blue or Stable Iodine

In the case of Prussian Blue therapy, individual effective half-lives for whole body retention of caesium isotopes could be determined and applied in the dose assessment [HPA 2010]. Alternatively the number of decays could be estimated by direct

(numerical) integration of the measured activity retention data, with an extrapolation covering the 50 year committed dose integration period after the intake. The result can then be multiplied by a radiation-weighted S-value [Bolch 2009] to estimate the dose. This approach can be applied if the radionuclide is assumed to be homogeneously distributed in the whole body (e.g. isotopes of caesium) or is mainly located in one organ which can be monitored (e.g. isotopes of iodine in the thyroid). Thus, this approach may also be applied to thyroid retention data after administration of stable iodine, which reduces the uptake of radioactive iodine in the thyroid [SFMT 2011]. However a large set of *in vivo* monitoring data is required to apply this approach. Data from excretion analysis are not suitable for this type of calculation because the influence of Prussian Blue or stable iodine on the biokinetic behaviour of the corresponding radionuclides cannot be taken into account by the reference models of ICRP. If available, excretion data may be used to assess the biological half-time of elimination (clearance) of the radionuclide, to confirm the results of the *in vivo* measurements and/or reduce the uncertainties on the derived parameter values.

## Dose Assessments after administration of DTPA

In the case of DTPA therapy, one simple option for dose assessment is to exclude data affected by the therapy from the fitting procedure, using only the "late data" (i.e. monitoring data which have been measured after the effect of the therapy has vanished). The IDEAS Guidelines [EURADOS 2013] make a recommendation based on [Jech 1972] to use only data collected later than 20 days after the end of therapy. A baseline excretion may then be established that corresponds to an "apparent intake", which is equivalent to the real intake minus the activity removed by the therapy. ICRP biokinetic and dosimetric models could be applied to calculate the apparent intake and subsequently the dose. In this approach, it is assumed that the biokinetics of the plutonium that was not chelated is unaffected by the treatment and that the dose from the chelated plutonium is insignificant. It should be kept in mind that the biokinetic behaviour will have been altered by the therapy and that the estimates of absorbed dose to organs and tissues may be biased. Strictly speaking, the reference dose coefficient is therefore not applicable. However, it may be used to obtain an estimate of the resulting doses. The disadvantages of this "waiting" approach are that no dose information is available during and immediately after therapy, and the efficacy of the therapy is not evaluated.

In its recommendations, the French Society of Occupational Medicine [SFMT 2011] proposes – for dose assessment purposes – to divide the plutonium activity excreted in urine during the day following the DTPA treatment by a "DTPA action (or enhancement) factor". This factor represents the nominal increase of plutonium urinary excretion on the day of DTPA administration and is given a nominal value of 50, based on a review of contamination cases [Grappin 2007]. However, the true value of this factor is known to vary greatly among individuals and cases. This action factor is only valid if the DTPA administrations are separated by at least 2 days. The corrected urine excretion may be used for dose assessment using reference biokinetic models. If, at some point, the DTPA therapy is interrupted (e.g. because of the worker's vacation) for at least 20 days, the excretion is assumed to return to its undisturbed rate. Consequently, a new DTPA administration allows the estimation of an individual-specific value of the DTPA action (or "enhancement") factor by comparing excretion before and after DTPA administration. This individual-specific factor may be used subsequently in the dose evaluation for this individual.

An empirical model which describes the effect of the therapy by means of mathematical modifications of the resulting bioassay function is also available [Hall 1978]. According to this approach, the user can fit the model predictions to the monitoring data and thus estimate the apparent intake during the therapy. Biokinetic models that directly include the effect of DTPA administration are under development [Breustedt 2009; Fritsch 2010; Kastl 2014; Konzen 2015], but currently no "standard model" for the calculation of bioassay functions after therapy is available. Application of these models needs to be case-specific and requires expertise in biokinetic modelling.

The IDEAS Guidelines [EURADOS 2013] conclude:

> *It is difficult however to give any specific advice or formulation as the treatment of any excretion data will depend upon the circumstances of the exposure and the need and timescale for the dose assessment.*

Taking into consideration the fact that decorporation therapy always requires case-specific expert assessments, it is advisable to consult other experts in internal dosimetry in order to discuss the case and its interpretation, as well as to review published studies that are relevant to the case.

# E6 - Radiation Protection for Pregnant and Breastfeeding Workers

***Issues addressed by section E6***

***MAIN QUESTION***

***Q22*** *Is it necessary to change the working conditions if a worker is pregnant or breastfeeding?*

***Subsidiary questions***

***Q23*** *Which dose limits apply for the unborn child?*

***Q24*** *Is it necessary to change the monitoring programme if a worker becomes pregnant?*

***Q22:*** *Is it necessary to change the working conditions if a worker is pregnant or breastfeeding?*

The 2013 Directive [EC 2014] states in Article 10 (Protection of pregnant and breastfeeding workers):

> *1. Member States shall ensure that the protection of the unborn child is comparable with that provided for members of the public. As soon as a pregnant worker informs the undertaking or, in the case of an outside worker, the employer, of the pregnancy, in accordance with national legislation the undertaking, and the employer, shall ensure that the employment conditions for the pregnant worker are such that the equivalent dose to the unborn child is as low as reasonably achievable and unlikely to exceed 1 mSv during at least the remainder of the pregnancy.*
>
> *2. As soon as workers inform the undertaking, or in case of outside workers, the employer, that they are breastfeeding an infant, they shall not be employed in work involving a significant risk of intake of radionuclides or of bodily contamination.*

The IAEA Basic Safety Standards (BSS) [IAEA 2014] state in 3.114:

> *The employer of a female worker, who has been notified of her suspected pregnancy or that she is breast-feeding, shall adapt the working conditions in respect of occupational exposure so as to ensure that the embryo or fetus or the breastfed infant is afforded the same broad level of protection as is required for members of the public.*

For breastfeeding workers, the working conditions should be such that there is no significant risk of intake of radionuclides and so monitoring for intakes of radionuclides is not needed. However, for pregnant workers the situation is much more complicated.

The embryo and foetus receive a radiation dose not only from intakes by the mother during pregnancy but also from intakes by the mother before pregnancy, if the effective half-life of the radionuclides considered is not very short. For a chronic inhalation of $^{63}$Ni with a constant intake rate, for example, the committed effective dose to the offspring could be higher than the annual committed effective dose to the mother by about a factor of 3 [Noßke 2003].

ICRP, in its Publication 88 [ICRP 2001], developed biokinetic and dosimetric models for the assessment of doses to embryo and foetus due to activity intakes by the

mother. According to these models, the dose to the embryo (up to 8 weeks after conception) is considered to be identical to the uterus wall dose of the mother. After 8 weeks after conception, uptake of activity by the foetus and by the placenta is taken into account. Organ doses and effective dose (using the same tissue weighting factors as for children and adults) for the foetus are calculated for various acute and chronic intake scenarios, taking into account external radiation from maternal tissues and placenta and internal radiation from activity taken up by the foetus.

According to the 2013 Directive, the aim of radiation protection of the pregnant worker and her offspring is to ensure that the "equivalent dose" to the unborn child is unlikely to exceed 1 mSv, at least between the notification of the pregnancy and its end. Similarly, the IAEA BSS demands the same broad level of protection for embryo and foetus as is required for members of the public, i.e. a limitation of the effective dose to 1 mSv $y^{-1}$.

***Q23:*** *Which dose limits apply for the unborn child?*

The following questions highlight several issues for which there is currently no clear consensus:

- How is the (equivalent) dose to the foetus defined?
    - total body (equivalent) dose or effective dose?
    - committed (equivalent / effective) dose (integrated over which time period)?
    - does it include doses from intakes by the mother before pregnancy / before declaration of pregnancy?
- Which dose to the offspring gives the same broad level of protection as is required for members of the public?
    - 1 mSv from declaration until end of pregnancy
    - 1 mSv from conception to the end of pregnancy
    - 1 mSv from conception to 3 months after end of pregnancy (taking into account also the dose to the infant from ingestion of mother's milk)

To clarify these issues, IAEA planned to publish a Technical Report on Radiation Protection for Pregnant Workers and their Offspring [Cruz-Suárez 2007; 2011] under the framework of the International Action Plan for Occupational Radiation Protection. When preparing the IAEA report, it was concluded that the assessed dose for the offspring should be the effective external dose and the internal committed effective dose received from the time of conception to 3 months after birth (i.e. over a total time of 1 year) [Cruz-Suárez 2007]. This total dose should include contributions from exposures that have occurred prior to the declaration of pregnancy, those received during gestation and those received after birth, possibly including exposures due to intakes of radionuclides during breastfeeding.

***Q24:*** *Is it necessary to change the monitoring programme if a worker becomes pregnant?*

The proposed IAEA approach [Cruz-Suárez 2007] is taken as a basis for the recommendations made here. However, because the 2013 Directive states that there should be no activity intake by the mother during the breastfeeding period, it is sufficient to consider the dose to the embryo and foetus resulting from intakes by the mother before and during pregnancy only.

It is recommended to implement the following procedure:

- As soon as a worker becomes aware that she is pregnant, she should inform her employer about her pregnancy immediately.
- If a worker has informed her employer about her pregnancy, the employer should assess the dose to embryo and foetus resulting from previous

occupational intakes by the pregnant worker and external exposure so far during the pregnancy.

- Based on these results, a first dose level should be determined and applied for the rest of the pregnancy to ensure that the effective dose for the embryo and foetus for the whole period of pregnancy does not exceed 1 mSv.
- A second dose level should be established by subtracting from the first dose level an estimate of potential external doses after the declaration of pregnancy. This dose level should not be exceeded as a result of intakes by the mother during the remaining period of pregnancy.
- If necessary, the working conditions of the pregnant worker should be modified to meet this requirement.
- For monitoring for intakes of radionuclides, the monitoring programme may need to be modified (to take into account the need for monitoring of other radionuclides more relevant for foetal doses, and that monitoring intervals should not exceed one month during the remaining period of pregnancy).

# Recommendations for Chapter E

## E1 - Interpretation of Monitoring Data

| R# | G | Text of the recommendation |
|---|---|---|
| | | ***Q2**: What additional information and data is required in order to interpret individual monitoring data?* |
| E01 | A | To aid the interpretation of individual monitoring data, information should be collected on: the identity of radionuclide(s) to which workers are exposed, exposure locations, working practices, any exposure event, likely route of intake, whether exposure is likely to be continuous or discrete, time pattern of exposure, physical and chemical form of the radionuclide(s), use of PPE, any treatment with blocking or decorporation agents.<br>Judgements should be made on: (a) the extent of the information required and on (b) the effort expended on its examination. Interpretation of special monitoring requires more information and effort than routine monitoring, as do cases where the potential dose for an individual worker could approach or exceed the annual dose limit. This proviso also applies to recommendations E03 and E04. |
| | | ***Q3**: Where can this information be found?* |
| E02 | A | Arrangements should be made to allow collection of such information from sources within the workplace, from workplace monitoring, and on individual monitoring from within the dosimetry service. |
| | | ***Q4**: What information can workplace monitoring provide?* |
| E03 | A | Workplace monitoring data should be examined to provide additional information on the topics addressed in recommendation E01, as well as information on: contamination in the workplace, airborne particle size distribution, and (where appropriate) on potential exposures to parent radionuclides and their progeny, other associated radionuclides, isotopic ratios. |
| | | ***Q5**: How can the results of individual monitoring be used to guide and inform the formal dose assessment procedure?* |
| E04 | A | Individual monitoring data should be examined to provide additional information: nose blow/nasal swab data and personal air sampler data provide information on the likelihood of an inhalation exposure event, *in vivo* and sample bioassay monitoring data can provide information on the biokinetic behaviour of the radionuclide/element. |
| | | ***Q6**: How much emphasis should be placed on information derived from data fitting procedures on exposure conditions and material-specific model parameter values?* |
| E05 | A | Examination of the information addressed by E01, E03 and E04 should be performed in order to provide a better understanding of the exposure, and to aid and direct the formal dose assessment process. |
| | | ***Q7**: What are the issues that might prevent a straight-forward interpretation of individual monitoring data?* |
| E06 | A | Dose assessors should be aware of a number of confounding factors that can result in erroneous dose assessments: external contamination of the body, treatment with medical radioisotopes, contamination of bioassay samples, errors in the bioassay sample collection period, background radiation in *in vivo* monitoring, contribution to *in vivo* measured counts from activity in other organs, dietary intakes (for NORM materials), independent biokinetic behaviour of radioactive progeny used to monitor for intake of the parent, independent biokinetic behaviour of mixtures of radionuclides, radionuclides in an unusual physical or chemical form. |

## E2 - Dose Assessment and Interpretation: Routine Monitoring

| R# | G | Text of the recommendation |
|---|---|---|
| | | ***Q8**: How should dose assessments after routine monitoring be performed in practice?* |
| E07 | I | Newly established dosimetry services and services that have not yet adopted a systematic approach, are recommended to adopt the methodology for dose assessment after routine monitoring described in Section E2 [ISO 2011; EURADOS 2013]. The use of the IDEAS Guidelines by dosimetry services that have already adopted them as a reference methodology, irrespective of the assessed dose, is not excluded by these recommendations for cases where it can be concluded that the |

| R# | G | Text of the recommendation |
|---|---|---|
| | | annual dose limit would not be exceeded. |
| | | ***Q9**: How does the recommended approach for routine monitoring compare with the ISO 27048:2011 and the IDEAS Guidelines methodologies?* |
| E08 | I | The recommended approach comprises the ISO 27048:2011 approach (left side of Figure E.1 and Table E.1) [ISO 2011], and, when the analysis indicates that the annual dose limit may potentially be exceeded, the IDEAS Guidelines [EURADOS 2013]. |

## E3 - Dose Assessment and Interpretation: Special Monitoring

| R# | G | Text of the recommendation |
|---|---|---|
| | | ***Q10**: How should dose assessments after special monitoring be performed in practice?* |
| E09 | I | New established dosimetry services and services that have not yet adopted a systematic approach are recommended to adopt the methodology described in Section E3 for dose assessment after special monitoring [ISO 2011; EURADOS 2013]. The use of the IDEAS Guidelines, by dosimetry services that have already adopted them as a reference methodology, is not excluded by these recommendations, for cases where it can be concluded that the annual dose limit would not be exceeded. |
| | | ***Q11**: How does the recommended approach for special monitoring compare with the ISO 27048:2011 and the IDEAS Guidelines methodologies?* |
| E10 | I | The recommended approach comprises the ISO 27048:2011 approach (right side of Figure E.1 and Table E.2) [ISO 2011] and, when the analysis indicates that the annual dose limit may potentially be exceeded, the IDEAS Guidelines [EURADOS 2013]. |
| | | ***Q12**: When selecting dose assessment software, what are the desired capabilities that should be taken into consideration?* |
| E11 | A | In selecting dose assessment software tools, a graded approach following Tables E.3 should be applied: "ESSENTIAL" capabilities, which refer to the application of the ICRP reference models, ISO 27048:2011 and the IDEAS Guidelines, are recommended; consider giving preference to those software tools which implement the capabilities indicated as "ADVISABLE". |
| | | ***Q13**: What issues should be considered when using dedicated software?* |
| E12 | A | The standard type of software tool should allow the evaluation of intakes and doses using default ICRP models and parameter values, taking into account contributions of previous, already assessed intakes. For advanced types of software tool, use of non-default assumptions and material-specific or site-specific model parameter values should be included. |

## E4 - Monitoring and Dosimetry for Cutaneous and Wound Cases

| R# | G | Text of the recommendation |
|---|---|---|
| | | ***Q14**: Which dose should be estimated in the event of contamination of the intact skin?* |
| E13 | I | In the case of cutaneous contamination of intact skin, local equivalent dose for the skin ($H_{skin}$) should be assessed over any area of 1 cm² at 0.07 mm nominal depth, according to ISO 15382:2016. |
| | | ***Q15**: How should the equivalent dose to the skin be assessed after intact skin contamination?* |
| E14 | I | With repeated measurements by skin monitors or local detectors, the equations E.7 and E.8 and the tables of dose coefficients provided by ISO 15382:2016 and NCRP |

| R# | G | Text of the recommendation |
|---|---|---|
| | | Publication 156 should be used to evaluate $H_{skin}$. |
| E15 | I | A special monitoring programme should be implemented when a pre-defined reference level of cutaneous contamination on intact skin is exceeded. A combination of *in vivo* and *in vitro* measurements should be performed in order to assess the uptake in the body. |
| | | ***Q16**: Which doses should be estimated in case of contaminated wounds?* |
| E16 | M | In the case of wounds, both the equivalent dose to the area of wounded skin and the committed effective dose resulting from uptake from the wound site should be quantified. |
| | | ***Q17**: What relevant exposure indicators may be used to define the initial assessment following exposure via a wound?* |
| E17 | A | Wound cases should be treated on a case-by-case basis. Monitoring of the local activity around the wound site, the sharp object, dressings and compresses and excised tissue should be implemented to evaluate the equivalent dose to the area of wounded skin. |
| | | ***Q18**: How should the special case of a contaminated wound be treated?* |
| E18 | I | A special monitoring programme should be implemented for wound cases by a combination of *in vivo* and *in vitro* measurements in order to estimate the systemic uptake.<br>In order to evaluate the committed effective dose:<br>• to a first order of magnitude, the assessment should be made assuming a direct injection into blood [SFMT 2011; EURADOS 2013];<br>• depending on circumstances, a more precise wound model may be used. The excretion and retention functions of the NCRP Publication 156 wound model and dose coefficients for radionuclides using a wound model combined with systemic models [Ishigure 2003; Toohey 2011] could be used. |

## E5 - Monitoring and Dose Assessment in the Event of Decorporation Therapy

| R# | G | Text of the recommendation |
|---|---|---|
| | | ***Q19**: How and why is decorporation therapy applied?* |
| E19 | A | The application of decorporation therapy must be balanced against the (toxicological) risks imposed by the drugs used. In occupational contexts, decorporation therapy should only be applied in cases where significant doses are expected. |
| | | ***Q20**: What monitoring is required in the event of decorporation therapy?* |
| E20 | I | In the case of decorporation therapy, special monitoring should be performed. The special monitoring programme should be designed individually for the case considered [ISO 2006]. |
| E21 | A | The data provided by the monitoring should be sufficient for an assessment of the dose and if possible an evaluation of the efficacy of the therapy. |
| | | ***Q21**: How is dose assessed in the event of decorporation therapy?* |
| E22 | A | Dose assessments after decorporation therapy require an expert assessment and need to be case-specific. Consultation of experts in internal dosimetry for the discussion and interpretation of the case is considered helpful and recommended. Publication of the case, the data and its interpretation in a scientific journal should be considered. |
| E23 | A | In the case of administration of stable iodine, the assessment of dose resulting from exposure to radioactive iodine should be based on direct thyroid measurement rather than urine monitoring. For the dose assessment the data can be extrapolated to the 50 year commitment period, numerically integrated and then multiplied with radiation weighted S-coefficients. |
| E24 | A | In the case of Prussian Blue treatment after cesium exposure, the dose assessment should be based on direct whole body counting measurements. For the dose |

| R# | G | Text of the recommendation |
|---|---|---|
| | | assessment the data can be extrapolated to the 50 year commitment period, numerically integrated and then multiplied with radiation weighted S-coefficients. Alternatively modified biokinetic models can be applied, if the observed long-term retention period of the individual can be taken into account. |
| E25 | A | In the case of DTPA treatment, the plutonium intake may be estimated from urine measurements obtained more than 20 days after DTPA administration and/or from urine excretion measured on the day following DTPA administration after correction with a DTPA enhancement factor. This factor may be taken to have a nominal value of 50 or adjusted to an individual-specific value determined after a therapeutic window. The application of the enhancement factor is only valid if the DTPA administrations are separated at least by 2 days. |

## E6 - Radiation Protection for Pregnant and Breastfeeding Workers

| R# | G | Text of the recommendation |
|---|---|---|
| | | ***Q22**: Is it necessary to change the working conditions if a worker is pregnant or breastfeeding?* |
| E26 | M | As soon as a pregnant worker informs the undertaking or, in the case of an outside worker, the employer, of the pregnancy, in accordance with national legislation the undertaking, and the employer, must ensure that the employment conditions for the pregnant worker are such that the equivalent dose to the unborn child is as low as reasonably achievable and unlikely to exceed 1 mSv during at least the remainder of the pregnancy.<br>As soon as workers inform the undertaking, or in case of outside workers, the employer, that they are breastfeeding an infant, they must not be employed in work involving a significant risk of intake of radionuclides or of bodily contamination. [EC 2014] |
| | | ***Q23**: Which dose limits apply for the unborn child?* |
| E27 | M | Member States must ensure that the protection of the unborn child is comparable with that provided for members of the public [ISO 2006]. The equivalent dose to the unborn child must be as low as reasonably achievable and unlikely to exceed 1 mSv during at least the remainder of the pregnancy. [EC 2014] |
| E28 | A | The effective external dose and the internal committed effective dose received from the time of conception to 3 months after birth should not exceed 1 mSv. |
| | | ***Q24**: Is it necessary to change the monitoring programme if a worker becomes pregnant?* |
| E29 | A | The monitoring programme may need to be modified (to take into account the need for monitoring of other radionuclides more relevant for foetal doses, and that monitoring intervals should not exceed one month during the remaining period of pregnancy). |

G = Grade: M = Mandatory, I = International, A = Advisory

# Appendix to Chapter E

## Origins, structure and contents of the IDEAS Guidelines and ISO 27048:2011 methodologies for internal dose assessment

### Origin of the IDEAS Guidelines

The need for harmonisation of procedures for internal dose assessment has been pointed out since the Third European Intercomparison Exercise on internal dose assessment [Doerfel 2000].

During the 5th Framework Programme, a project was developed for the elaboration of guidelines for the assessment of internal dose. Eight European institutions, coordinated by Forschungszentrum Karlsruhe (FZK, now Karlsruhe Institute of Technology, KIT), produced the document known as the "IDEAS Guidelines" [Doerfel 2006].

In 2005 the EUropean RAdiation DOSimetry Group (EURADOS) initiated the CONRAD Project, "Coordinated Network for Radiation Dosimetry" funded by the European Commission (EC), within its 6th Framework Programme. Among other initiatives, CONRAD included a project to update and refine the IDEAS Guidelines [Lopez 2007].

Further improvements of the IDEAS Guidelines were performed by members of EURADOS Working Group 7 during 2008-2012. The outcome of the work is Version 2 of the IDEAS Guidelines, published as a EURADOS report [EURADOS 2013].

### Structure of the IDEAS Guidelines

The structure of the IDEAS Guidelines (in both its original and revised forms) is based on the application of the principles of harmonisation (i.e. by following the guidelines, any two assessors should obtain the same estimate of dose from a given dataset), accuracy (i.e. the best estimate of dose should be obtained from the available data set) and proportionality (i.e. the effort applied to the evaluation should be proportionate to the dose – the lower the dose, the simpler the process should be).

For the application of the third principle, a step-by-step approach was established for the usual routes of intake (inhalation, ingestion, mixture of both routes, and intake via a contaminated wound). Structured flow charts representing the different stages in the process comprising different steps in the evaluation are presented as well as explanations of the actions to be performed in each step.

The structure of the levels of dose assessment is as follows: Level 0 (doses below 0.1 mSv/y): no dosimetric evaluation is needed (Stage 1); Check on significance of new measurement and consistency of previous evaluation (Stage 2); Level 1 (doses in range 0.1 to 1 mSv): simple dose evaluation (Stage 3); Identification of intake route for evaluation above Level 1 (Stage 4) ; Level 2 (doses in range 1 to 6 mSv): evaluation of dose, taking material-specific parameters into consideration (e.g. for inhalation: Stage 5A and 5B); Level 3 (doses more than 6 mSv): advanced evaluation (more sophisticated): subject specific parameter values can be modified (Stage 5C). The introduction of special monitoring, which may require the collection of additional monitoring data, is considered in Stage 3 and in Stage 5B.

Similar stages are specified for ingestion (Stages 6A, 6B and 6C), mixed inhalation and ingestion (Stages 7A, 7B and 7C), and the wound pathway (Stages 8A, 8B and 8C).

### Other topics presented in the IDEAS Guidelines

Other topics related to treatment of data and dose assessment are addressed in the report. Namely:

- Criteria for the evaluation of the adequacy and the rejection of the fit between model predictions and monitoring data.
- Explanation of Decision Threshold and Detection Limit (DL), including values of typical and achievable values for different types of bioassay.

- Handling monitoring data – normalisation, multiple radionuclides, natural background subtraction, uncertainties.
- Processing of measurement data to obtain an intake estimate.
- Special aspects: identification and treatment of rogue data, use of data below DL, influence of decorporation therapy.
- Direct dose assessment.
- Examples of application of the Guidelines.
- Annexes with explanations of the maximum likelihood method for data fitting and autocorrelation test statistics as a tool for goodness-of-fit evaluation.

## Origins of ISO 27048:2011

During the period 2005 – 2011, the work of ISO/TC85/SC2/Working Group 13 on "Monitoring and dosimetry for internal exposure" was devoted to a specific task of developing a series of three standards with the main aim of improving the reproducibility of dose assessments carried out by dosimetry services, while ensuring that the level of effort required is proportional to the magnitude of exposure.

The last of the three standards, ISO 27048:2011, published in January 2011 with the title of "Dose assessment for the monitoring of workers for internal radiation exposure" [ISO 2011], provides minimum requirements for the evaluation of data from monitoring of workers occupationally exposed to the risk of internal contamination.

## Structure of ISO 27048:2011

The procedure for assessment of dose using measurements performed either for routine monitoring or for special monitoring is described in Figure 2 of ISO 27048:2011.

In it, eight steps, comprising tests and calculations, are used for the interpretation of routine monitoring data (the left side of the figure). A similar procedure, on the right side of the figure, describes the six steps related to the evaluation of measurements originating from special monitoring.

The circumstances in which special monitoring rather than routine monitoring is required are codified in Step 1 and Step 5, which identify situations different from those expected for the work environment (i.e. situations that could result in "unexpected exposures").

The central part of Figure 2 describes the requirements to document, with increasing level of detail, the measurements performed and the evaluated dose, for both types of monitoring procedure.

In ISO 27048:2011, standardised assumptions for the interpretation of data are specified as well as procedures to guarantee acceptable levels of reliability. The procedures allow the quantification of committed effective dose for the purpose of demonstrating compliance with regulations and radiation protection programmes. Limits are also set for the applicability of the procedures specified in the standard, in terms of the dose levels above which more sophisticated methods have to be applied.

## Other topics presented in the ISO 27048:2011

Other topics related to treatment of data and dose assessment are addressed. Namely:

- How to evaluate and report simple information on different components of uncertainty related to the assessed doses.
- Interpretation of multiple data arising from special monitoring.
- The maximum likelihood method for data fitting.
- Handling of data below the Decision Threshold.
- Identification of rogue data.
- Doses to embryo/foetus and infant.
- Recording.
- Reporting.

- Quality assurance.
- Graphs and tables of predicted ranges of measured bioassay quantities (the "band approach").
- Scattering factor values.
- Retention and excretion rates tabulations for single acute or constant chronic intake.

# CHAPTER F - Accuracy Requirements and Uncertainty Analysis

***MAIN QUESTION***

***Q1*** *Under what circumstances should uncertainties in assessed dose be assessed, and how should information on uncertainties be used?*

## Special Terms used in this Chapter

Accuracy, Conditional probability, Confidence interval, Correlation, Cumulative distribution function, Error (of measurement), Lognormal distribution, Monte Carlo method, Normal distribution, Poisson distribution, Probability, Probability distribution, Precision, Probability density function, Scattering factor, Sensitivity analysis, Uncertainty.

## Introduction

The doses resulting from intakes of radionuclides are assessed from measurements of radionuclide activities in bioassay or air samples, and interpreted using biokinetic and dosimetric models making assumptions about the exposure conditions. As a consequence, the assessment of internal doses is subject to uncertainty due to errors, variability and imprecision relating to activity measurements, to biokinetic and dosimetric models, and to the exposure scenario. It is generally acknowledged that the determination of realistic uncertainties in assessed internal doses presents major difficulties. The uncertainty considered here is essentially the range of possible values for the dose that could reasonably be determined from monitoring results. This range arises from the uncertainty in activity measurements and from lack of knowledge of the time of intake and of the physico-chemical form of the incorporated material. These sources of uncertainty may be controlled by an appropriate choice of measurement technique and frequency of measurement, and by analysis of the radioactive material present in the workplace. In routine monitoring, requirements are set on the measurement technique and frequency, in order to guarantee an acceptable level of accuracy that is defined by the maximum acceptable underestimation of the assessed dose.

In this chapter, the extent to which uncertainty should be analysed and quantified is discussed. The various sources of uncertainty in assessed dose are described, with particular attention given to the sources of measurement uncertainty and its quantification. Then, three main uses of uncertainty analysis in monitoring and dose assessment are discussed.

## Purpose of Uncertainty Analysis

***Q1*** *Under what circumstances should uncertainties in assessed dose be assessed, and how should information on uncertainties be used?*

No requirements to evaluate or record the uncertainty on a dose assessed for an individual worker are specified either by EC Directives or by ICRP. The words "uncertain" and "uncertainty" are not used in Council Directive 96/29/Euratom [EC 1996]. In the 2013 Directive, the word "uncertainty" appears once (Chapter III, Article 5b) but this does not refer to the uncertainty in dose assessment; rather, it qualifies the knowledge of the health effects of doses below the threshold for deterministic effects [EC 2014].

The dose coefficients and bioassay functions provided by ICRP are nominal values that are not subject to uncertainty. They are intended for the calculation of the effective

dose received by a Reference Worker, as a tool for optimisation of occupational exposure and demonstration of compliance with regulatory limits, within the framework of radiation protection policy. Indeed paragraph 166, of ICRP Publication 103 [ICRP 2007] states that:

> *for regulatory purposes, the dosimetric models and parameter values that the Commission recommends are reference values. These are fixed by convention and are therefore not subject to uncertainty.*

In the OIR report series [ICRP 2015b] it is noted at page 22 that:

> *The structure and parameter values of biokinetic models of the Reference Worker are invariant on the sex, age, race and other individual-specific characteristics, but based on reference male parameter values where sex-specific models are available.*

and in paragraph 304:

> *There is no requirement to assess or record the uncertainty associated with an individual dose assessment performed to demonstrate compliance with regulatory requirements.*

A global evaluation of the uncertainty on the assessed dose is generally not warranted as it would not improve operational radiation protection. However, assessment of uncertainties in assessed dose should be considered for three main reasons. First, a consideration of uncertainty in assessed dose provides important information for the design of a monitoring programme. Part 1 of the OIR report series advises in paragraph 304:

> *Nevertheless, the assessment of uncertainties associated with a specified monitoring procedure (including the dose assessment procedure) provides important information for optimising the design of a monitoring programme.*

Indeed, ISO 20553:2006 [ISO 2006b] specifies criteria for routine monitoring programmes that take into account uncertainty in measurement results and time of exposure, as indicated in **Chapter C**.

Second, the evaluation of uncertainties associated with a particular monitoring procedure provides valuable information relating to the reliability of assessed doses. Section 8.1 of ISO 27048:2011 [ISO 2011] specifies:

> *It is important for a dosimetry service to provide information on the uncertainty in assessed doses for two main reasons:*
> *- the reliability of an assessed dose cannot be judged without at least a qualitative indication of the associated uncertainty;*
> *- information on the relative contributions to the overall uncertainty in assessed dose may indicate where effort should be placed in order to reduce uncertainty.*

The sensitivity and the accuracy of a monitoring programme can and should be evaluated through an assessment of the uncertainty on assessed doses (**Chapter C**). As such, an uncertainty analysis of the variable parameters associated with a monitoring programme and the corresponding dose assessment procedure (particularly measurement uncertainty and the exposure scenario), complements the quality assurance programme (**Chapter G**).

Third, uncertainties in assessed dose should be taken into account in any assessment of individual risks to health. ICRP Publication 103 indicates that (page 13, point m; Annex B, paragraphs B251 and B252):

> *For individual retrospective dose and risk assessments, individual parameters and uncertainties have to be taken into account […] At higher doses, for example following accidental exposures, or for epidemiological studies, more specific information on the individual and the exposure conditions are needed. In such situations all sources of uncertainty should be taken into consideration including the variability of individual anatomical and physiological data, specific information on radionuclide source-term, biokinetics […] In cases where this is*

*done the uncertainty must be critically reviewed […] For the assessment and judgement of individual cases absorbed doses to organs or tissues should be used together with the most appropriate biokinetic parameters, data on biological effectiveness of the ionising radiation and risk coefficients. In these cases uncertainties should be taken into consideration.*

Thus, an analysis of the uncertainty on the dose is required for any individual assessment of stochastic or deterministic health risk, as explained in **Annex IV**.

## Sources of Uncertainty

As discussed in Chapter E, a number of confounding factors may impact individual monitoring data and their interpretation, which can possibly lead to erroneous dose assessments. The most relevant are:

- External contamination of the body may be misinterpreted as internal contamination.
- In vivo measurement results may be influenced by radionuclides in air, in construction materials or in organs other than the one of specific interest.
- Radiopharmaceuticals administered in nuclear medicine might interfere with the monitoring of internal contamination.
- Biossay samples may be contaminated during or after collection.
- The collection period of excreta samples may be incorrectly recorded.
- Dietary intakes contribute to the measurements performed for monitoring of occupational exposure to naturally occurring radionuclides.
- When the intake of a radionuclide is monitored through the measurement of another radionuclide in its progeny or in an incorporated mixture, independent biokinetics should be accounted for.
- Large inhaled particles may be cleared to the GI tract faster than predicted by models.
- Unusual chemical forms may cause differences with the reference biokinetic model.

If they cannot be avoided, such confounding factors should be taken into consideration to minimise their effect of the dose assessment. When this is done, the residual uncertainty in the measurement, in the scenario of exposure and in the models used will still impact the assessed dose.

### Measurement

Uncertainties in activity measurement have been discussed in several international documents and standards [ISO 2010a; 2010b; IAEA 1996a; 2000; NCRP 2010a]. As explained in **Chapter D**, the measurement of activity is subject to random uncertainty because of the variable background noise and because radioactive decay is a stochastic process. This uncertainty is represented by a Poisson distribution which tends to a normal probability distribution if the counts are large enough, above about 30 [ISO 2007, 2015c]. A high count caused by a random fluctuation of the background may indicate that activity is present in the sample where there is none (a false positive). To avoid false positives, a decision threshold (*DT*) is defined as a (1-α) percentile of the background, where α is the probability of a false positive (typically, α is set at 5%). A measurement is considered to indicate that activity is present only if the gross count is above the *DT*. Conversely, a low count of the radionuclide of interest caused by a random fluctuation of the background may result in a measurement below the *DT* which would be interpreted as 'no evidence for the presence of activity' where activity is actually present in the sample (a false negative). A detection limit (*DL*) is defined such that the measurement of activity present at a level corresponding to the *DL* has a probability ß of not detecting that activity in the sample (i.e. the probability of a false negative is ß, typically also set at 5%).

The measurement result is also subject to other uncertainty sources. Notably, *in vivo* measurement is sensitive to calibration uncertainty [Toohey 1991; Lopez 2003] and *in vitro* measurement is influenced by the sampling procedure [Hurtgen 2003; Moss 1969]. Those sources of uncertainty are dominant when the measured activity is well

above the *DL* [EURADOS 2013]. For activities close to or below the *DL*, uncertainty due to counting statistics is generally dominant.

## Exposure Scenario

The dosimetric interpretation of monitoring data depends on information and hypotheses regarding the exposure conditions: time of event, route of intake, the radionuclides to which workers are exposed, and the physico-chemical form of the radionuclides. Any uncertainty in the exposure scenario will lead to an uncertainty on the assessed dose whose magnitude can be quantified by evaluating the dose using the different possible assumptions and recording the resulting range of values.

[Molokanov 2007] and [Birchall 2007b], among others, studied the influence of an unknown time of intake on dose assessment. Since most bioassay functions are decreasing over time, the assumption of a time of intake earlier than the actual one will cause the intake and dose to be overestimated, while the assumption of a time of intake later than the actual one will lead to underestimation. Similarly, an incorrect assumption on the time pattern of intake: single acute intake, multiple intakes or chronic intake, will yield an unrealistic estimate of intake and dose. In routine monitoring, when the time of intake is not known, it is recommended to assume that the intake occurred at the middle of the monitoring interval [ICRP 1997; 2015b; ISO 2006] (see also **Chapter E**). If the probability of intake over time is constant in the interval, this assumption has an equal probability of underestimating or overestimating the dose. However, because most bioassay functions decrease more rapidly in the first few days after intake, overestimates associated with this assumption tend to be larger than underestimates. To avoid this biasing of average intake estimates when the probability of intake is constant over time, a constant chronic intake throughout the monitoring interval may be assumed. However, if the measurement uncertainty is assumed to be lognormal, then a correction factor needs to be applied to obtain unbiased estimates of intake [Birchall 2007b]. Nevertheless, for routine monitoring, a default assumption of a single intake at the mid-point of the monitoring interval is recommended in **Chapter E**, consistently with [ICRP 1997; 2015] and [ISO 2011].

If there is no clear evidence of ingestion, it is usually assumed that intakes occur by inhalation of radioactive particles or gases (**Chapter E**). By default, it is assumed that inhaled particles have a lognormal size distribution with an AMAD of 5 μm and geometric standard deviation $\sigma_g$ = 2.5, and a reference respiratory tract absorption Type F, M or S that depends on the chemical compound [ICRP 1994b]. In the OIR report series [ICRP 2015b] specific absorption parameter values are given for a number of elements and chemical compounds. When information is available on the physico-chemical form of the radionuclide, it should be used to apply specific bioassay functions and dose coefficients. When it is not precisely characterised, the difference between assumed and actual particle size distribution and absorption kinetics contributes to the uncertainty on the dose. However particle size generally has limited influence on the dose per unit urine bioassay content [Berkovski 2003].

If intake took place partly or totally through unnoticed ingestion, an unrealistic estimate of intake, lung dose and effective dose would be obtained. Nevertheless, ingestion or a mixture of inhalation and ingestion can also be approximated by assuming inhalation of large aerosols, with AMAD greater than 10 μm.

When workers are exposed to a mixture of radionuclides, the dose due to intake of each of those radionuclides should be evaluated separately. In a few cases, where all the radionuclides have the same biokinetics, the dose may be estimated directly for the mixture. This is the case for mixtures of uranium isotopes or mixtures of plutonium isotopes, for example. If some of the incorporated radionuclides cannot be measured, their contribution to the dose should still be taken into account using information on isotopic ratios. Assuming incorrect isotopic ratios or failing to identify all incorporated radionuclides will lead to unrealistic dose assessment. ISO 20553:2006 [ISO 2006] indicates that the additional uncertainty introduced in the dose assessment by the uncertainty in the composition of the mixture of radionuclides

in the intake should be kept below 10% (section 5, p8). This composition could be confirmed by measurement of radionuclides in the workplace.

### Biokinetic and Dosimetric Models

The models used for dose assessment (**Chapter B**, **Annex I**) are based on simplifications of human physiology and anatomy. As such, they provide only an approximation of the real distribution of radionuclides and radiation-matter interaction in the human body, so contributing to the uncertainty in dose assessment [Leggett 2001; NCRP 1998]. Furthermore, the models are intended to represent a Reference Person [ICRP 2002] defined by central estimates of variable anatomical and physiological parameter distributions among the population. A specific individual differs from the Reference Person in many aspects that will make the result of a reference dose assessment different from the actual dose absorbed by tissues and organs of the individual. In unusual situations where an individual dose assessment is warranted (e.g. for individual health risk assessment), it is possible, with sufficient expertise and tools, to adapt the biokinetic and dosimetric models to the characteristics of a specific individual. However, it is likely than even a thorough investigation of an individual will not allow accurate determination of specific values for all dosimetrically relevant parameters (e.g. the respective position in organs of the radiosensitive stem cells and of radionuclides emitting short range radiation). The characterisation of uncertainty in biokinetic and dosimetric models is a field of significant research and expert work that is presented and discussed by the US National Council on Radiation Protection and Measurements [NCRP 2010a].

## Measurement Uncertainty

The sources of uncertainty in air sampling are discussed in **Chapter D**. In the case of a measurement of activity in the body or in a biological sample, Type A uncertainties are taken to arise only from counting statistics, which can be described by the Poisson distribution and Type B uncertainties are due to all other sources of uncertainty (see the Appendix to this chapter).

### *In vitro* measurement

Examples of Type B uncertainty components for *in vitro* measurements include the quantification of the sample volume or weight; errors in dilution and pipetting; evaporation of solution in storage; stability and activity of standards used for calibration; similarity of chemical yield between the tracer and the radioelement of interest; blank corrections; background radionuclide excretion contributions and fluctuations; electronic stability; spectroscopy resolution and peak overlap; contamination of sample and impurities; source positioning for counting; density and shape variation from calibration model and assumptions about homogeneity in calibration [Skrable 1994]. These uncertainties apply to the measurement of activity in the sample. With excretion measurements, the activity in the sample is used to provide an estimate of the subject's average excretion rate over 24 hours for comparison with the model predictions. If the samples are collected over periods less than 24 hours then they should be normalised to an equivalent 24-hour value. This introduces additional sources of Type B uncertainty: the uncertainty in the collection period, which depends on the sampling procedures and the techniques used to calculate the collection period, and the uncertainty relating to biological (inter-and intra-subject) variability. This uncertainty may well be greater than the uncertainty in the measured sample activity.

### *In vivo* measurement

*In vivo* measurements can be performed in different geometries (whole body measurements, and organ or site-specific measurement such as measurement over the lung, thyroid, skull, or liver, or over a wound). Each type of geometry needs specialised detector systems and calibration methods. IAEA [IAEA 1996a] and ICRU

[ICRU 2003] have published reviews of direct bioassay methods that include discussions of sensitivity and accuracy of the measurements.

Examples of Type B components for *in vivo* monitoring include counting geometry errors; positioning of the individual in relation to the detector and movement of the person during counting; chest wall thickness determination; differences between phantom and individual or organ being measured, including geometric characteristics, density, distribution of the radionuclide within the body and organ and linear attenuation coefficient; interference from radioactive material deposits in adjacent body regions; spectroscopy resolution and peak overlap; electronic stability; interference from other radionuclides; variation in background radiation; activity of the standard radionuclide used for calibration; surface external contamination of the person; interference from natural radioactive elements present in the body; and calibration source uncertainties [IAEA 1996a; Skrable 1994].

For partial body measurements it is generally difficult to interpret the result in terms of activity in a specific organ because radiation from other regions of the body may be detected. Interpretation of such measurements may require assumptions concerning the biokinetics of the radionuclide and any radioactive progeny produced *in vivo*. An illustration using $^{241}$Am is given in the IAEA Safety Report on Direct Methods for Measuring Radionuclides in the Human Body [IAEA 1996a]. A fundamental assumption made in calibrating a lung measurement system is that the deposition of radionuclides in the lungs is homogeneous, but deposition rarely follows this pattern.

## Expression of measurement uncertainty

Measurement errors associated with counting statistics (Type A uncertainties) decrease with increasing activity or with increasing counting time, whereas the Type B components of measurement uncertainty may be largely independent of the activity or the counting time. Therefore, when activity levels are low and close to the detection limit, the total uncertainty is often dominated by the Type A component (i.e. by counting statistics). For radionuclides that are easily detected and present in sufficient quantity, the total uncertainty is often dominated by the Type B components (i.e. by uncertainties other than counting statistics).

The overall uncertainty of measurement may be described by a lognormal probability distribution. Its geometric standard deviation is called a scattering factor (*SF*) [Marsh 2007]. Typical values of *SF* are provided by the IDEAS Guidelines [EURADOS 2013] and in Annex B of ISO 27048:2011 [ISO 2011]. For *in vivo* measurement, the value of *SF* depends on the emitted photon energy, while for *in vitro* measurement it depends on the sampling procedure.

The values of scattering factors in the IDEAS Guidelines and in Annex B of ISO 27048:2011 are given in terms of Type A (counting statistics) and Type B (all other components) uncertainties. For *in vivo* measurements, both types of uncertainty are reported while for *in vitro* determination only the Type B uncertainty is presented. The component A may be evaluated by means of the following equation:

$$SF_A = e^{\left(\frac{\sigma_M}{M}\right)} \qquad \text{(Eq F.5)}$$

where

| | |
|---|---|
| $M$ | Measured value |
| $\sigma_M$ | Uncertainty of measured value due only to counting statistics with coverage factor k = 1. |

Typical $\sigma_M$ values for alpha spectrometry were calculated by [Hurtgen 2003] and are reproduced in Figure 4.1 of the IDEAS Guidelines. The different components of the scattering factor can be combined using the following equation [EURADOS 2013]:

$$SF = e^{\sqrt{(\ln(SF_A))^2 + (\ln(SF_B))^2}} \qquad \text{(Eq F.6)}$$

[Miller 2007] considers that the assumption that the overall uncertainty on an individual monitoring value can be described in terms of a lognormal distribution is reasonable provided that the ratio $ln(SF_A)/ln(SF_B)$ is less than one-third.

The values of *SF* of ISO 27048:2011 were based on the original version of the IDEAS Guidelines [Doerfel 2006] and were revised by [EURADOS 2013] to better account for the respective contributions of Type A and Type B uncertainty. These revised values of *SF* are adopted here in Table F.1.

**Table F.1** Typical values of *SF* for typical measurements [EURADOS 2013].

| Type of measurement | Scattering factor, *SF* | | |
|---|---|---|---|
| *In vivo* | Type A | Type B | Total |
| low photon energy (< 20 keV) | 1.5 | 2.06 | 2.3 |
| intermediate photon energy | 1.3 | 1.25 | 1.4 |
| high photon energy (>100 keV) | 1.07 | 1.15 | 1.2 |
| Urine (Type B uncertainty) | | | |
| true 24-hour sample or $^3$H concentration | 1.1 | | |
| simulated 24-hour sample (normalised activity) | 1.6 (1.3-1.8) | | |
| spot sample | 2.0 | | |
| Faeces (Type B uncertainty) | | | |
| 24-hour sample | 3 (2-4) | | |
| 72-hour sample | 1.9 (1.5-2.2) | | |

## Use of Uncertainty Analysis in the Design of Monitoring Programmes

ICRP and ISO have set accuracy requirements for the design of routine monitoring programs by specifying the maximum absolute and relative underestimation of the dose that may be accepted as a consequence of an unknown time of intake and of the limit of detection of the measurement technique. ICRP Publication 78 [ICRP 1997] notes that (paragraph 15):

> *as the relative uncertainty in assessing the dose will increase at lower dose levels, it is generally inappropriate to assess formally doses when they are lower than 1 mSv in a year.*

Similarly, section 7.3 of ISO 20553:2006 notes that [ISO 2006]:

> *the measurement frequency required for a routine monitoring programme depends on the retention and excretion of the radionuclide, the sensitivity of the available measurement techniques and the uncertainty that is acceptable when estimating annual intake and committed effective dose […] this requirement shall be adjusted accordingly so that a total annual dose of 1 mSv can reliably be detected and assessed.*

In ICRP Publication 78 monitoring intervals were selected so that any underestimation introduced by the unknown time of intake is no more than a factor of three. Similarly, ISO 20553:2006 requires in section 7.3 that:

> *The maximum potential underestimation shall not exceed a factor of three.*

Part 1 of the OIR report series [ICRP 2015b] refers to the ICRP Publication 78 rule for the selection of monitoring intervals, and notes in paragraph 236:

> *if a substantial part of the intake occurs just before sampling or measurement, the intake could be overestimated by more than a factor of three*

and adds in paragraph 237:

> *an alternative, graphical approach has been developed by Stradling et al. [Stradling 2005], which takes into account uncertainties in material-specific parameters such as those describing absorption and particle size distribution, as well as time of intake.*

This is the method adopted in ISO 20553:2006. When designing a monitoring programme for a radionuclide, the measurement technique(s) and the monitoring interval should be chosen so that any intake leading to an annual effective dose of more than 1 mSv can reliably be detected (see **Chapters C** and **D**). Taking into account the uncertainty on the time of intake and on the measurement, this translates mathematically into the condition that:

$$e(50) \cdot n \cdot \frac{DL}{m(\Delta T)} \leq 1\,mSv \qquad \text{(Eq F.1)}$$

or equivalently:

$$n \cdot z(\Delta T) \cdot DL \leq 1\,mSv \qquad \text{(Eq F.2)}$$

where

| | |
|---|---|
| *e(50)* | dose coefficient for the radionuclide |
| *n* | number of monitoring intervals of length Δ*T* in a year |
| *DL* | detection limit of the measurement technique |
| *M* | corresponding bioassay function |
| *Z* | dose per unit measured activity. |

When *n* is greater than one and *m* is sufficiently extended such that intake at the beginning of an interval contributes significantly to the measured bioassay quantity in later monitoring intervals (e.g. plutonium in urine, see **Annex II** Example 1), Eq F.1 and F.2 may be unrealistically conservative and may need to be corrected to subtract the contribution of intake in each interval from measured activity (DL) in the next intervals (see also **Chapter E**).

An additional condition on the monitoring interval is that the maximum underestimation of the dose estimated from a positive measurement, assuming an intake at the middle of the monitoring interval, should not exceed a factor of three:

$$\frac{m\left(\Delta T/2\right)}{m(\Delta T)} \leq 3 \qquad \text{(Eq F.3)}$$

or equivalently

$$\frac{z\left(\Delta T/2\right)}{z(\Delta T)} \leq 3 \qquad \text{(Eq F.4)}$$

ICRP Publication 78 and ISO 20553:2006 propose monitoring programmes that comply with these two conditions for commonly used radionuclides. The proposed intervals will need to be revised according to latest values of dose coefficients, dose per measured activity functions and bioassay functions following adoption of the OIR report series.

This interval approach to uncertainty due to activity measurement and time of intake is part of the accuracy requirements for routine monitoring programmes. Optionally, other sources of uncertainty could be considered in the same way by selecting the least favourable of possible hypotheses on potential exposure and checking that the above conditions are still respected [Stradling 2005]. Alternative approaches were proposed which consider a probabilistic uncertainty analysis of monitoring programmes to determine minimum detectable doses [Etherington 2004; Davesne 2010].

Over-estimation of intake and dose is of less concern than under-estimation in a conservative approach to radiation protection. However, if not corrected, it could lead to an unrealistic evaluation of the exposure and expenditure of effort and resources where it is not needed. [ICRP 1997] therefore suggests that (Paragraph 91 at page 27):

> *If an unexpectedly high result is found in a routine monitoring programme, it would be appropriate to repeat the sampling or measurement a few days later, and adjust the estimate of intake accordingly. Alternatively, if appropriate and if convenient, the sample could be collected or the measurement made after a period of non-exposure.*

**Chapter E** gives indications on how to address unexpectedly high results of monitoring.

## Use of uncertainty analysis to assess reliability of a monitoring procedure

ISO 27048:2011 [ISO 2011] notes that it is important for a dosimetry service to provide information on the uncertainty of assessed doses as it provides an indication of reliability and may indicate which of the factors that contribute to uncertainty could be investigated further, in order to improve the reliability of doses. It is noted however that most dosimetry services do not have the capability to carry out a full assessment of uncertainty. ISO 27048:2011 specifies the information on uncertainties that it is reasonable to expect a dosimetry service to provide and provides a format that could be used to compile this information (reproduced in Table F.2). In practice this information needs to be collected only once for a particular monitoring method (assuming a measurement result 10 times greater than the DL), rather than for each individual dose assessment performed using the method.

Information is given in the Appendix to this chapter on probabilistic methods of uncertainty analysis and sensitivity analysis that have been applied to internal dosimetry. More detailed information is provided by [NCRP 2010a]. This is still an area of research and it is not expected that internal dosimetry services would use such methods. Those that do should use the validated method of their choice to determine a 95% confidence interval on assessed doses. Others may use the procedure described by ISO 27048:2011 and summarised here:

The sources of uncertainty to consider depend on the assessed dose. A sensitivity analysis should be conducted independently for each of them. The following sources of uncertainty and intervals of variation should be considered as factors contributing to overall uncertainty:

- Below 0.1 mSv:

  None

- From 0.1 mSv to 1 mSv:

  *Time of intake*: within the routine monitoring interval or the interval of potential exposure.
  *Measurement uncertainty*: A 95% confidence interval may be defined for each measurement result from its observed value divided by $SF^{1.96}$ to its observed value multiplied by $SF^{1.96}$, where *SF* is the scattering factor for the type of measurement.

- Above 1 mSv:

  *Time of intake* and *measurement uncertainty*, plus:
  *Particle size*: If no more specific information is available, a 95% confidence interval on AMAD from 1.35 µm to 14.25 µm may be assumed [Dorrian 1995].
  *Respiratory tract and gastro-intestinal absorption*: If no more specific information is available, all the default lung absorption Types and $f_1$ or $f_A$ values specified by ICRP for the material or radionuclide of interest may be considered as possible hypotheses (Table E of Annex III of Council Directive

96/29/Euratom [EC 1996] or Annex F of ICRP Publication 68 [ICRP 1994b]). If several absorption Types are possible, then the mixture of absorption Types with respective fractions varying from 0 to 1 should be considered.

The variation interval of the assessed dose should be evaluated when each of the factors considered is allowed to vary within its 95% confidence interval, the other parameters being fixed at best estimate values or according to default assumptions. To do so, it may be useful to plot a graph of the assessed dose as a function of the variable factor. The results of this sensitivity analysis should be recorded in the format of Table F.2.

**Table F.2** Contributions to overall uncertainty in assessed dose (reproduced from Table 7 of [ISO 2011]). Data on the contribution to overall uncertainty from the factors considered should be recorded in the format shown.

| Factor contributing to overall uncertainty | Lower value of assessed dose | Assessed dose using best estimate parameter values and/or default assumptions | Upper value of assessed dose |
|---|---|---|---|
| Uncertainty in time or period of intake | | | |
| Uncertainty in measured quantity (Type A and Type B combined) | | | |
| Uncertainty in particle size distribution | | | |
| Uncertainty in absorption classification and gastro-intestinal absorption factor | | | |

## Uncertainty Analysis for Individual Risk Assessment

Assessment of risks to health resulting from radiation exposure are subject to a large uncertainty [NCRP 2012, UNSCEAR 2014]. For the individual assessment of health risk from intakes of radionuclides, which is the subject of **Annex IV** of this report, the most realistic information on absorbed doses to sensitive tissues should be provided. As a consequence, the evaluated doses should be provided together with the associated uncertainty, determined as precisely as possible from the available information, when it is at all feasible. For example, [Marsh 2002] and [Puncher 2016] have evaluated uncertainties respectively on lung dose per unit exposure to radon progeny in the home and on life-long lung, liver and red bone marrow doses for Sellafield workers exposed to plutonium. Explanations and illustrations of state-of-the-art methods are presented and discussed by NCRP [NCRP 2010a]. Suitable methods to evaluate and to take into account dosimetric uncertainty in risk assessment are currently under discussion within epidemiological studies of European workers exposed to plutonium [Puncher 2016] and uranium [Laurent 2016].

## Recommendations

| R# | G | Text of the recommendation |
|---|---|---|
| | | ***Q1**: Under what circumstances should uncertainties in assessed dose be assessed, and how should information on uncertainties be used?* |
| F01 | I | The uncertainty on assessed dose should be considered in the design of a monitoring programme [ICRP 2015b; ISO 2006], to assess the reliability of a monitoring procedure [ISO 2011] and for the assessment of risks to health [ICRP 2007]. |
| F02 | I | For statistical tests in the dose assessment procedure and to evaluate its contribution to overall uncertainty in assessed dose, the measurement uncertainty should be expressed by a scattering factor (SF). The values of SF from Tables 4.8 and 4.10 of the IDEAS Guidelines [EURADOS 2013] should be adopted. |
| F03 | I | A routine monitoring programme should be sufficiently sensitive to reliably detect any intake leading to an annual effective dose of more than 1 mSv and sufficiently accurate to avoid an underestimation of the dose by more than a factor of 3 due to uncertainty in the time of intake [ISO 2006, ICRP 1997]. |
| F04 | I | In order to evaluate and improve the reliability of doses assessed using the ISO 27048:2011 procedure [ISO 2011], uncertainties associated with particular monitoring procedures should be assessed using sensitivity analyses. If the assessed dose is more than 0.1 mSv, the uncertainty on dose due to measurement uncertainty and to uncertainty on time of intake should be assessed and documented. If the assessed dose is more than 1 mSv, the uncertainty on particle size distribution and absorption characteristics should also be taken into account in the assessment of dose uncertainty. |
| F05 | A | The uncertainty on assessed dose should be expressed as an interval from the minimum to the maximum value of dose assessed for each factor contributing to overall uncertainty. Each factor is to be considered separately as varying within its 95% confidence interval, while other parameters are fixed as best estimates or default assumptions. The results of this sensitivity analysis should be recorded in the format indicated by Table 7 of ISO 27048:2011 [ISO 2011]. |
| F06 | A | For the evaluation of individual health risk, the uncertainty on all measurements, models and parameters should be taken into account The method to be applied depends on the individual case and the available information. The indications given in NCRP Publication 164 [NCRP 2010a] may be followed. |

G= Grade: M = Mandatory, I = International, A = Advisory

# Appendix to Chapter F

## Mathematical framework of uncertainty analysis

This Appendix complements the main text by providing information on some mathematical aspects of uncertainty analysis. It is not intended to provide operational guidance; rather, it outlines some of the main approaches and points the reader towards studies in the literature that describe methods to analyse uncertainty and their application to internal dosimetry.

### Expression of uncertainty

#### Measurement uncertainty

ISO's Guide to the Expression of Uncertainty in Measurement (GUM) [ISO/IEC 2014] defines error of measurement as a

> *result of a measurement minus a true value of the measurand*

and uncertainty of measurement as a

> *parameter, associated with the result of a measurement, that characterises the dispersion of the values that could reasonably be attributed to the measurand*

The components of uncertainty in a quantity may be divided into two main categories, referred to as Type A and Type B uncertainties. [ISO/IEC 2014] discriminates between the Type A evaluation of uncertainty - that based on statistical means - and the Type B evaluation of uncertainty - that based on non-statistical means. However, as noted in a publication of the UK National Physical Laboratory [Cox 2004], it is sometimes more useful to make a distinction between effects that can be regarded as random, and those that can be regarded as systematic. [Cox 2004] notes that the subdivision into Type A and Type B evaluations of uncertainty corresponds in some instances to random and systematic effects, respectively, but not in all circumstances.

#### Uncertainty of dose

One way to express uncertainty on dose is to evaluate the interval of its possible values given the range of uncertainty sources. When several uncertain variables representing uncertainty sources are involved, the dose resulting from all possible combinations of values of these variables should be investigated. If the relation between an uncertain variable and the dose is monotonic, i.e. the dose only decreases or only increases over the interval of variation, only the minimum and maximum values need to be considered to quantify the influence of the variable in terms of interval on the assessed dose. If it is not monotonic, the full range of variation should be investigated. The interval of possible dose values is a conservative way to express uncertainty: it may not be very precise, but it is very reliable.

A general framework to represent imprecise knowledge is given by the possibility theory [Dubois 1988]. It was applied by [Davesne 2009] to model imprecision in the prospective dosimetry of exposure to uranium.

Another way to express uncertainty is to determine a probability distribution of the dose, considered as a random variable. All sources of uncertainty may be represented as random variables following probability distributions. Such uncertainty is propagated onto the dose by Monte Carlo calculation or by other methods: that is, by sampling a representative number of values for all uncertain variables, following causality relationships, biokinetic and dosimetric models, measurement uncertainty expressed as a conditional probability of observed measurement results given an intake value, and correlations. The resulting probability distribution on the dose is an expert way to express uncertainty: it is very precise but it is itself subject to uncertainty, since the choice of probability distributions for uncertainty sources, conditional probabilities and correlations is conditioned by the available information and determined by expert judgement.

## Monte Carlo calculation

In probabilistic methods, a probability density function (PDF) is selected to quantify the degree of belief associated with each value of the input quantities. If dependencies between uncertain parameters are known and judged to be potentially important, then they need to be quantified. The direct probabilistic propagation of uncertainty consists of evaluating from this knowledge the degree of belief associated with each possible result of dose and measurable quantities as a PDF.

Accurate results require precise knowledge of the PDF of each uncertain parameter and of the possible correlations. Such knowledge is rarely available in practice and some information has often to be subjectively added based on expert judgment. In practical studies, some particular choices of PDF are commonly made to represent the lack of knowledge on uncertain parameters. For example, a uniform probability law is often used when no information other than the extreme values is available. A triangular law is used when the extreme values and the mode are known. However, subjective information may lead to less realistic results and may arbitrarily change the confidence interval. Indeed, when the variability of a parameter is not well known, several different PDFs could be applied and the overall uncertainty may be underestimated by considering only one. In the same way, unknown correlations may lead to unrealistic estimation of the uncertainty.

Direct propagation of uncertainty is performed by deriving the uncertainty in an 'output variable' from known uncertainties in a set of 'input variables'. One method is the Monte Carlo method, a numerical technique that converges faster than other methods in multi-dimensional space. It consists of generating a large number of random sets of input parameter values according to their probability and then estimating the output of interest from discrete sums approximating the integrals to be calculated. In Monte Carlo simulation, a physical model is applied repeatedly, using different values for each of the uncertain parameters each time. The values of each of the uncertain parameters are drawn from their PDFs, as follows.

If F(x) is the cumulative distribution function (CDF) of x, then the variable y = F(x) is uniformly distributed between 0 and 1. N numbers, $r_1$, $r_2$,…, $r_N$ are drawn randomly between 0 and 1. The sample of x ($x_1$, $x_2$, …, $x_N$) is determined by $x_i = F^{-1}(r_i)$ where $F^{-1}$ is the inverse function of F. The sample of x is therefore distributed according to F(x). It can be used to estimate any typical statistics such as the mean or the variance, and can also be used to determine the CDF of the output quantities. It follows from the law of large numbers that the mean ( $\overline{x}$ , Eq F.7), the standard deviation (S, Eq F.8) and the CDF (Eq F.9) can be calculated without knowing the PDF, using a Monte Carlo simulation:

$$\overline{x} = \frac{1}{N}\sum_{i=1}^{N} x_i \xrightarrow[N\to+\infty]{} \mu = \int_{-\infty}^{+\infty} xP(x)dx \qquad \text{(Eq F.7)}$$

$$S^2 = \frac{\sum_{i=1}^{N}(x_i - \overline{x})^2}{N-1} \xrightarrow[N\to+\infty]{} \sigma^2 = \int_{-\infty}^{+\infty}(x-\mu)^2 P(x)dx \qquad \text{(Eq F.8)}$$

$$\frac{1}{N}\sum_{i=0,x_i\le a}^{N} x_i \xrightarrow[N\to+\infty]{} F(a) = \int_{-\infty}^{a} P(x)dx \qquad \text{(Eq F.9)}$$

The Monte Carlo simulation is therefore a simple way to obtain useful statistics about the model outputs and can be used for complex models where no analytical solution exists. Two methods for sampling random or pseudo-random sets of numbers are widely used. In the Simple Random Sampling (SRS) method [Cochran 1977], a number between 0 and 1 is randomly drawn for each uncertain parameter to sample its CDF. In the Latin Hypercube Sampling (LHS) [McKay 1979] method, the interval [0, 1] is first divided into sub-intervals from which numbers are randomly or deterministically drawn. This ensures that each of the uncertain parameters is

represented in a fully stratified manner, no matter which component might be found to be important.

The propagation of the uncertainty on the model parameter values to the dose coefficient has been studied by Monte Carlo techniques in several cases. [Bolch 2001, 2003] assessed the uncertainties on parameter values for particle deposition and clearance in the HRTM following inhalation of a mono-dispersed aerosol, and propagated them to the dose coefficient. [Fritsch 2006] applied the same method to polydispersed aerosols. [Farfan 2003] evaluated the uncertainties on parameters characterising the geometries of source and target tissues in the HRTM and derived resulting uncertainties on the dose. [Farfan 2005] studied uncertainty in electron absorbed fractions and lung doses from inhaled beta-emitters.

Other studies were carried out with specific radionuclides in order to assess the effect on the dose coefficient of uncertainties on the absorption and of systemic model uncertainties. [Harrison 2001] estimated the uncertainty on the fraction of activity absorbed in the gut for 14 radionuclides and observed no direct effect of it on the uncertainty in the dose coefficients. Later, the same authors studied the uncertainties on the parameters describing the systemic model for tritium in order to determine the uncertainty on the dose coefficient from intake of tritiated water and organically bound tritium [Harrison 2002]. Uncertainties in dose coefficients from ingestion of iodine and caesium were extensively studied [Dunning 1981; Schwartz 1982; Hamby 1999; Harvey 2003; Apostaei 2004]. [Krahenbuhl 2005] determined the uncertainty on the radionuclide content of organs of Mayak workers. [Bess 2007] assessed the uncertainty on the dose from plutonium inhalation. [Khursheed 1998] determined the uncertainty in dose coefficients for systemic plutonium. [Puncher 2012; 2013a; 2014a; 2014b] assessed the reliability of dose coefficients for the exposure of the public to a number of significant radionuclides.

[Blanchardon 2007] and [Molokanov 2007] estimated a distribution of assessed dose values assuming a priori PDF for input data including measurement result, model parameters and conditions of exposure. [Etherington 2006] developed a method to determine the uncertainty in the dose assessments for a population of workers when default assumptions are made about model parameter values and intake patterns.

## Bayesian inference

In internal dosimetry, the dose and the bioassay measurement are determined by the intake amount, the time of intake, and the biokinetic and dosimetric model. The intake may be evaluated from the combination of prior knowledge and observed bioassay measurement results. Figure F.1 provides a simple representation of the mathematical problem of internal dose assessment, highlighting the key variables and their dependencies.

In Figure F.1, the arrows represent cause-to-consequence relations between the variables of the internal dose assessment problem: the cause is the intake event characterised by the time t when it took place, the incorporated activity I, and the physico-chemical form of the radioactive material represented by biokinetic parameters X, including AMAD, $f_A$ and absorption Type. The intake event has two consequences: the presence of radionuclide activity S in the body or excreta, and the committed effective dose E. The relations between those variables are deterministic, i.e. any given set of t, I and X corresponds to a single value of S and a single value of E. The body activity or excreted activity S is the product of the incorporated activity I and the corresponding bioassay function m, the value of which depends on the time t and on the biokinetic parameters X:

$$S = I\, m(t,X) \qquad \text{(Eq F.10)}$$

The committed effective dose is the product of the incorporated activity I by the dose coefficient e(50), the value of which depends on the biokinetic parameters X:

$$E = I\, e(50,X) \qquad \text{(Eq F.11)}$$

The body/excreted activity S may be measured, but the measurement result M is affected by the measurement error, usually represented by a lognormal PDF of geometric standard deviation *SF*. The relation between S and M is therefore probabilistic:

$$P(M|S) = \frac{1}{M \cdot \ln(SF)} \frac{1}{\sqrt{2\pi}} e^{-\frac{\ln(M)-\ln(S)}{2\cdot[\ln(SF)]^2}} \quad \text{(Eq F.12)}$$

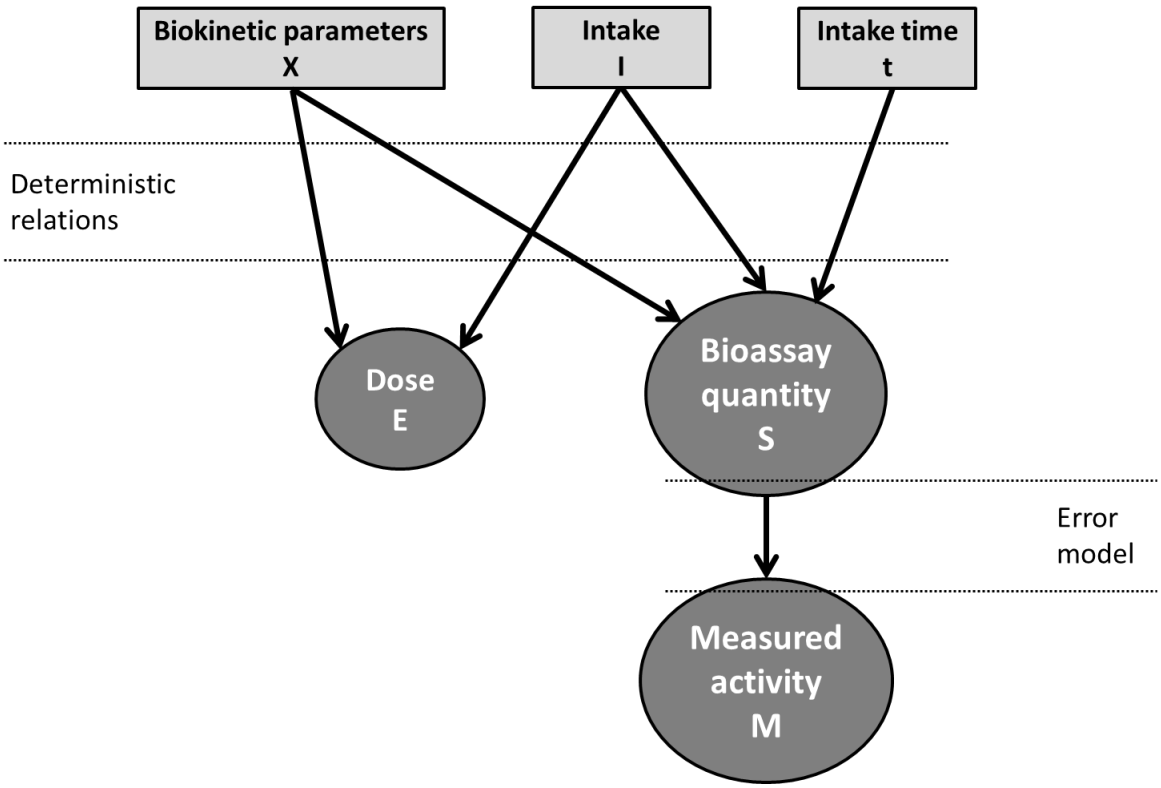



**Figure F.1**. Graphical representation of the mathematical problem of internal dose assessment by [Davesne 2011].

The mathematical problem of internal dose assessment is to infer the values of intake I and dose E from an observed measurement result $M_{obs}$. In the Bayesian framework, all uncertain quantities are modelled by random variables with possible values weighted by their degree of belief in the form of a PDF. Before a bioassay measurement, the values of intake and dose are described by prior probability distributions P(I) and P(E) and the knowledge of the biokinetic parameters is described by the PDF P(X). The result of the measurement gives information that is used to update the PDFs of intake and dose by applying Bayes's theorem (Eq F.13), where P(A|B) is the conditional probability of A knowing B.

$$P(A|B) = \frac{P(A \cap B)}{P(B)} = \frac{P(B|A) \times P(A)}{P(B)} \quad \text{(Eq F.13)}$$

The posterior probability distribution of the intake $P(I|M=M_{obs})$ is calculated given an observed measurement result $M_{obs}$ as follows:

$$P(I|M) = C \times L(M|I) \times P(I) \quad \text{(Eq F.14)}$$

L(M|I) is the likelihood of observing a measurement result M knowing the intake value I. The likelihood of the measurement given the intake is obtained by averaging the likelihood associated with each set of values of the other uncertain parameters (biokinetic parameters X and intake time t) weighted by their prior probability:

$$L(M|I) = \int_X \int_t P(M|I,X,t) \times P(X) \times P(t) \times dX \times dt \quad \text{(Eq F.15)}$$

C is a normalisation constant:

$$C = \frac{1}{\int_I \int_X \int_t P(M|I,X,t) \times P(I) \times P(X) \times P(t) \times dX \times dt \times dI} \quad \text{(Eq F.16)}$$

Similar calculations are performed to evaluate the posterior PDF of the dose $P(E|M=M_{obs})$, using Eq. F.11.

In order to calculate posterior probabilities of intake and effective dose, [Miller 1999] developed the Los Alamos UF code in which the bioassay functions and dose coefficients for each biokinetic model are tabulated. This code was used to determine if a plutonium measurement in Los Alamos monitoring programme is considered as positive. The PDFs are calculated using a Markov Chain Monte Carlo algorithm [Miller 2002] that uses up to about 200 biokinetic models to solve equations F.11-F14. The Markov Chain Monte Carlo algorithm samples the posterior PDFs of the variables to concentrate calculation effort where it is most useful, but the computation time may still be prohibitive.

The Weighted Likelihood Monte Carlo Sampling (WeLMoS) method [Puncher 2008] is a Bayesian Monte Carlo method which uses a weighted LHS to calculate the posterior distribution of parameter values including intake and dose. Random samples are generated from the continuous prior distributions of I, X, and t using LHS. Then a weight is assigned to each set of uncertain parameters that is equal to the likelihood of the measurement M given the set (I, X and t). The weighted values are summed to compute the posterior distributions P(I|M) and P(E|M). [Puncher 2008] showed that the WeLMoS method and the UF code obtained the same results for the same study. The WeLMoS method was applied to evaluate the uncertainty on lung doses from occupational exposure to plutonium [Puncher 2011] and uranium [Puncher 2013a; 2013b].

A Bayesian network [Pearl 1988] was developed by [Davesne 2011] and applied to the optimisation of routine monitoring. The network is based on the graphic representation of dependences between variables of Figure F.1. All variables are discretised, i.e. limited to a finite set of possible values, and assigned prior probabilities. Their values are related through tables of conditional probability. When new information is obtained on a variable, the whole network is updated by Bayesian inference.

## Sensitivity Analysis

Sensitivity analyses assess the contribution from each uncertainty source to the uncertainty on the assessed dose. The results of a sensitivity analysis allow evaluation of the order of magnitude of the contribution from each uncertainty source to the overall uncertainty on the dose. Efforts to evaluate and reduce uncertainty may then be focused on the parameters that significantly contribute to it.

A simple and common approach is to change one factor at a time to investigate the effect that this produces on the output. Following this simple approach, a single uncertain variable is allowed to vary in an interval or along a probability distribution, while the other variables are fixed at their nominal values, and the resulting variation of the assessed dose is recorded. For example, [Marsh 2000] conducted an analysis of sensitivity of lung dose to parameters of exposure to radon progeny. For example, Marsh conducted a sensitivity analysis of lung dose depending on parameters of exposure to radon progeny [Marsh 2000]. A drawback of this approach is that it cannot detect interactions between input variables. In contrast, variance-based methods allow exploration of the total input parameter space simultaneously, at the cost of computational expense [Saltelli 2000; 2008]. In these global methods, uncertainties are quantified as probability distributions and the output variance is decomposed into parts attributable to input variables and combinations of input variables. If $Y$ is the output from inputs $X_{i\ (i=1,2\ldots d)}$ and $X_{\sim i}$ indicates the set of input variables except $X_i$, the output variance may be decomposed as:

$$\mathrm{Var}(Y) = \sum_{i=1}^{d} V_i + \sum_{i<j}^{d} V_{ij} + \cdots + V_{12\ldots d} \qquad \text{(Eq F.17)}$$

Where $V_i = \mathrm{Var}_{X_i}\left(E_{X_{\sim i}}\left(Y|X_i\right)\right)$; $V_{ij} = \mathrm{Var}_{X_i,X_j}\left(E_{X_{\sim i,j}}\left(Y|X_i,Xj\right)\right)$ and so on. Variance based indices of sensitivity are formed by dividing the terms of this decomposition by *Var(Y)*.

Such an approach has been applied to identify the most important parameter in a biokinetic model [Li 2015a].

# CHAPTER G – Quality Assurance and Criteria for Approval and Accreditation

***MAIN QUESTION***

***Q1*** *How should the quality of internal dose assessments be assured?*

***Subsidiary questions***

***Q2*** *How should the reliability of monitoring data used in the assessment of internal doses be guaranteed?*

***Q3*** *How should the reliability of assessments of dose due to occupational intakes of radionuclides be guaranteed?*

***Q4*** *How is accreditation of internal dosimetry laboratories and services according to ISO/IEC standards obtained?*

***Q5*** *What are the purpose, scope and requirements for participation of internal dosimetry laboratories/services in national and international intercomparisons on monitoring and dose assessment?*

***Q6*** *How should internal doses be recorded and reported?*

***Q7*** *For how long should dosimetry data records be retained?*

***Q8*** *What results should be communicated?*

## Special Terms

Accreditation Body, Approved Dosimetry Service, Audit, Competence, Intercomparison, Internal Dosimetry Service, Occupational Health Service, Qualified Expert, Quality, Quality Assurance (QA), Quality Control (QC), Quality management, Quality management system, Radiation Protection Expert, Radiation Protection Officer, Registrant, Requirement, Traceability, Undertaking, Validation.

## Introduction

This chapter presents the more important issues relating to: quality assurance and quality control for monitoring and for dose assessment; the principles and criteria for accreditation/certification according to ISO/IEC standards; education and training of internal dosimetry experts; intercomparison programmes as part of method validation; and dose recording and reporting.

Individual monitoring for occupational intakes of radionuclides forms part of the evaluation of occupational hazards in radiological protection (see Figure G.1). Results from bioassay monitoring and subsequent dose assessment provide feedback for radiological protection units involved in the management of events bearing risks of radionuclide intakes resulting in internal exposures. Figure G.1 summarises the optimisation of the prevention of risks of radionuclide intakes by means of evaluation

of occupational hazards, taking into account complementary workplace and routine bioassay monitoring data as well as lessons learned from the management of exposure events.

In the context of evaluation of occupational hazards, individual monitoring fulfils a fourfold goal:

1. Regulatory: compliance with dose limits (committed effective dose limits and/or equivalent dose limit to the skin and to the lens of the eye);
2. Health: evaluation of the related risk;
3. Contribution to the radiological cleanness of workplaces according to the optimisation principle (formerly referred to as ALARA, "As Low as Reasonably Achievable");
4. Provision of information to exposed workers on the exposure conditions associated with their work.

Many partners such as dosimetry services, occupational health services and radiation protection experts are involved in the process of individual monitoring. This chapter focusses on the internal dosimetry service (IDS), which perform the monitoring measurements and subsequent dose assessments.

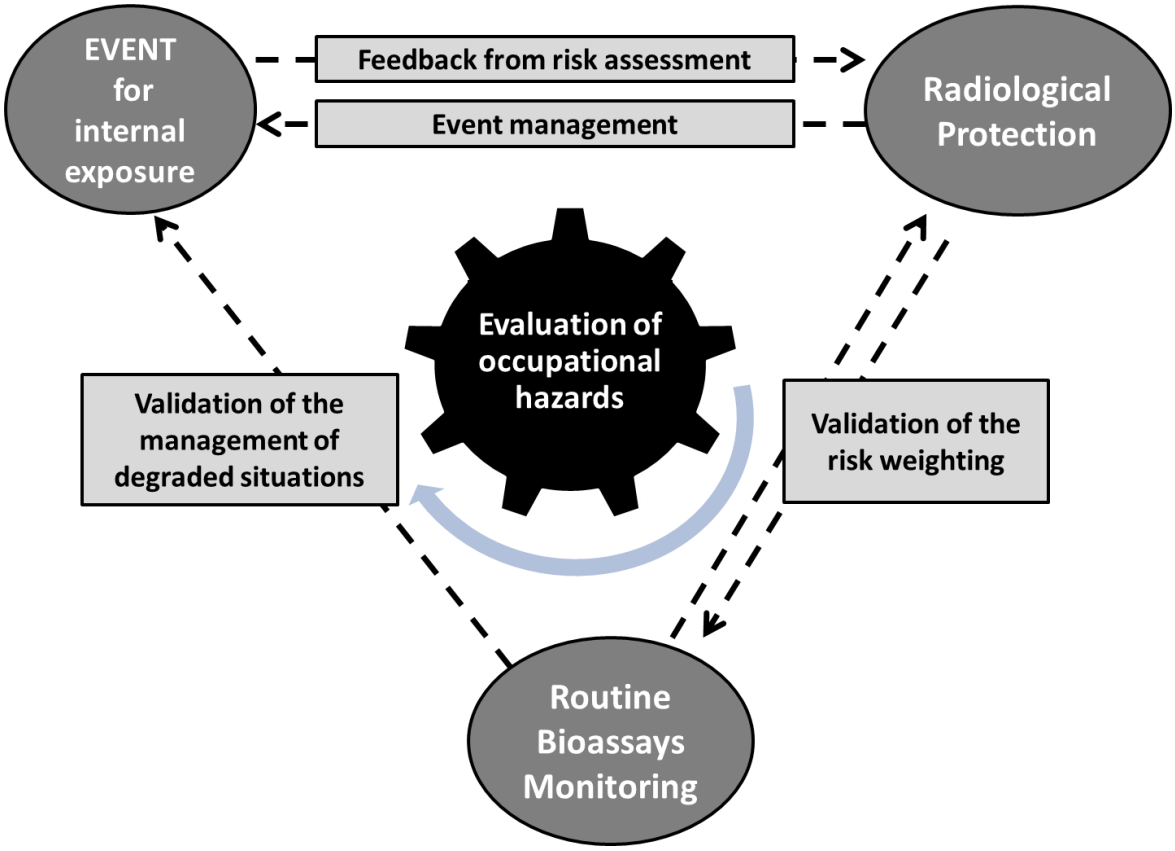



**Figure G.1** Evaluation of occupational hazards in radiological protection

***Q1*** *How should the quality of internal dose assessments be assured?*

To ensure the quality of the IDS over an extended period of time and to guarantee the reliability of monitoring data and dose assessments due to intakes of radionuclides, an appropriate quality assurance programme should be established, based on solid scientific principles and method validation, including participation in national and international intercomparisons.

Implementation of the recommendations presented in the ISO standards on internal dosimetry [ISO 2006; 2010b; 2011], the ISO standards on quality management [ISO 2015a; 2015c] and the ISO standard on general requirements for testing and

calibration laboratories [ISO/IEC 2005], should allow the competence of *in vivo* and *in vitro* monitoring laboratories and of services responsible for the evaluation of intakes and committed effective doses to be demonstrated.

## Quality Assurance (QA) and Quality Control (QC)

### Monitoring

***Q2*** *How should the reliability of monitoring data used in the assessment of internal doses be guaranteed?*

The continued effectiveness of any internal dosimetry programme relies on those responsible for implementing its various components, which include an effective quality assurance (QA) programme. ISO standards 17025:2005 [ISO/IEC 2005], 28218:2010 [ISO 2010b], 20553:2006 [ISO 2006], 27048:2011 [ISO 2011], 16638-1:2015 [ISO 2015d] and 16637:2016 [ISO 2016b] provide an effective basis for such a QA programme.

QA includes quality control, which involves all those actions by which the adequacy of tools and procedures is assessed against established requirements.

The requirements for a documented in-house measurement and dose assessment QA plan that guarantees compliance with operational requirements should be stated in accepted written criteria. These requirements are well described in the section on "Accreditation/Certification according to ISO/IEC Standards", in this chapter.

Management and performance criteria of internal dosimetry laboratories should follow the principles set down in ISO 28218:2010. A summary of all the topics that should be addressed in the QA and QC plans of an IDS follows:

#### QA Plan: Monitoring and dose assessment

- Organisational structure, management and operational responsibilities;
- Qualification and training of laboratory staff;
- Instructions and procedures;
- Document control;
- Identification and control of material and samples (chain of custody);
- Inspection and testing of material and equipment;
- Control and maintenance of calibration standards;
- Validation of methods, procedures and software (e.g. commercial codes for spectra analysis or internal dose assessment);
- Documentation of detection limit and QC results (e.g. accuracy and repeatability tests);
- Periodic performance evaluations including proficiency activity measurements and/or dose assessment tests;
- Corrective actions.

#### QC Plan

- Performance checks of instrumentation, calibration and procedures for *in vivo*, *in vitro* and workplace monitoring;
- Verification of detection limit determinations;
- Performance checks on *in vitro* radiobioassay procedures regarding biological samples;
- Computational checks;
- Use of reference radioactive materials for equipment calibrations (traceable radionuclide reference standards);

- Intra-laboratory analysis;
- Participation in inter-laboratory intercomparison programmes;
- Evaluation of conformance to the performance criteria of ISO standards on internal dosimetry;
- Evaluation of quality control data.

Reviews or audits should be conducted periodically, and also when one of the following conditions prevails:

- when significant changes are made to parts of the assessment procedures, such as staff or management reorganisation or procedural revision;
- to validate the implementation of previously identified corrective actions.

## Dose Assessment

***Q3*** *How should the reliability of assessments of dose due to occupational intakes of radionuclides be guaranteed?*

The assessment of internal doses is a step-by-step procedure where the traceability of the results should be ensured from the start of the process (workplace characterisation and design of individual monitoring programmes) to the end (assessment of committed effective dose, recording and reporting). A summary of steps, tools and reference documents to be applied by IDSs and experts for the assessment of occupational intakes and doses follows:

1. Characterisation of exposure conditions in the workplace (**Chapter E1**)

   This information is essential and should be provided in detail by the Radiation Protection Officer (RPO) or the Radiation Protection Expert (RPE), or by the customer after consulting an RPE on topics including radionuclides (type of radiation, energy, half-life, biokinetics), chemical composition and particle size (AMAD) of materials to which workers may be exposed.

2. Design of routine and special monitoring programmes (**Chapter C**)

   The application of ISO 20553:2006 is recommended for the monitoring of workers exposed to a risk of internal contamination in the facility using the information obtained on characterisation of exposure conditions. Human and economic resources as well as national regulations should also be taken into consideration.

   Specification of a routine monitoring programme consists of establishing appropriate monitoring techniques and frequencies that guarantee the detection of E(50) at the RL, taking into account the availability and sensitivity of the monitoring techniques.

3. Individual monitoring of workers (**Chapter D**)

   *In vivo* and/or *in vitro* measurements should be carried out according to the specified monitoring programme. Monitoring data should be obtained by internal dosimetry laboratories using well-validated methods according to the principles described by ISO 28218:2010, taking into account the QA/QC plans of the laboratory which should themselves be in coherence with ISO/IEC 17025:2005.

   Uncertainties on measurements should be provided together with the monitoring data (**Chapter F**).

4. Assessment of intake and dose (**Chapter E**)

   The interpretation of monitoring data should be carried out as described in **Chapter E**, taking into account ICRP recommendations, models, data and tools, and the structured approaches (see Figure G.2) described in ISO 27048:2011 and the IDEAS Guidelines [EURADOS 2013].

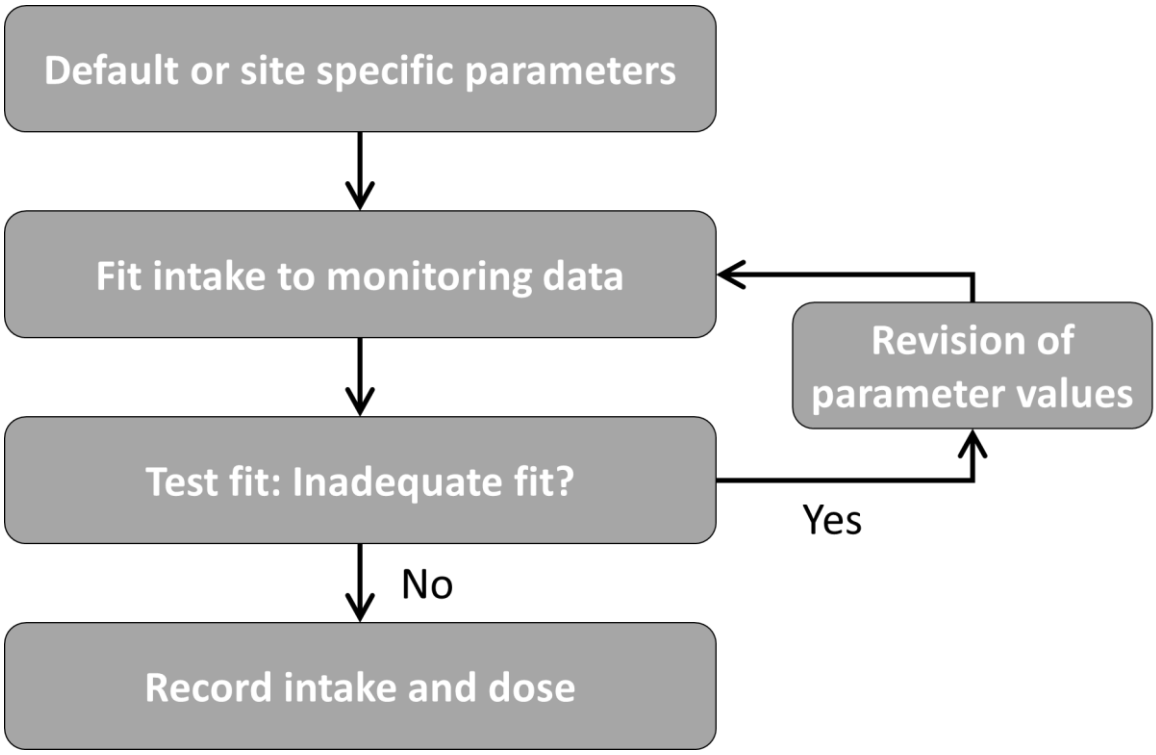



**Figure G.2** Interpretation of monitoring data for the calculation of intake I and dose *E(50)*: step-by-step procedure

Where computer codes are applied for the calculation of doses and/or intakes, compliance with ICRP reference biokinetic and dosimetric models should be demonstrated in addition to compliance with the requirements of those procedures described in ISO 27048:2011 that the codes address.

Available commercial (validated) software should be used with the authorisation of the national competent authority. Examples of commercial software include: IMBA Professional [Birchall 2007a], the IDEA System [Doerfel 2007], and AIDE [Bertelli 2008].

## Accreditation/Certification according to ISO/IEC Standards

### Quality Management

***Q4*** *How is accreditation of internal dosimetry laboratories and services according to ISO/IEC standards obtained?*

The implementation of a quality management system (QMS), accredited or certified, according to international standards has become one of the most important ways of achieving continuous improvement of an organisation.

A series of ISO standards for managing quality systems has been developed over many years, and the work of laboratories is included within their scope. Standards have been developed for quality management (ISO 9001:2015) [ISO 2015c] and for demonstration of the technical competence of testing laboratories (ISO/IEC 17025:2005) [ISO/IEC 2005]. ISO 15189:2012 [ISO 2012a] specifically addresses clinical testing laboratories. These standards are continually updated by ISO, and future revisions should be taken into account by the IDS.

Taking into account the scope of its activities, its risk assessment system and its management system, a laboratory may decide on certification of its activities (in which case an ISO 9001:2015 scheme is necessary). Alternatively, it may decide on accreditation (in which case an ISO/IEC 17025:2005 scheme, or an ISO 15189:2012 scheme, is necessary). Requirements of the national regulatory body and the competent certifying or accrediting authority should be taken into account.

Certification according to ISO 9001:2015 is a confirmation by an independent and recognised authority that the organisation has established a quality management system in accordance with certain requirements defined in standards or specifications.

The accreditation of laboratories under ISO/IEC 17025:2005 or ISO 15189:2012 represents the formal recognition, by a third party, of their competence in carrying out its technical activities and the reliability of their results. An accredited laboratory can be a reference laboratory for other laboratories and industry.

Both accreditation and certification may apply to all of the services provided by the laboratory or just to some of them.

The elements and requirements for quality management listed in the reference standards are described in general terms, so that each one can be applied to laboratories in different fields of operation which use a wide variety of techniques and methods. Each organisation has its own particular characteristics and the quality management system should be designed to fit the needs, objectives and activities of the organisation.

The quality management system should be documented in a quality manual. A quality policy and management procedures and technical procedures also need to be developed, in accordance with ISO 9001:2015 and/or ISO/IEC 17025:2005 specifications. The procedures should include plans for training of personnel, for control of equipment, for validation of methods, and for quality control (including participation in intercomparison exercises). Methods applied by the IDS should be validated, for example by successful participation in intercomparison exercises. The implementation of the system should be demonstrated with appropriate evidence (e.g. by keeping records of QA/QC tests performed). A specific software package could be employed for efficient administration of the system and to ensure that the requirements for documentation according to the relevant ISO standards are met.

Specification of a quality management system implies increased complexity of the activities that guarantee compliance with the requirements, and the activities associated with the implementation of a quality system should be coordinated with routine work activities.

The implementation of a quality management system provides many advantages. Internally, they include a well-defined working structure, optimisation of available resources and control of the processes performed. Externally, advantages include recognition of the technical competence of the organisation to carry out its activities, resulting in a higher degree of customer confidence in the results reported.

## ISO Standards on Quality Systems

### ISO 9001:2015, Quality Management Systems – Requirements

This standard [ISO 2015c] specifies requirements for a quality management system that demonstrates the ability of an organisation to provide a product that meets customer and other applicable requirements, and to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements. It is a generic standard, applicable to all organisations, regardless of type, size and product provided. Conformity to this standard does not imply that the laboratory is competent to produce valid data and results.

### ISO/IEC 17025:2005, General Requirements for the Competence of Testing and Calibration Laboratories

This standard [ISO/IEC 2005] is a generic reference guide, applicable to all laboratories regardless of the scope of testing or calibration activities. It demonstrates that a laboratory operates a system of effective quality management and continuous improvement, is technically competent and able to generate technically valid results. It is divided into two types of requirements:

- Management requirements related to the quality management of the laboratory, which are similar to ISO 9001:2015;
- Technical requirements related to aspects of direct influence on the results of testing and calibration activities.

ISO/IEC 17025:2005 is a reference guide for accrediting bodies to operate the processes of conformity assessment of testing and calibration laboratories, and is used worldwide for accreditation purposes. The Accreditation Body is responsible for assessing compliance with the requirements of the standard and attests to the competence of the laboratory to perform specific test or calibration activities.

### ISO 15189:2012, Medical Laboratories - Requirements for Quality and Competence

This standard [ISO 2012a] is based on ISO/IEC 17025:2005 and ISO 9001:2015, and specifies requirements for competence and quality that are specific to medical laboratories. The results of a clinical laboratory have implications for the health of patients, and the ISO/IEC 17025:2005 standard does not cover all the necessary aspects. ISO 15189:2012 provides guidance and services to the patient and physician, and aims to improve working conditions and biosafety. It covers the entire analytical process, giving importance to biological and analytical variability and instrumental analysis techniques to meet medical requirements and diagnostic utility.

ISO 15189:2012 can also be used for confirming or recognising the competence of medical laboratories by laboratory customers, regulating authorities and accreditation bodies. The standard consists of two main parts. The Management Requirements are similar to the requirements of ISO 9001:2015. The Technical Requirements include topics related to personnel, environmental conditions, patient and staff safety, laboratory equipment, reagents, analysis processes, pre- and post-analysis considerations including sampling, transport of samples, traceability, validation and measurement uncertainty of results, reporting of results and information management.

Ethical issues and human dignity, particularly with respect to sampling and monitoring regimes, are important and should be addressed in accordance with the principles set down in the Convention on Human Rights and Biomedicine [CE 1999]. It is recommended to follow the requirements of ISO 15189:2012 relating to concepts and ethical aspects of protection of information relating to the individual, and the ethical and confidentiality issues relating to laboratory measurements and results.

## Accreditation of Internal Dosimetry Services and Laboratories according to ISO/IEC 17025:2005

ISO/IEC 17025:2005 sets out requirements for testing and calibrating laboratories. It covers tests performed by standard methods, non-standard methods and methods developed by laboratories. The standard is applicable to all laboratories regardless of the number of employees or the scope of the activities of testing or calibration, and so can be used to guarantee the technical competence of radiobioassay, calibration and dose assessment activities. Laboratory customers, regulatory authorities and accreditation bodies may also use it for confirming or recognising the competence of laboratories.

As noted above, ISO/IEC 17025:2005 specifies both management and technical requirements, including requirements on quality management systems to ensure the technical competence of a laboratory. A summary of some aspects of ISO/IEC 17025:2005 follows.

### Management requirements

These requirements are related to the quality management of the laboratory, and cover the following aspects:

- Organisation: The laboratory must meet legal requirements. The responsibilities of key personnel must be identified to avoid conflicts.

- System Quality Management: The laboratory must have policies, procedures, programmes and documents to ensure compliance with the quality requirements.
- Control of documents: There must be procedures to describe all the activities developed in the laboratory. A plan must exist to control the documents.
- Review of requests, tenders and contracts: The laboratory must establish procedures for the review of requests, tenders and contracts with customers to ensure that requirements are reviewed and understood by both parts, before offering any service.
- Subcontracting of tests and calibrations: When for any reason, a laboratory subcontracts other laboratory services, it must be ensured that the subcontracted laboratory is competent to perform the orders requested.
- Purchasing services and supplies: The laboratory must have a procedure for the selection and evaluation of suppliers and subcontractors based on the quality of their products or services.
- Customer service: The laboratory must ensure cooperation with customers, to clarify all the matters related to requests and contracts, and must ensure confidentiality.
- Claims: The laboratory must have a method to address and respond to complaints received from customers, which should be analysed.
- Job Control of nonconforming testing and calibration: This requirement refers to the need for a method to detect, treat and resolve issues that may occur in the normal course of the activities of the laboratory.

### Technical Requirements

The technical requirements of ISO/IEC 17025:2005 address those factors which contribute to the accuracy, reliability and validity of tests and calibrations. The most important factors are:

- Personnel: There must be technically competent personnel to operate the laboratory equipment, to carry out technical activities and to evaluate results.
- Local and environmental conditions: The facilities where the tests or calibrations are performed, including environmental conditions, should permit their adequate performance.
- Test and calibration methods and method validation: The laboratory should use the most appropriate methods and procedures for each test or calibration activity. Methods must be validated before use. The laboratory must have a procedure for estimating uncertainty of measurement.
- Equipment: The laboratory must have all equipment and facilities necessary for the proper conduct of the tests and/or calibrations.
- Traceability of measurements: The laboratory must have a programme and procedure for the calibration of its own equipment.
- Sampling: Sampling plans should be based on appropriate statistical methods and the validity of the results must be ensured.
- Handling of test and calibration: A method for identifying objects for testing or calibration must be established.
- Assuring the quality of test results and calibrations: The laboratory must have a quality control procedure to corroborate the validity of the tests or calibrations performed.
- Reports of results: Results should be reported and should contain all information for their interpretation.

### Education and Training in Internal Dosimetry

One of the most important aspects of the quality management system is the qualification of personnel performing the tests, based on training and work experience, so that each member of staff can relate their work to other parts of the system.

Staff must have adequate knowledge of the quality system and requirements in the laboratory in order to ensure that they are committed to, and take responsibility for, proper operation of the laboratory.

The establishment of specific training plans is essential to maintaining the capacity of staff in the development of technical activities and the maintenance of the management system. Such training programmes should cover all the technical and management aspects deemed necessary. For new personnel, an initial induction plan must be established. The latter requirement has also to be seen in the light of Article 79 of the 2013 Directive [EC 2014], which requires Member States to take measures to ensure the continuity of expertise of services and experts (the IDS, OHS, RPE and MPE).

Training courses, both internal and external, and technical activities supervised by qualified personnel, are all useful for maintaining staff qualifications.

## Participation in National and International Intercomparisons

***Q5*** *What are the purpose, scope and requirements for participation of internal dosimetry laboratories/services in national and international intercomparisons on monitoring and dose assessment?*

Participation in national and international intercomparisons is an essential part of QA and QC programmes and is an important step towards the accreditation of laboratories according to ISO/IEC 17025:2005 [ISO/IEC 2005].

Laboratories performing internal dose assessments should participate in national or international inter-laboratory comparisons ("intercomparisons"). These exercises allow participants to compare the results of dose assessments made under clearly defined conditions with reference values and with the results of other laboratories. Intercomparisons of the results of interpretations of monitoring data from case studies are useful in improving the reliability of the results and facilitating the harmonisation of methods nationally and internationally.

### Advantages and Requirements

Participation in intercomparison programmes has great advantages from various perspectives. First, it can be considered as an essential part of quality control activities, checking and demonstrating that the measurement or dose assessment procedure applied meets performance criteria requirements. Systematic deviation from the true or expected values indicates the need to determine the reason for any discrepancy and the need to improve the method used, the calibration, etc. (if necessary). Another advantage is that since most intercomparison exercises are organised at international level, satisfactory performance provides evidence that can promote international acceptance of the measurements and the dose assessments provided by the laboratory.

A summary of information relating to national and international internal dosimetry intercomparisons is presented in the Appendix of this chapter.

## Dose Recording and Reporting

***Q6*** *How should internal doses be recorded and reported?*

The strategy and objectives for the monitoring of workers for occupational intakes of radionuclides should be documented. The dose records should set out the purpose and the frequency of each type of measurement and the way the monitoring results are interpreted for the assessment of the intake and the committed effective dose.

Dose recording and reporting should reflect the objectives of the monitoring programme, and should include the basis for the interpretation of the individual monitoring results in respect of regulatory requirements. Records of individual occupational exposure should include any assessed committed effective dose, intake and equivalent dose to the skin, as appropriate. Details of any involvement of the worker in abnormal events that may contribute to dose should be included. It is also important to retain records referencing the monitoring methods and biokinetic and dosimetric models used for data analysis and interpretation, because they may be needed for future interpretation of the records of occupational exposure. Traceability of the measurement results and the dose assessment is essential.

## Recording Obligations and Recording Levels of Internal Dose

Dose record keeping is a requirement of the 2013 Directive [EC 2014] and applies to all partners involved in internal dose assessment. Apart from demonstrating compliance with legal regulations, dose records may also be used many years later in the event of a claim for compensation or for epidemiological studies (**Annex IV**).

According to ISO 20553:2006 [ISO 2006], committed effective doses (*E(50)*) above or equal to the recording level (RL) (which is set to be no more than 5% of the dose limit, i.e. 1 mSv $y^{-1}$ for a dose limit of 20 mSv $y^{-1}$) must be recorded. One year is defined as twelve consecutive months or as one calendar year, depending on national regulations. The RL is the reference level used to initiate the actions implemented as a result of including the dose in the worker's annual accumulated dose record (see **Chapter C**). Values of total annual internal dose less than the recording level do not need to be recorded, but "below recording level" should be added to the dose record to show that the individual was subject to routine internal monitoring.

Dose values below the recording level may need to be recorded, depending upon the frequency of the monitoring and magnitude of the assessed dose. For instance, if a cumulative annual dose may reach the RL, then with n monitoring periods per year, the effective recording level for each monitoring period would be RL/n.

As a general approach, for an RL of 1 mSv:

(1) if *E(50) is* below 0.1 mSv, no dose value is to be recorded;

(2) if *E(50)* from a single intake falls in the range 0.1-1.0 mSv, it should be included in the annual accumulated *E(50)*;

(3) if the annual accumulated *E(50)*, over a twelve consecutive months period or during the calendar year (depending on national regulations), is equal or greater than 1 mSv, it should be recorded.

## Dose Record Keeping and the Transfer of Data

According to the 2013 Directive, employers, registrants and undertakings must maintain records of occupational exposure for every worker for whom assessment of occupational exposure is required, must provide workers with access to records of their own occupational exposure and must provide the supervisor of the programme for workers' health surveillance with access to those records.

The 2013 Directive also states that the competent authority and the relevant employer with access to workers' records of occupational exposure must facilitate the provision of copies of workers' exposure records to new employers when workers change employment, must make arrangements for the retention of exposure records for former workers by the employer, registrant or undertaking, as appropriate and must give due care and attention to maintaining the confidentiality of records.

Many roles are involved in the process of individual monitoring. Data are generated in many places and for proper dose recording and dose record keeping, all roles must interact effectively. According to Article 43 of the 2013 Directive, all dose records from individual monitoring should be transferred to a data system for radiological monitoring. The data system could be implemented either as a network or as a

National Dose Register maintained by the competent authority. The duties of the main partners involved in maintaining dose records are described below.

### Approved Dosimetry Service

As a general approach, approved Internal Dosimetry Services should be either responsible for, or informed of, the planning of the monitoring programme. Therefore, dosimetry services should be informed of work situations and levels of exposures (see **Chapters C and E**), then design the monitoring programme in the light of risk assessment and management (see Figure G.1) (or be informed of its design), and finally proceed with monitoring and dose assessment. All the information related to exposure conditions, the monitoring programme, and the dose assessment should be recorded.

Individual monitoring carried out by Approved Dosimetry Services should ensure that any significant intake [ISO 2006] is detected at an early stage, based on a suitable combination of *in vivo* measurements and *in vitro* analysis (**Chapter C**). The design should include the basis for the interpretation of the monitoring results and should specify how this meets the objectives of the programme. All data should be recorded.

### The undertaking

The undertaking must maintain records of occupational exposure as required by legislation, and should grant workers, at their request, access to the results of their individual monitoring. The undertaking should also inform workers of the importance of complying with the monitoring requirements. In the case of outside workers, the employer should interact with the undertaking to ensure that all requirements relating to the workers are met.

### The worker

The worker is responsible for correctly following the instructions of all monitoring programmes put in place in the workplace (for example, attending appointments for *in vivo* measurements, complying with the instructions for biological sample collection).

### Radiation Protection Expert (RPE)

The RPE is an individual having the knowledge, training and experience needed to give radiation protection advice in order to ensure the effective protection of individuals, and whose capacity to act is recognised by the competent authorities [EC 2014]. The 2013 Directive states that the RPE must, on the basis of professional judgment, measurements and assessments, give competent advice to the undertaking on matters relating to occupational exposure and public exposure; and that the advice of the RPE must cover, among others, the following matters:

- the classification of workers;
- the content of workplace and individual monitoring programmes;
- appropriate methods of personal dosimetry.

### Radiation Protection Officer (RPO)

The RPO is an individual who is technically competent in radiation protection matters relevant to a given type of practice and is designated by the undertaking to oversee the implementation of the radiation protection arrangements of the undertaking [EC 2014]. The tasks of the RPO may be carried out by a radiation protection unit established within an undertaking or by an RPE. The tasks of the RPO include, among others:

- supervision of the implementation of the programme for workplace monitoring;
- maintainance of adequate records of radioactive sources;
- supervision of the implementation of the personal monitoring programme.

In general terms, the RPO provides information on the characterisation of the workplace, and for the design of individual monitoring programmes in the event of risk of occupational intakes of radionuclides at the workplace. The results and findings of

workplace monitoring (air monitoring, swipe tests, monitors, etc.) should be recorded and made available to radiological management.

The RPO and the RPE should have access to the internal dosimetry results of individual monitoring (unless national regulations indicate differently). Management should record information about the way in which optimisation of protection and safety is implemented and should disseminate the information where appropriate.

### Occupational Health Service (OHS)

An OHS is responsible for guaranteeing appropriate health conditions and the capacity of the worker, and should have access to the internal dosimetry results of the individual monitoring of workers. All medical data should be recorded.

According to the 2013 Directive, Approved Dosimetry Services must determine the internal and external dose to exposed workers subject to individual monitoring in order to record the dose, in cooperation with the undertaking and the OHS. In some countries, dosimetry data is considered as confidential medical data, and is managed by the OHS.

## Content of the Dosimetry Data Records for Individual Monitoring

The internal dosimetry laboratories and services should maintain records of exposure information, measurement data and dose assessment results. Final assessed doses should be passed to the dose record keeping service where they are maintained with the rest of the individual's dose record.

## Duration of the Dosimetry Data Files of Individual Monitoring

***Q7*** *For how long should dosimetry data records be retained?*

Dosimetry records should be confidential and should be preserved in a manner approved by the competent authority. According to the 2013 Directive, dosimetry records:

> *shall be retained during the period of the working life of the workers concerned involving exposure to ionizing radiation and afterwards until they have or would have attained the age of 75 years but in any case not less than 30 years after termination of the work involving exposure.*

## Dose Assessment and Dose Reporting

Results should be reported to the customer accurately and in a comprehensible way so as to fulfil the requirements of regulatory bodies and to meet the needs of customers.

### Report Keeping for Workplace Monitoring

Records should be kept to demonstrate compliance with regulations, for the identification of significant changes to the working environment, to retain details of radiation surveys (e.g. date, time, location, radiation levels, instruments used, surveyor), and to retain the results of measurements of concentrations of radionuclide(s) in air that may be used to quantify workers' exposure if the monitoring programme does not require mandatory individual measurements. In this case, the dose assessment procedure assumes that the measured activity concentration is representative of the air in the breathing zone. Finally the hypothesis and methods of internal dose assessment (including default parameter values of biokinetic models used, software) and details of any appropriate actions taken should be recorded.

### Report Keeping for Individual Monitoring Data

ISO/IEC 17025:2005 [ISO/IEC 2005] and ISO 28218:2010 [ISO 2010b] state that sufficient records must be kept of the details of all measurements, including the results, instruments used, calibrations, background measurements, quality control, uncertainties, etc. Exact conditions of measurement should be reproducible. These standards specify a number of specific requirements: all reports and records must be authenticated by the competent responsible person; account must be taken of national requirements in respect of record-keeping; each measurement and each analysis must

be given a unique identification; in the case of sample measurements, this identification must be used to denote the identity of the sample measured and the date and time of the collection of the sample and the date and time of the measurement of the sample; and in the case of direct measurements on individual workers, the identification must denote the identity of the worker and the date and time of the measurement.

### Report Keeping for Dose assessments

The procedure for assessing committed effective dose *E(50)* should be documented. This should include the assumptions made in respect of temporal pattern of intake (acute, chronic), route of intake (inhalation, ingestion, etc.), the default or specific values of AMAD and $f_A$ used, the chemical and physical nature of the radioactive aerosol, and assumptions on the absorption Type. The dose calculation should be recorded if it is done manually. If computer software is used to calculate the dose, the identity of the software used should be recorded together with all parameter values used in the calculation. Results should be expressed in terms of 50-year committed effective dose, *E(50),* (in units of mSv or Sv). For routine monitoring, the dose recorded should be that resulting from intakes occurring during each monitoring interval. Dose results below the predefined recording level may be reported as "below recording level" (as specified by ISO 27048:2011 [ISO 2011]).

### Traceability of Internal Dose Assessment

Dose records should be easily retrievable and should preserve the consistency of data fields in order to allow the reconstruction of results at any later time. Consideration may need to be given to any applicable national requirements or international agreements concerning the privacy of individual data records.

### Access to the Results of Individual Internal Dose Assessments

***Q8*** *What results should be communicated?*

The results of the individual doses due to occupational intakes of radionuclides should be made available to the worker concerned, to the undertaking (and in the case of outside workers additionally to their employer), to the competent authority and to the data system for individual radiological monitoring (e.g. a National Dose Register). Committed effective dose results should also be made available to the OHS in order that the implications of the results for human health may be assessed [EC 2014]. Intake data from the monitoring programmes and dose records are treated as personal data and provisions should be made for confidential communication of this type of data among the partners involved in individual monitoring.

Responding to actual intakes or incidents, and performing the required dose assessments, is an invaluable source of experience for dosimetry service staff. Whether or not such experience is acquired, a a a good level of technical competence, education and training should be guaranteed, and so the following measures are recommended:

- employee training and/or periodic information about workplace risk prevention (in association with the RPO), and about biological effects of radiation, and available treatments;
- presentation of systematic and special monitoring protocols to managers, the risk prevention committee, personnel representatives and workers.

Following a contamination event, it is necessary:

- to inform the worker of their results;
- to explain the need for repeated measurements to increase dose assessment accuracy, rather than suggesting that there is uncertainty in the results (which can be source of anxiety);
- to explain the dose assessment approach;

- to separate regulatory aspects (requiring assessment of effective dose) from any assessment of health risks (requiring assessment of absorbed doses to organs);
- to provide psychological counselling, if necessary.

### Dose Information Systems

A data system for individual radiological monitoring must be implemented by the Member State [EC 2014]. Annex X of the 2013 Directive gives the general requirements for the system, which may be realised either as network or as a National Dose Register. The arrangements should be made for each itinerant worker, providing up-to-date records of the doses received and of health surveillance. This could take the form of an output from a centralised database of workers' exposure records or an individual radiological monitoring document (sometimes referred to as an individual radiation passbook) or alternatively an individual dose record. The information stored in the data system should allow follow-up of doses received by a person during their whole working life.

### Information to Workers

When informing workers of their monitoring results and the consecutive dose assessment due to intakes of radionuclides in the workplace, the occupational health practitioner, the head of the internal dosimetry service and the RPOs and RPEs should all take into consideration the potential psychological impact of providing this information.

The general presentation of radiological risk should be adapted to the worker's level of understanding and the emotional impact on the worker of information previously provided.

## Recommendations

| R# | G | Text of the recommendation |
|---|---|---|
| | | ***Q1**: How should the quality of internal dose assessments be assured?* |
| G01 | A | An appropriate quality assurance programme should be established to ensure the quality of internal dosimetry services and to guarantee the reliability of monitoring data and internal dose assessments. |
| | | ***Q2**: How should the reliability of monitoring data used in the assessment of internal doses be guaranteed?* |
| G02 | I | It is recommended that monitoring should conform to the performance criteria of the ISO standards on internal dosimetry [ISO 2006; 2010; 2011; 2015d, 2016b] and ISO/IEC 17025:2005 [ISO/IEC 2005].<br>Participation in inter-laboratory measurement intercomparison programmes and appropriate training of the employees are recommended. |
| | | ***Q3**: How should the reliability of assessments of dose due to occupational intakes of radionuclides be guaranteed?* |
| G03 | I | It is recommended that dose assessment procedures should conform to the quality assurance and quality control criteria and recommendations established in ICRP publications [ICRP 2007; 2015b], ISO 27048:2011 [ISO 2011], the IDEAS Guidelines [EURADOS 2013], IAEA publications [e.g. IAEA 2014] and the 2013 Directive [EC 2014].<br>Participation in intercomparison programmes of dose assessments of internal exposures and appropriate training of the employees are recommended. |
| | | ***Q4**: How is accreditation of internal dosimetry laboratories and services according to ISO/IEC standards obtained?* |
| G04 | I | The process of implementing any quality standards requires the implementation of a management system and appropriate documentation and procedures and requires the commitment of the organisation in terms of facilitating economic and personal support.<br>A test or calibration laboratory seeking recognition of their technical competence by means of accreditation under ISO/IEC 17025 [ISO/IEC 2005] should meet and show evidence of compliance with all of the requirements contained in that standard. |
| G05 | I | A Quality Manual, a quality policy and management and technical procedures should be developed and records kept as evidence of its implementation. Specific software for quality management system administration may be used to allow more efficient handling of the quality system [ISO/IEC 2005; ISO 2012a, 2015c]. |
| G06 | I | Plans for training of personnel, for control of equipment, for validation of methods, and for quality control (including participation in intercomparison exercises) should be established [ISO/IEC 2005; ISO 2012a, 2015c]. |
| G07 | I | Requirements of the Competent Authority should be taken into account. In the case of accreditation for assessments of dose, a quality management system based on international standards and ICRP recommendations should be used to avoid subjectivity.<br>If implementation is adequate and operation of the quality management system found to be successful, the organisation should apply for accreditation to the National Accreditation Body. |
| | | ***Q5**: What are the purpose, scope and requirements for participation of internal dosimetry laboratories/services in national and international intercomparisons on monitoring and dose assessment?* |
| G08 | A | It is recommended to participate in intercomparison programmes of *in vivo* and *in vitro* monitoring and dose assessment whenever possible as the final step of method validation. In many countries, participation is a mandatory requirement for accreditation of both measurements and assessment of doses resulting from occupational intakes of radionuclides. |
| | | ***Q6:** How should internal doses be recorded and reported?* |
| G09 | A | Approval procedures for dosimetry services in relation to dose recording and reporting should state the justifications for the monitoring programme, the monitoring and |

| R# | G | Text of the recommendation |
|---|---|---|
| | | reporting periods, the dose information to be reported and the internal dose assessment methods (including principles and software used), specifying the recipient(s) of the dose report. |
| G10 | M | Every Member State must define and fix a recording level (RL) for committed effective dose, E(50) [EC 2014]. |
| G11 | I | An RL of 1 mSv $y^{-1}$ is recommended. If the annual accumulated *E(50)*, over a period of twelve consecutive months or during the calendar year (depending on national regulations), is equal to or greater than 1 mSv, it should be recorded. Values of total annual internal dose less than 1 mSv do not need to be recorded, but an entry "below recording level" should be added to the dose record to show that the individual was subject to routine internal monitoring [ISO 20553]. |
| G12 | A | For doses above the RL, traceability information should be recorded, together with all parameter values used in the assessment (exposure conditions, physico-chemical properties of the compound to which the worker is exposed, justification of the assumptions made, the software used, and the results). |
| | | ***Q7:*** *For how long should dosimetry data records be retained?* |
| G13 | M | Every Member State must create and maintain a data system for individual radiological monitoring, either as a network or as a National Dose Register, that contains internal dose values for each worker for whom assessments of occupational exposure are required. Dosimetry records must be retained during the period of the working life of the worker concerned and afterwards until they have or would have attained the age of 75 years, but in any case not less than 30 years after termination of the work involving exposure [EC 2014]. |
| | | ***Q8****: What results should be communicated?* |
| G14 | A | Every Member State should guarantee the communication of intake data and dosimetry data (that is, the internal dose component for workers) by means that takes into account confidentiality aspects of this information. The communication should also consider the psychological impact on the individual. |

G= Grade: M = Mandatory, I = International, A = Advisory

# Appendix to Chapter G

## Internal Dosimetry intercomparisons

### Intercomparisons and Intercalibrations

Internal dosimetry intercomparisons (of monitoring and dose assessment) and intercalibrations are effective mechanisms for upgrading dosimetry programmes. Some programmes referred to as intercomparisons are actually intercalibrations, and it is important to distinguish between the two, particularly when organising such an activity and establishing objectives. An intercomparison may be considered to be a programme of measurement or information interpretation using participants' standards or references, to assess the comparability of results. An intercalibration may be considered as a programme of measurements conducted using a single standard, a set of standards or reference values to establish a common basis for measurement.

### *In vitro* and *in vivo* Method Comparisons: a Tool for the Validation of Individual Monitoring Methods

Any practices involving radiation exposure need to be licensed or authorised for operation by the national regulatory authorities, which establish all the requirements for good practices. The reliability of the results of measurements is an important requirement. The technical competence of the service laboratories is demonstrated by approval, authorisation or accreditation. A number of technical steps can be taken to improve internal dosimetry programmes. The requirements cover several items, including the implementation of QA and QC programmes, equipment, facilities, personnel qualifications and technical procedures [ISO/IEC 2005; ISO 2012a].

#### Requirements

*In vivo* monitoring and *in vitro* analysis are highly technical fields and are carried out by a relatively small number of specialists. QC programmes must include, as a minimum:

- review of procedures;
- specifications and operating logs;
- evaluating compliance with written performance criteria;
- instrument calibration records;
- use of traceable radionuclide standards;
- interlaboratory comparisons;
- daily response checks of measurement systems.

#### Performance Criteria

Guidelines are laid down in several countries, based on standards specifying requirements on measurements in which performance criteria, mostly for the quantities of relative bias and relative precision, are formulated:

- ISO/IEC 17043:2010 [ISO/IEC 2010] describes different types of proficiency testing schemes and gives guidance on the organisation and design of these schemes;
- ISO 13528 [ISO 2015b] is complementary to ISO/IEC Guide 43, and provides detailed guidance that is lacking in that document on the use of statistical methods in proficiency testing. It is to a large extent based on a harmonised protocol for the proficiency testing of analytical laboratories, but is intended for use with all measurement methods;
- ISO 28218:2010 [ISO 2010b] establishes the requirements commonly accepted for the bias (accuracy) and precision (repeatability) of measurements, i.e.:

- Relative bias ($B_r$) : -0.25 < $B_r$ < +0.50

  where

$$B_r = \frac{1}{N}\sum_{i=1}^{N} B_{ri}$$

$$B_{ri} = \frac{A_i - T}{T}$$

  $A_i$ is the activity of the $i^{th}$ measurement, $B_{ri}$ is the relative bias of the $i^{th}$ measurement, T is the true activity, and N is the number of measurements.

- Relative precision (repeatability) ($S_B$)

$$S_B = \sqrt{\frac{1}{N-1}\sum_{i=1}^{N}\left(B_{ri} - B_r\right)^2} \leq 0.4$$

The relative bias involves systematic errors while the relative precision has a random character.

### Objectives of Intercomparisons

Properly formulated and executed programmes should address several objectives:

- Evaluation of the abilities of participating dosimetry services to conduct individual monitoring;
- Provision of access to unique calibration resources, phantoms and facilities;
- Provision of assistance to participants in identifying and correcting problems;
- Comparison of the performance of various detector systems and methods for assessment of radionuclides;
- Comparison with other phantoms and calibration methods used by each facility;
- Provision of a forum for the exchange of information and increased experience;
- Provision of training for dosimetry service staff;
- Provision of information to management to obtain resources for upgrading counting systems; and
- Provision of information that can be given to regulatory authorities to demonstrate compliance with regulations.

Furthermore, internal dosimetry comparisons can be effective mechanisms for upgrading dosimetry programmes.

## *In vivo* Measurement Intercomparisons

A number of intercomparisons have been conducted in recent years at national, regional and inter-regional levels [Thieme 1998; Kramer 1999; 2001; Bérard 2011; IAEA 2013]. There are essentially two types: measurement and interpretation. Measurement intercomparisons generally involve use of one or more phantoms containing one or more radionuclides. Radionuclides are present usually either in a solid form such as pre-loaded, simulated organs or as discrete sources that can be inserted at specified locations in the phantoms. The objective of measurement intercomparisons is to assess the participant's ability to quantify the body or organ content of radioactive material. A variety of phantoms have been fabricated for calibration and intercomparison purposes [ICRU 1992]. The selection of a phantom depends on the specific objectives of the programme.

A practical aspect of such intercomparisons is that phantoms need to be robust and be suitably housed for transportation between laboratories. Some specialised phantoms have been developed for this purpose, such as the St. Petersburg Phantom [Kovtun

2000], used for the first time in the EC 1995/96 European intercomparison of *in vivo* monitoring systems [Thieme 1998]. The phantoms must be transported according to legal requirements and the "European Agreement concerning the International Carriage of Dangerous Goods by Road" (ADR) [ECE 2014].

The normal method of carrying out such intercomparisons is to construct a phantom, or a set of phantoms, with a radionuclide content that is traceable to a national standard. The half-lives and activities of the radionuclides must be chosen so that all should be measurable throughout the schedule of measurements by all participating laboratories. The phantom is then circulated to participating laboratories for measurement. Usually, laboratories are asked to identify the radionuclides in the phantom and quantify their activities. The phantoms may be designed to investigate technical issues such as subject size, e.g. by use of child phantoms; radionuclide distribution, by having a non-uniform but known distribution of one or more radionuclide in the phantom; wound monitoring; or the measurement of low energy photon-emitting radionuclides.

Intercomparison exercises are the best tools to check and demonstrate the capability and quality of whole body counter measurements. Participation in intercomparison programmes has a number of important benefits. First of all, it can be considered as an essential part of QC activities, checking and demonstrating that the applied measuring procedure meets the requirements formulated for performance criteria. Systematic deviation from the true or expected values indicates the need to determine the reason for any discrepancy and the need for improvement of the method used, the calibration, etc. (if necessary).

The results of such intercomparison measurements must, however, be treated with caution and with certain precautions. In most cases, the final outcome of the intercomparison indicates only whether the agreement of the results obtained by the participants is good or bad; that is, it provides relative results only. If a phantom is the subject of the intercomparison, then the degree to which the human body and the radionuclide distribution are simulated may be open to question, while in the case of a human subject, knowledge of the radionuclide activities present is usually uncertain. Nevertheless, participation in intercomparison programmes is a very valuable and necessary part of QC procedures; all the more so because the above-mentioned sources of systematic uncertainty can be kept, with proper care, well within the range of performance criteria specified for the relative bias.

### *In vitro* Bioassay Measurement Intercomparisons

In comparison with *in vivo* measurements, the position with respect to availability of suitable intercomparison exercises for bioassay measurements is much more straightforward.

Several series of intercomparisons are conducted, of which the most important is that conducted annually by the Association for the Promotion of Quality Control in Radiotoxicological Bioassay (PROCORAD, http://www.procorad.org/uk/index.html). PROCORAD was founded by the Association of French Nuclear Industry Biologists (ABNF), which draws its members from CEA (the French Atomic Energy Commission), COGEMA (Nuclear Fuel Corporation), EDF (Electricité de France) and the French Armed Services. It organises bioassay intercomparisons in order to verify the quality of measurements made by participating laboratories, and to promote good laboratory practice [Bérard 2003; 2011].

Intercomparisons are devoted to radiochemical analysis of urine samples or faecal ash samples in real matrices. The samples to be analysed are either from real internal contamination cases or are spiked, with levels of activities likely to be encountered in practice in occupational monitoring. Although the original participants were exclusively French, participants now include 70 laboratories from 20 different countries who take part, each year, in the proficiency testing programmes.

PROCORAD organises a scientific meeting each year during the Association's General Assembly, which is held alternately in France and in other countries. A technical report is published each year in French and English.

The experience shows that PROCORAD offers a comprehensive, regular and well organised intercomparison programme. A major positive attribute of PROCORAD's programme is that it operates to a well-established schedule, with an annual cycle time. As a result, both laboratories and regulators can be confident that results will be provided by the specified date.

Other *in vitro* monitoring exercises have been organised at the international level in the context of individual routine monitoring (e.g. the BfS (Germany) intercomparisons), and for accidental intakes in the event of a radiation emergency (e.g. the 2014 EURADOS Emergency Bioassay intercomparison [Li 2015b]). The development of *in vitro* monitoring protocols for use in the event of radiological and nuclear accidents is an important issue for bioassay laboratories. Such protocols aim to optimise sample collection time, radiochemistry analysis time (if appropriate) and measurement time, while keeping reasonable levels of uncertainty and sensitivity of the techniques (taking into account the dose scenarios) and guaranteeing reliability in the results. Further *in vitro* emergency monitoring intercomparisons are expected.

## Intercomparison Exercises on Internal Dose assessment: a Tool for Harmonisation

The second phase of monitoring, i.e. dose assessment, is particularly important because of the number of variables and uncertainties involved. Although ICRP and IAEA have published extensive tables of dose per unit intake (dose coefficients), these are default values based on assumptions about the various parameters that may not be valid in specific situations. Determination of the intake and the resulting committed effective dose can, therefore, be approached in many different ways, depending on the amount and quality of the data, the skill of the dosimetrist, computational tools available and the assumptions made. When a set of bioassay data is given to two different dosimetrists, it is commonly found that these data are interpreted differently, and different numerical solutions are obtained.

### The 3rd European Intercomparison Exercise on Internal Dose Assessment

This issue has been demonstrated in various intercomparison exercises [IAEA 1999b; Doerfel 2000]. The 3rd European Intercomparison Exercise on Internal Dose Assessment [Doerfel 2000] is a good example; it specifically considered the effects of the new models and the choice of input parameter values on the assessment of internal doses from monitoring results. The results in terms of intake and committed effective dose were roughly lognormally distributed with the geometric standard deviation ranging from 1.15 for cases involving $^{3}H$ and $^{137}Cs$ intakes, up to 2.4 for cases involving $^{239}Pu$ intakes. A key feature of the exercise was a Workshop, involving most of the participants, at which each case and the approaches taken in assessing it were discussed.

Reasons for the differences in the results were identified, including different assumptions about the pattern of intake, and the choice of model. One of the main reasons for differences in results was that the intercomparison included laboratories which did not necessarily have specific experience in the type of case studies used. The most important conclusion of the exercise was the need to develop agreed guidelines for internal dose evaluation procedures in order to promote harmonisation of assessments between organisations and countries. This has particular importance in EU countries, because of the mobility of workers between Member States.

### The joint Intercomparison Exercise under the 5th Framework Programme and IDEAS Project

After the 3rd European Intercomparison, the need for harmonisation of the procedures for internal dose assessment was recognised within an EU research project under the 5th Framework Programme. The IDEAS project was designed with the goal of

developing general guidelines for standardising assessments of intakes and internal doses.

The IDEAS Guidelines have been revised and refined on the basis of the experiences and discussions at a Virtual Workshop. A joint intercomparison exercise on internal dose assessment was then organised and conducted in 2004 in collaboration with IAEA, in order to test the guidelines and to provide an opportunity for the participating laboratories to check the quality of their internal dose assessment methods [Hurtgen 2007]. This was open to all internal dosimetry professionals. Six cases were developed and circulated together with a copy of the revised IDEAS Guidelines, which participants were encouraged to follow, to test their applicability and effectiveness. The results were collated and a workshop was organised early in 2005 with the IAEA to discuss the results of the exercise with all interested participants. The final version of the Guidelines [EURADOS 2013] has been offered as a basis for national and international guidance.

However, exercises of this type contain a degree of artificiality. In reality, dose assessment cases develop over a period of weeks, months or even years and the assessor is involved in decision-making at almost every stage of this process. Organised by the UK's Internal Radiation Dosimetry Group (IRDG), a real-time internal dose assessment exercise was conducted, in which participants were required to make decisions about sampling requirements, seek relevant information about the 'incident' and make various interim dose assessments [Bingham 2013]. At the end of the exercise, each participant was requested to make a formal assessment, and to provide statements of the methods, models and assumptions used in that assessment. The results show that the methods and assumptions used by the assessors differed considerably and the intakes obtained show quite a large variation. The choice of these differing assumptions may reflect the difficulties some participants reported in interpreting and applying the IDEAS Guidelines in this case. However, the assessed committed effective dose seems to be a relatively robust quantity, with much less variation than was found for the assessed intake.

# CHAPTER H – Radon Measurement and Dosimetry for Workers

***MAIN QUESTION***

***Q1*** *How should workers be protected against radon exposure?*

***Subsidiary questions***

***Q2*** *What are the strategies for radon risk communication?*

***Q3*** *How should it be ensured that measurements are reliable?*

***Q4*** *What measurement strategies for workplace monitoring should be adopted to demonstrate compliance with reference levels and dose limits?*

***Q5*** *When should radon progeny measurements be employed?*

***Q6*** *When should individual monitoring be employed?*

***Q7*** *Which dose coefficients should be used?*

## Introduction

Radon is an inert gas that is encountered in elemental form either as a gas or dissolved, usually in water. There are a number of isotopes of radon but the most important isotopes for radiation protection are $^{222}$Rn (radon) and $^{220}$Rn (thoron). They are formed as decay products of radium isotopes ($^{226}$Ra and $^{224}$Ra), which are members of the two natural radioactive decay series, headed by the primordial radionuclides $^{238}$U and $^{232}$Th respectively. Uranium and thorium occur naturally in soil and rocks and provide a continuous source of radon. Radon gas emanates from the earth's crust and as a consequence is present in the air outdoors and in buildings. Radon and its short-lived progeny can reach high concentrations within enclosed spaces, and as a result gives rise to a radiation hazard. This applies to all buildings, and particularly to workplaces such as underground mines, natural caves, tunnels, thermal spas, and water supply facilities where ground water with a high radon concentration is treated or stored. Exposure to radon in buildings may also arise in areas contaminated with radium from past industrial activities. Outdoor radon levels are generally low. There are exceptions, such as in mid-continent locations or as a result of stable air, for instance a temperature inversion, but these factors are generally not amenable to control and radon levels are generally much lower than the levels at which control is considered.

In general, the problems posed by radon ($^{222}$Rn) are much more widespread than those posed by thoron ($^{220}$Rn). Radon ($^{222}$Rn), which has a half-life of 3.8 d, can migrate in the ground before decay. As a result, the ground underneath buildings is usually the main source of indoor radon ($^{222}$Rn): soil gas carrying radon enters the building mainly due to pressure driven convective flow. The radon levels in a building, thus, depend on the local geology, on details of the building construction, and on factors that affect the pressure differential between the inside and outside of the building such as ventilation rates, heating within the building and meteorological conditions. The radon levels also show large, random short-term fluctuations over periods of hours and days; tend to exhibit diurnal, seasonal and annual variations; and can vary greatly between buildings even within the same geological area. In

contrast, because thoron has a very short radioactive half-life, (56s), it is less able than radon ($^{222}$Rn) to escape from the point where is formed. Consequently, building materials are the most usual source of indoor thoron exposure. In general, for buildings with high levels of radon, thoron and its progeny is not an important additional source of exposure unless the materials of the internal surfaces of the building have a high content of thorium.

This chapter mainly focuses on control of radon ($^{222}$Rn) in the workplace. It covers measurement strategies, individual and workplace monitoring, measurement devices and dose assessment.

## Protection against Radon for Workers

***Q1**: How should workers be protected against radon exposure?*

ICRP's protection policy against radon is based on setting reference levels and applying the principle of optimisation to reduce exposures as low as reasonably achievable (ALARA). For indoor radon, the reference level is expressed as an annual average radon activity concentration and represents a level where action would almost certainly be warranted to reduce exposure. In its latest publication on 'Radiological Protection against Radon Exposure', ICRP recommends an upper reference level of 300 Bq $m^{-3}$ for all workplaces and for dwellings [ICRP 2014]. However, it is the responsibility of competent authorities to establish their own national reference level (NRL), taking into account the prevailing economic and societal circumstances and then to apply the process of optimisation of protection in their country. Council Directive 2013/59/Euratom [EC 2014] states in its Article 54 that:

> *the reference level for the annual average activity concentration in air shall not be higher than 300 Bq $m^{-3}$, unless it is warranted by national prevailing circumstances.*

If following optimisation, the annual average radon concentration in a workplace continues to exceed the NRL, then a dose assessment or a time-integrated radon exposure assessment is required and if an effective dose of 6 mSv per year or a corresponding time-integrated radon exposure value is exceeded, then this should be managed as a planned exposure situation (Article 35). For some workplaces, such as thermal spas, caves, mines and other underground workplaces, competent authorities may consider from the outset that workers' exposure to radon is occupational regardless of whether the exposure is above or below the reference level [ICRP 2014].

The 2013 Directive, Article 103, includes a requirement that EU Member States should have national radon action plans. A list of items that should be considered in such action plans is included. Guidance for the development of national action plans is also given by WHO [WHO 2009], and ICRP [ICRP 2014]. The issues of radon measurement, radon surveys, mitigation and prevention should be addressed for indoor workplaces and mixed-use buildings (i.e. buildings used by both members of the public and workers). A strategy for communication to increase public awareness and inform local decision makers, employers and employees of the risks of radon should also be addressed in the action plan (item 10, Annex XVIII of the Directive).

Member States are required to ensure that radon measurements are carried out in workplaces within areas where the radon concentration (as an annual average) in a significant number of buildings is expected to exceed the relevant NRL (Article 54(2a)). Radon measurements are also required in specific types of workplaces identified in the national action plan such as schools, underground workplaces and those in certain areas, on the basis of a risk assessment, considering for instance occupancy hours (Article 54(2b)). This may include workplaces with a known radon source such as areas contaminated with radium from past industrial activities, or a store of geological samples with a high content of radium.

## Characteristics and Behaviour of Radon and Radon Progeny

Radon ($^{222}$Rn) and thoron ($^{220}$Rn) gas decays into a series of short-lived radionuclides creating an aerosol of solid particles suspended in air. These short-lived decay

products are present in indoor and outdoor air as unattached particles or can attach to existing particles forming the so-called attached progeny. The magnitude of the unattached fraction depends mainly on ambient particle concentration, which depends on local conditions. It is the inhalation of the unattached and attached progeny in the air that dominates the dose to the lungs.

Because radon progeny in the air can be removed by plate-out (i.e. by deposition on surfaces), the activity concentrations of the short-lived radon progeny in the air are less than that of the radon gas. This is quantified by the equilibrium factor, *F,* which is a measure of the degree of disequilibrium between the radon gas and its progeny. *F* is decreased further (i.e. there is greater disequilibrium) as a result of ventilation because as the ventilation rate increases, there is less time for the radon gas to decay (i.e. for the radon progeny to grow-in).

Because radon ($^{222}$Rn) is an inert gas, nearly all of the radon that is inhaled is subsequently exhaled. However, a large proportion of the inhaled radon progeny deposits in the airways of the lungs. Due to their short half-lives, dose is delivered to the lung tissues before clearance can take place, either by absorption into blood or by particle transport to the gastro-intestinal tract. Two of these short-lived progeny, $^{218}$Po and $^{214}$Po, emit alpha particles whose deposited energy dominates the dose to the lung. By contrast, doses to systemic organs and gastro-intestinal tract regions are low. As a consequence, the equivalent dose to the lungs contributes more than 95% of the effective dose following inhalation of radon progeny [ICRP 2014; 2017]. The effective dose from the inhalation of radon gas alone is typically less than 10% of that from inhaled radon progeny [ICRP 2014; 2017].

## Special Quantities and Units

- Concentration

  The *radon activity concentration* is the activity per unit volume of the gas, expressed in units of Bq $m^{-3}$.

  The concentration of any mixture of short-lived radon progeny in air was historically expressed in terms of the '*potential alpha energy concentration* (PAEC)' and was expressed in terms of the *working level* (WL). A concentration of 1 WL is defined, in ICRP Publication 65 [ICRP 1993a], as any combination of the short-lived radon progeny in 1 $m^3$ of air that will result in the emission of 1.300 $10^8$ MeV of alpha energy (i.e. a PAEC of $1.300 \times 10^8$ MeV $m^{-3}$ or $2.08 \times 10^{-5}$ J $m^{-3}$).

  The *equilibrium equivalent concentration* (EEC) is defined as the activity concentration of radon gas, in equilibrium with its short-lived progeny, which would have the same potential alpha energy concentration as the existing non-equilibrium mixture. One WL equals approximately 3750 Bq $m^{-3}$ of EEC of $^{222}$Rn. The EEC is therefore a measure of the radon progeny concentration or more precisely the PAEC.

- Equilibrium Factor F

  The *equilibrium factor*, *F* is defined as the ratio of the EEC to the radon gas concentration. In other words, it is the ratio of the PAEC for the actual mixture of radon decay products to that which would apply at radioactive equilibrium.

- Exposure

  Exposure is the time integral of the concentration. The potential alpha energy (PAE) exposure is the time integral of the PAEC in air and has the historical unit of the *working level month* (WLM). The WLM is defined as the cumulative exposure from breathing an atmosphere at a concentration of 1 WL for a working month of 170 hours. For $^{222}$Rn, if the exposure is expressed in terms of the radon gas concentration then the two units are related via the equilibrium factor: 1 WLM = ($6.37\ 10^5$ / *F*) Bq h $m^{-3}$.

- Unattached Fraction

  The *unattached fraction*, $f_p$ is defined as the fraction of the potential alpha energy concentration (PAEC) of the short-lived progeny that is not attached to the ambient aerosol. If there is a need for a more precise definition of unattached progeny, then [ICRU 2012] proposes 5 nm diameter as an upper limit for the unattached progeny (i.e. clusters carrying progeny).

## Risks from Radon

Radon has long been recognised as a cause of lung cancer, and was identified as a human lung carcinogen in 1986 by the World Health Organisation [WHO 1986]. Assessments of risks of radon-induced lung cancers have been mainly based on epidemiological studies of underground miners. More recent studies on miners have considered the lower levels of exposures and lower exposure rates that occur in homes and indoor workplaces [ICRP 2010a]. Based on these recent miner studies, ICRP recommends a detriment-adjusted nominal risk coefficient for a mixed adult population of non-smokers and smokers of $8x10^{-10}$ per Bq h $m^{-3}$ for exposure to $^{222}Rn$ in equilibrium with its progeny, i.e. $5x10^{-4}$ per WLM or $14x10^{-5}$ per mJ h $m^{-3}$ [ICRP 2010a]. This is approximately double the previous nominal risk coefficient given in ICRP Publication 65 [ICRP 1993a].

Pooled residential case-control studies have also been carried out in Europe, North America and China. These three studies gave results that were statistically compatible and showed that the risk of lung cancer increased by at least 8% for an increase in radon concentration of 100 Bq $m^{-3}$. After correcting for random uncertainties in the radon activity concentration measurements, the European pooled residential study gave an excess relative risk of 16% per 100 Bq $m^{-3}$ increase [Darby 2006]. There was evidence of a risk of lung cancer even for those exposed to an activity concentration below 200 Bq $m^{-3}$ [Darby 2006]. The data are consistent with a multiplicative interaction between the risks from smoking and radon, yielding a higher absolute value of risk of lung cancer per unit increase in radon exposure for smokers compared with non-smokers. Assuming a multiplicative interaction, the absolute risk of lung cancer by age 75 years for lifelong non-smokers was estimated as 0.4%, 0.5% and 0.7% for long-term average residential radon activity concentrations of zero (theoretical non-exposure situation), 100 and 400 Bq $m^{-3}$, respectively [Darby 2006]. For current smokers (of 15-24 cigarettes per day) the corresponding estimates were about 25 times greater (10%, 12% and 16% respectively). However, for ex-smokers who gave up smoking more than 10 years ago, the lung cancer rates were about 5 times greater than that for lifelong non-smokers (2%, 2.3% and 3.1% respectively).

Although comparisons between residential studies and miner studies are complex, appropriate comparisons of lung cancer risks estimates from recent miner studies and indoor studies show good consistency.

In Europe, radon is considered to be the second leading cause of lung cancer after smoking. Although, radon is much more likely to cause lung cancer in people who smoke or have smoked in the past, radon is the primary cause of lung cancer among people who have never smoked.

### Communication of risks

***Q2**: What are the strategies for radon risk communication?*

A national action plan should include a strategy for communication of risks of radon to employers and employees as well as to members of the public and local decision makers. A set of core messages which are simple, brief and to the point should be developed. For example: Radon exposure increases the risk of lung cancer. The lower the radon concentration in a workplace or in a home, the lower the risk. Radon is the single biggest source of workplace radiation exposure in many countries. Workplaces in some areas and certain types of workplaces are more likely to have high radon levels that should be measured and reduced where necessary.

Employers should: find out if their workplace needs to be tested for radon, carry out appropriate tests, act on the results and share information with employees and building users as appropriate. It should be stressed that practical techniques for mitigation are available. The synergistic effect of tobacco smoking and radon should also be communicated. Comparing radon related lung cancer risks with other cancers risks can be a useful communication tool. Examples of core messages and guidance on the development of such campaigns are given by the WHO handbook on indoor radon [WHO 2009].

An assessment of the level of knowledge and the perceptions of radon risks of the target audience should be carried out both before and after a risk communication campaign.

## Measurement Devices, Quality Assurance and Uncertainties

In this section the types of detectors available for activity concentration measurements of radon and radon progeny are described. In most cases, the average radon activity concentration over the detectors' exposure period is measured. However, some active detectors provide time-resolved recording, which allows the calculation of the integrated radon concentration for specific periods. The importance of quality assurance in providing confidence in the results of radon measurements is discussed. Measurement strategies, including the choice of the detector, type of measurement and the duration of measurement, are discussed in detail in the next section.

A brief description of the methods and techniques for the measurement of the unattached fraction and the activity size distribution of the radon progeny is also given. The reader is referred to the ICRU report on 'Measurement and reporting of radon exposures' for further details [ICRU 2012].

### Radon Gas Detectors for Area Measurements

#### Activated Charcoal Detectors

These passive detectors are only suitable for short-term screening measurements carried out over 2-7 days. They consist of a small container containing activated charcoal, which adsorbs radon. After exposure, the detector is sealed and returned to the laboratory for measurement of the quantity of radon adsorbed using gamma spectrometry or liquid scintillation counting. The detectors are sensitive to humidity and temperature and should be calibrated under the various levels of humidity and temperature likely to be encountered in the field. A minimum detectable concentration (MDC) of about 20 Bq $m^{-3}$ can be achieved for a 2-7 day measurement.

#### Solid State Nuclear Etch Track Detectors

Passive etched track detectors (or so-called alpha track detectors) are used to measure long-term average radon activity concentrations in indoor air, for measurement periods of several weeks to one year. They consist of a plastic element mounted in a small diffusion chamber that allows the entry of radon gas by diffusion but inhibits the radon progeny. The radon gas inside the chamber decays and emits alpha particles that damage the plastic element's surface creating small tracks. Following exposure, the device is returned to the laboratory where the plastic element is treated by chemical or electrochemical etching to reveal the tracks, which can be counted using several methods, e.g. an image analysis system. The number of tracks per unit surface area, after subtracting background counts, is directly proportional to the integrated radon exposure. These detectors perform well at normal indoor ambient conditions. They are insensitive to background beta and gamma radiation, but could be sensitive to neutrons and may also be sensitive to thoron, depending on the diffusion half-time of the chamber. Several studies have shown that some closed etched track detectors that are used to measure radon are also sensitive to thoron (e.g. [Tokonami 2010]). However, thoron interference can be reduced if they are not placed near walls, as building materials are often the source of thoron. In situations of suspected high thoron activities and where the thoron activity concentration is of

interest, it is recommended to use radon-thoron discriminative detectors as described by [Tokonami 2005]. For etch track detectors, an MDC of about 30 Bq $m^{-3}$ is achievable following a 1 month exposure, or 10 Bq $m^{-3}$ for a 3 month exposure.

At high humidity, (>95% relative humidity (RH) or as described in the technical specification of the specific detector), the etch track detectors can give unreliable results, with significant underestimation of the actual radon concentration, due to condensation on the plastic element that may prevent some alpha particles reaching its surface. To measure radon in such environments, the detectors should be placed in moisture-resistant plastic bags and they should also be calibrated in the bags [Miles 2009].

### Electret detectors

Electret detectors are passive devices which are suitable for measurements from a few hours up to one year, depending on the selected sensitivity (electret and chamber combination). They consist of a small chamber containing a positively-charged disk (electret), usually made from Teflon™, which is gradually neutralised by the ionisation of the air by alpha particles emitted by radon and its progeny. Radon gas passively enters the chamber via a filter which inhibits radon progeny entry. The reduction of the voltage level of the electret allows the calculation of the radon exposure. These monitors are sensitive to heat but not to humidity, except at >95% RH. Allowance must be made for ionisation caused by background gamma radiation. Also the detectors should not be dropped as this may cause a change in the electret voltage.

### Active monitors

There are various types of electronic monitors available including electronic integrating devices (EIDs) and continuous radon monitors (CRMs).

- EIDs:

  Most EIDs use a solid-state silicon detector within a diffusion chamber, to detect alpha particles emitted by radon and radon progeny. High humidity may affect the measurements and EIDs need to be calibrated before use and at regular intervals, especially where regulatory compliance is required. Many EIDs have a low sensitivity, especially with lower cost devices, which limits performance at levels similar to NRLs. However, the display may also give the appearance of time resolution when this is not a true feature of the EID, whereas better instruments can give a measure of the short term radon level averaged over a few days as well as the average over the total exposure time.

- CRMs

  There are several types of commercial CRMs using various types of sensors such as scintillation cells, current or pulse ionisation chambers, and solid-state silicon detectors. These active monitors have the ability to produce time-resolved measurements. Some types have specific advantages; for example, the ability to discriminate between radon and thoron, and to dry incoming air making the device insensitive to humidity as long as the desiccant is maintained. Usually, the CRMs are equipped with a thermometer, humidity sensor and pressure sensor, which supply additional data that may be important for the measurement evaluation. The humidity sensor also allows automatic correction of the measured data due to changes in the humidity. The CRMs require routine calibration. Achievable MDCs are about 5 Bq $m^{-3}$.

## Radon Progeny Measurement Devices

Radon progeny measurements are more complex than radon gas measurements. Results of radon progeny measurements are usually expressed in terms of the EEC or the PAEC of the radon progeny mixture or the activity of each decay product. All methods are based on the collection of the radon progeny on filters and subsequent activity measurements on the filter. They require a sampling assembly, a radiation detection device, and a data processing and recording unit, which may be integrated within a single instrument. Examples of radiation detection devices for radon progeny

measurements are gross alpha counters, integrating alpha-track decay product detectors, surface barrier detectors, and high purity germanium detectors. The requirements of such measurements are given by international standards, which may have been adopted by the country. For example, ISO 11665-2:2016 [ISO 2016a] describes an integrated measuring system for the determination of the PAEC.

## Personal Monitors

Various types of passive and active personal monitors have been used to measure radon gas exposure. In the uranium mining industry, personal monitors have been employed to determine the PAEC of the radon progeny mixture. These devices typically use a pump to collect the radon progeny on filters. In the non-uranium mining industries, passive alpha track detectors are used as personal monitors to measure individual radon gas exposures.

More recently, electronic personal devices that are suitable for long-term radon gas measurements have been developed, which consist of a diffusion chamber with silicon detectors. Such devices have the ability to perform time-resolved analysis with on-line information [Karinda 2008; Gruber 2011].

Commercial real time personal monitors to measure the radon progeny or the PAEC have been used in mining operations.

## Measurements of aerosol parameters

### Unattached fraction

To directly measure the unattached fraction, it is necessary to separate the unattached clusters, which have diameters less than about 5 nm, from the aerosol attached fraction. Measurements of the unattached fraction and the size distributions of unattached radon progeny are based on their diffusion properties. Because of their small size, unattached progeny diffuse more readily to surfaces than the aerosol attached progeny. Therefore, the unattached progeny can be separated from the attached fraction by their preferential deposition onto walls of a tube, parallel plates or wires of a wire screen. Single stage diffusion batteries with a 50% penetration for particles with 4 to 6 nm diameters have been applied to measure the unattached fraction [Porstendörfer 1996]. For practical reasons, single stage wire screen batteries have often been used to measure the unattached fraction, (e.g. [Reineking 1990; Vargas 2000]). However, they do have some disadvantages such as resuspension of deposited unattached radon progeny by recoil effects and collection of part of the attached fraction. It is recommended to correct for the latter using the method developed by Reineking and Porstendörfer [Reineking 1990]. The correction is more significant if the nucleation or coarse modes are present. In addition, annular diffusion channel (ADC) batteries have also been used to measure the unattached fraction [Huet 2001a]. The ADC geometry allows better selection of the particle size compared to the wire screen [Michielsen 2007].

### Activity size distribution of radon progeny

Activity size measurements in the range from about 0.5 nm to 300 nm (i.e. for the unattached and attached progeny) can be performed with multistage diffusion batteries operated in series or parallel and applying mathematical algorithms to deconvolute the data (e.g. [Solomon 1993; 1994; Reineking 1994; Porstendörfer 1996; Huet 2001b; Vargas 2005; Michielsen 2007]). The fraction of the PAEC in each mode, including the unattached fraction, can be derived from such data.

Cascade impactors can be used to measure the size distribution of the attached progeny, typically in the range 60 nm to 10000 nm [Porstendörfer 1996]. The size range of an impactor can be lowered to smaller sizes by applying low pressures in the impactor. Such low pressure impactors can be used to separate particles down to sizes of 50 nm. Because impactors are used to measure the size distribution of the attached progeny, a tube diffusion battery should be mounted in front of the impactor to remove the unattached radon progeny from the air stream [Gründel 2005]. By

applying mathematical algorithms to analyse the data, the size distribution can be represented by a combination of lognormal distributions.

## Quality Assurance of Radon Measurements

***Q3**: How should it be ensured that measurements are reliable?*

All radon measurements should have metrological traceability. This means that the measurement value can be related to a reference standard or primary method through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty. The primary method or standard originates at a national or international metrology laboratory.

A quality assurance programme (**Chapter G**) should be established and maintained by all those providing radon measurement services. Testing and calibration laboratories may wish to comply with ISO/IEC 17025:2005 [ISO/IEC 2005], which covers all aspects of quality assurance including requirements for accreditation. Quality assurance includes all matters that are necessary to provide adequate confidence in the results of the measurement. For example, it includes management and technical requirements, validation and quality control. This ensures equipment and instruments function correctly, procedures are established and followed, quantifiable errors are within acceptable limits, records are maintained, and internal audits are carried out.

As part of the quality assurance programme, radon services are recommended to participate in intercomparison exercises or performance tests. Radon facilities that have STAR (Systems for Test Atmospheres with Radon) host the exercises. Participants send their devices to the host facility for exposure in the STAR. The devices are returned without disclosing the radon concentration to which they were exposed. The participant reports its results to the host facility, which then issues a report comparing all participants' results with the reference value. Measurement results together with assigned uncertainties should be provided by the participants. The uncertainty budget may also be included, giving the components of uncertainty together with the combined uncertainty. If only one participant at a time is involved then this is called a performance test, whereas during an intercomparison exercise several participants are involved at the same time. A certifying or a licensing agency may wish to carry out a performance test on a radon service without their knowledge. Such tests are called "blind tests".

Regular calibrations, duplicate measurements, laboratory and field background measurements should also be part of the quality assurance programme [WHO 2009]. For duplicate measurements, two devices of the same type are exposed simultaneously and their results compared. If the difference is greater than the expected precision of the measurement, then further action is required.

For radon gas measurements, calibrations should be carried out within the range of activity concentrations that is expected to occur in the field. For example, for passive etched track detectors, the response to radon concentrations may not be linear at high concentrations and consequently an appropriate correction determined experimentally would need to be applied. At high radon exposures, a calibration in terms of the total area of tracks as opposed to number of tracks may be considered [Miles 2004; Ibrahimi 2009]. Again, a correction for non-linearity caused by overlapping areas of track would need to be applied.

## Uncertainties

The uncertainty of the measured average radon activity concentration over the detector exposure period includes both the calibration and field measurement uncertainty. Uncertainties should be calculated in accordance with the Guide to the Expression of Uncertainty in Measurement (GUM) [ISO/IEC 2014]. Procedures for the calculation of uncertainty associated with field measurements using passive detectors (i.e. alpha track, electret and activated charcoal detectors) are described in ISO 11665-4 [ISO 2012b] and are consistent with [ISO/IEC 2014]. Additional uncertainties occur in the estimation of the annual average radon activity concentration inferred from a measurement with an exposure period of less than a year.

## Measurement Strategies

***Q4**: What measurement strategies for workplace monitoring should be adopted to demonstrate compliance with reference levels and dose limits?*

***Q5**: When should radon progeny measurements be employed?*

***Q6**: When should individual monitoring be employed?*

The measurement strategies recommended are based on those developed by the World Health Organization [WHO 2009] and by the International Commission on Radiation Units and Measurements [ICRU 2012]. They are also consistent with the ICRP guidance on radiological protection against radon exposure and with the 2013 Directive.

### Choice between Radon Gas and Radon Progeny Measurements

Although it is the inhalation of the radon progeny that dominates the dose to the lungs, radon gas measurements are generally considered as a good indicator of risk for indoor exposures. In addition, radon gas measurements are simpler and cheaper than radon progeny measurements. Therefore, control of indoor radon exposure is generally based on radon gas activity measurements. If the equilibrium factor is relatively constant, then radon gas measurements are indeed a good surrogate for radon progeny measurements. However, in situations where the equilibrium factor varies significantly because of variation in the ventilation or fluctuations in aerosol particle concentration, for instance in underground mines, radon progeny measurements are usually performed.

For dosimetry purposes the equilibrium factor, $F$, is required when the radon gas is measured so that the radon progeny concentration in air can be estimated. However, the lung dose not only depends on the activity concentration of the inhaled progeny but also on their activity size distribution including that of the unattached fraction, $f_p$. For indoor air, where the ventilation rate is relatively low, $F$ is negatively correlated with $f_p$. As a consequence, it has been shown that the radon gas concentration is a more robust indicator of dose than the potential alpha energy (PAE) concentration under a range of aerosol conditions normally encountered, e.g. [Vargas 2000]. On this basis and because of practical considerations, radon gas measurements are generally preferred to radon progeny measurements for indoors. For the same reasons, reference levels are expressed as the radon gas concentration. For underground mines with forced ventilation, a consistent correlation between $F$ and $f_p$ is unlikely, so control of radon exposure in mines is usually in terms of PAE exposure.

For thoron ($^{220}$Rn), which has a short radioactive half-life of 56s, the situation is different; control of exposure to thoron is based on its progeny. That is, the EEC of thoron should be controlled. However, for radiation protection against thoron, it is usually sufficient to control the intake of the decay product, $^{212}$Pb, which has a half-life of 10.6 hours [ICRP 1993; 2017].

### Choice between Short-Term and Long-Term Radon Gas Measurements

Because of short-term fluctuations and cyclic diurnal and seasonal variations of indoor radon levels, short-term measurements have greater uncertainty than long term measurements in determining the annual average radon concentration within a given building or room. Short-term measurements can greatly underestimate or overestimate the annual average and hence their use is limited.

Long-term measurements are therefore recommended to estimate the annual average radon level to compare with the NRL. A measurement period of at least 3 months is recommended, although a period of one year is ideal in terms of reduced uncertainty. In some cases, one-year exposure periods produce a higher rate of lost or forgotten monitors. Detector loss can be minimised by effective communication between employer and employees. Moreover, detectors exposed for a single 12-month period could be affected by ageing and fading effects, which can depend on both detector characteristics and the track-counting system. Therefore, these effects should be

analysed for the measuring system and where necessary the results should be corrected to avoid underestimates. An alternative option is to use multiple detectors exposed over consecutive periods to give a combined 12-month exposure period in total (e.g. 6+6 months).

Seasonal correction factors can be applied, if appropriate, to convert 3-month measurements to annual averages but these have to be derived for a given climate or region. National or regional studies should, therefore, be undertaken to determine if there is an observable and reliable seasonal variation. Measurements carried out by Miles et al. [Miles 2012] showed that spring and autumn measurements gave a better estimate of the annual average radon concentration than the best seasonal correction factors applied to all seasonal measurements. The authors concluded that because of the wide variation in the amount of seasonal variation between buildings, applying seasonal correction factors to the results of three-month measurements can yield only relatively small improvements in the accuracy of estimates of annual mean concentrations. However, this is an area of ongoing research as not all buildings have the same behaviour where seasonal variations occur. In Nordic countries, only heating season measurements (i.e. measurements carried out during the winter months) are recommended and a derived correction factor is applied. An alternative approach is to use the heating season measurement without correction for a conservative estimate of the annual average radon concentration.

If seasonal correction factors are to be used, then guidance for their appropriate use is required, for instance in dwellings and in 'house-like' workplace buildings.

It is sometimes useful to carry out short-term screening measurements of radon, typically over a few days to a week. Screening measurements can be used to identify situations where the radon concentration is very clearly higher or lower than any relevant criterion, such as the NRL. However, the short duration of screening measurements means that they have significantly greater inherent uncertainty and that results within a wide range surrounding the NRL cannot be used as a definitive statement of whether the criterion is exceeded. In cases where a very low result is obtained, it is likely that no further monitoring will be needed. Where ambiguous results are obtained, long-term measurements should be undertaken as described above. However, where very high results are obtained, long-term measurements should be undertaken along with any necessary short term protection arrangements and/or remedial actions.

The threshold levels for short-term screening measurements that can be used to decide if the annual average radon activity concentration is likely to be above or below the NRL can be calculated as follows. It is assumed that the uncertainty associated with the short-term screening measurements in predicting the annual average radon concentration can be approximated by a lognormal distribution with a geometric standard deviation (gsd) of about 2. A gsd of about 2 is consistent with the measurement results of Steck [Steck 2005] who carried out a comparative study of short-term and long-term measurements. The short-term measurements were made with an activated charcoal detector and a sampling period of 2 or 4 days. The lower and upper threshold levels may be estimated as $NRL/gsd^2$ and $NRL \times gsd^2$ respectively [ICRU 2012]. Thus, if measurement, $M > NRL \times gsd^2$, it is assumed that the NRL is exceeded, in which case there is a 2.5% probability of a false positive (i.e. incorrectly assuming the annual average radon concentration is greater than the NRL). Likewise, if $M < NRL/gsd^2$ then it is assumed that the annual average radon concentration is less than the NRL. For a NRL of 300 Bq $m^{-3}$ and asssuming a gsd of 2, the lower and upper threshold levels are 75 Bq $m^{-3}$ and 1200 Bq $m^{-3}$ respectively.

To test the effectiveness of remediation, both short-term and long-term measurements may be started simultaneously at the location of the original measurements, a few days after the mitigation system is installed [WHO 2009].

## Choice of Detector for Radon Gas Measurements

The choice of the detector depends upon the purpose of the measurement, the detector's suitability and the cost (Table H.1). For long-term measurements, passive

alpha track detectors are recommended although electret ionisation chambers are a suitable alternative [ICRU 2012]. Activated charcoal detectors cannot be used for long-term measurements as they can only determine the average radon concentration over a few days. Because of this limitation they should not be used for workplace monitoring to determine the annual average radon concentration. They should also not be used for short-term measurements in workplaces with high humidity, i.e. underground workplaces, water treatment facilities and spas.

Continuous radon monitors are active devices, electrically or battery powered, and have the ability to record the radon activity concentration at least every hour. This allows the calculation of the integrated radon concentration for specific periods. Therefore, these devices can be used to determine the average activity concentration during working hours. Such measurements made over a week can be used to determine the ratio of the average concentration during the working hours of a week to the average concentration during the whole week. To obtain the annual average concentration during working hours, this ratio should be multiplied by the annual average concentration determined with a passive detector. However, further measurements may be required to determine if the cyclic variations in radon concentration over a week remain the same over longer periods. Also, checks should be made to ensure that the assumed working patterns and occupancy are accurate now and in the future.

For grab sampling techniques, the sampling duration is a few minutes and the measurement result only reflects the radon concentration at the time of measurement. These types of measurements are not recommended for the assessment of radon exposure or for making decisions regarding the need for mitigation [WHO 2009]. However, they can be used as part of a long-term measurement programme in underground workplaces (e.g. to detect the presence of very high radon levels)

**Table H.1** Recommended devices for radon ($^{222}$Rn) gas area measurements for indoor workplaces or mixed-use buildings

| Purpose | Measurement type | Device | Cost |
|---|---|---|---|
| Assessment of annual average activity concentration[(a)] | Long-term sampling (≥ 3 months) | Alpha track detectors | Low |
| | | Electret ionisation chambers | Medium |
| Determination of ratio of average working time to one week concentration[(b)]. | Short term sampling (1 week) | Continuous radon monitors | Medium to high |
| Post remediation test to test effectiveness[(c)] | Long-term sampling (≥ 3 months) | Alpha track detectors<br>Electret ionisation chambers | Low<br>Medium |
| | Short term sampling (1 week) | Continuous radon monitors<br><br>Passive detectors (Electret/ activated charcoal ) | Medium to high<br>Medium |

(a) Electronic integrating devices and continuous radon monitors could also be used for assessment for exposure [WHO 2009].
(b) Annual average concentration during working hours can be estimated by multiplying the annual average concentration by the ratio of the average concentration during the working hours of a week to the average concentration during the whole week.
(c) As well as long term testing, short term measurements (~1 week) may be started at the same time.

## Deployment of Detector for Radon Gas Measurements

Generally, the main source of indoor radon is the ground beneath and subjacent to the building and therefore radon levels are normally highest in lower floors. For radiation

protection purposes, it is required that an assessment of the exposure is made in workplace areas on the ground floor or basement level (Article 54(b) of the 2013 Directive [EC 2014]).

Stationary devices for area measurements should be installed at positions that are representative of the worker's exposure. They should be deployed in the normal breathing zone of the worker (between 1 and 2 metres above floor level) in regularly occupied locations. The aim is to measure radon in relevant parts of the workplace that are regularly occupied, including all regularly occupied spaces that are at ground floor and below ground level. Furthermore, the detectors should be positioned away from conditions that may bias the result or performance of the detector such as high temperatures, drafts, moisture, strong light, gamma rays or sources of thoron; otherwise such factors may need to be taken into account. For these reasons the detectors should not be placed close to windows, doors, radiators or other sources of heat, and in mixed-use buildings the detectors should be inaccessible to children. Deployment of detectors should also follow the manufacturer's instructions for use. Thoron-sensitive detectors should be deployed at least 10 cm from walls and the surface where the detector lies should be non-masonry [ICRU 2012]. The location of the detector should be representative of the normal ventilation in the working area.

Because of spatial variation of indoor radon more than one detector maybe required when carrying out area monitoring of indoor workplaces. For example, Public Health England gives a guide to employers for the number of detectors required for area monitoring of radon in a workplace [PHE 2016].

## Indoor Workplace Monitoring

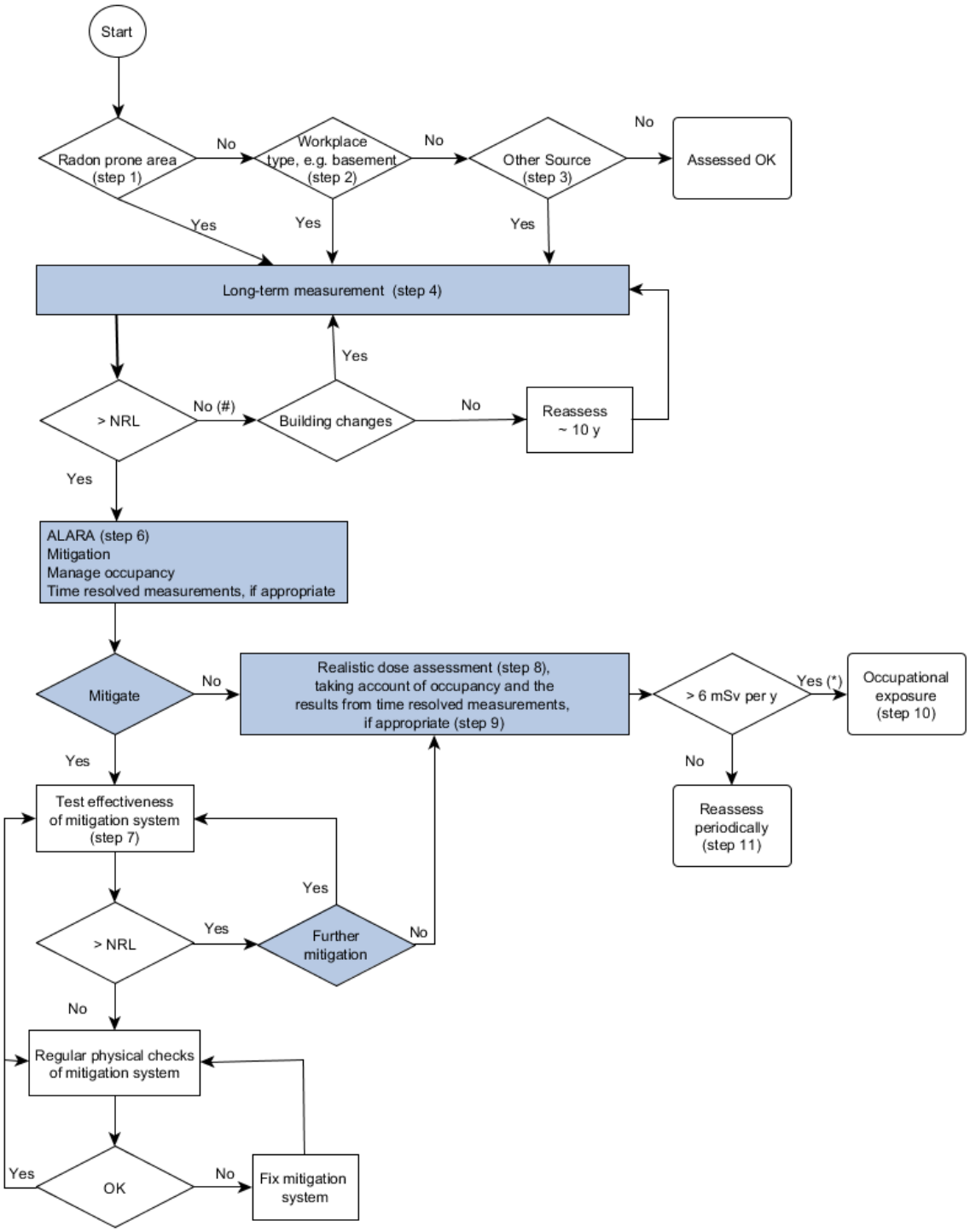
Area measurements are typically performed at indoor workplaces to evaluate the annual average radon concentration and to optimise worker protection, giving priority to exposures above the NRL. If, after optimisation (such as building remedial works), the reference level is still exceeded, a more realistic estimation of the workers' exposure or dose is required. Individual exposures may be reasonably approximated by area measurements if spatial and temporal variations can be neglected and occupancy times are known. Initially, the aim is to ensure the overall protection of the users of the building rather than control doses to specific individuals. However, if the workers' exposure is considered as occupational or is managed as a planned exposure situation, then individual as well area monitoring may be required (See next section).

The monitoring strategy for indoor workplaces should take account of the exposure and environmental conditions and the operation cycle. These include for example, the type of work activity, the occupancy, the size of the building or work space, special air environments, and the heating, ventilation and air conditioning (HVAC) operation. As a consequence, for area monitoring, multiple sampling locations are required, generally in workplace locations that are regularly occupied and where radon levels are likely to be highest, e.g. in ground floor rooms and occupied basements.

A generic monitoring strategy for indoor workplaces is presented in Figure H.1 and described below (references are to Articles in the 2013 Directive):

1. Determine whether the workplace is located in a radon prone area (Articles 54(2)a, 103(3)). If it is, undertake radon measurements (step 4).
2. Determine whether the workplace is of a type (Article 54(2)b) that is required by the competent authority to make radon measurement. This may include schools, underground workplaces or workplaces with occupied basements. If it is, undertake radon measurements (step 4).
3. Determine whether the workplace has a known radon source such as areas contaminated with radium from past industrial activities or a store of geological samples with a high content of radium. If it is, undertake radon measurements (step 4).
4. Undertake long-term measurements (e.g. 3 months or more) with appropriate devices. Use the results of the long term measurements to estimate the annual

average concentrations applying seasonal correction factors if appropriate, and compare with the NRL.




**#** Optimisation should be considered even if the radon level is less than or equal to the National Reference Level (NRL). However, priority for optimisation should be given to radon levels greater than the NRL; (step 5).

***** If doses are liable to exceed 6 mSv per year and mitigation measures have not yet been considered then mitigate as appropriate and go to step 7.

**Figure H.1** General approach for management of radon exposure for indoor workplaces.

5. Exposures should be reduced as low as reasonably achievable (ALARA) taking account of economic and societal factors. This means that optimisation should be applied as appropriate both above and below the reference level, and not only above it. However, priority for optimisation of protection should be given to exposures above the reference level (Article 7(1)). Therefore, in most cases, results well below the NRL will not require exposures or concentrations to be managed.
6. If the result exceeds the NRL then action is required, as specified in Articles 54(3), to optimise and, in general, reduce exposures. Optimisation actions may include physical remediation (mitigation) measures to reduce radon concentrations, management actions to reduce occupancy, and measurements to investigate the activity concentration during working hours, if appropriate [WHO 2009; ICRP 2014].
7. If mitigation measures have been taken to reduce radon concentrations then follow-up measurements are required to test their effectiveness. Long-term measurements should be made at the same locations as the original measurements, however short term measurements may also be started at the same time. The annual average concentration estimated from the long-term measurement should initially be compared with the NRL even if the mitigation system is only operated during working hours (i.e. during occupancy).

   If the reduction of radon levels has been optimised (i.e. radon concentrations have been reduced to levels well below the NRL), long-term tests should be repeated periodically (e.g. every few years), in addition to regular physical checks (e.g. the air flow through fans or pumps), to ensure sustained effectiveness of the mitigation system [WHO 2009]. If the annual average exceeds the NRL and no further mitigation is carried out then proceed to step 8.
8. Where, in spite of any action taken, radon levels (as an annual average) continue to exceed the NRL in terms of Bq $m^{-3}$ (Article 54(3)), the relevant regulator is to be notified and a dose assessment is required. The assessment needs to determine whether doses are liable to exceed 6 mSv per year. The dose assessment should aim to be realistic, reflecting occupancy patterns and, potentially, associated regular (e.g. diurnal) variations in radon levels.
9. In these circumstances or before mitigation is considered, it may be appropriate to undertake radon measurements to identify if there are significant cyclic variations in radon concentrations that would affect the dose assessment. Concentrations could follow a diurnal pattern and/or reflect regular periods (e.g. weekends) when the workplace is not occupied. Care must be taken to assess the full range of occupancy of the workplace, taking account of workers who might regularly have non-typical occupancy (shift workers, security guards, caretakers, cleaners, etc). If doses are liable to exceed 6 mSv per year and mitigation measures have not yet been considered then mitigate as appropriate and go to step 7.
10. If effective doses from radon are assessed to be more than 6 mSv per year they are to be managed as a planned exposure situation (Article 35(2)) and relevant national requirements must be met for managing such exposures.
11. If effective doses from radon are liable to be below or equal to 6 mSv, they should be kept under review (Article 35(2)). This would include review of radon concentrations, occupancy and other relevant parameters.
12. Records of all measurement results should be kept, including those of post-remediation test measurements.

If any significant building work has taken place or changes to the operational cycle affecting exposure conditions have occurred, such as to the heating, ventilation and air conditioning operation, then measurements should be repeated. For example, such changes may include new tight windows (e.g. double or triple glazing), thermal

insulation of the building, changes to the floor layer (e.g. reconstruction of piping) and extension of the building.

### Diagnostic Measurements for Mitigation Design

If the estimated annual average based on the long-term measurement is greater than the NRL then further radon and diagnostic measurements may be required for the design of effective remedial measures, e.g. [Moučka 2008]. As described in step 9, time resolved measurements might be useful to determine if radon levels are high only during occupancy. Such measurements are particularly appropriate if HVAC systems are used and the workplace is only occupied at fixed and regular times. ICRU recommends time-resolved measurements in cases where the long term measurement (as an annual average) only slightly exceeds the NRL [ICRU 2012]. However, significant diurnal and weekly variations have been observed in workplaces with mechanical ventilation [Reisbacka 2008].

If limited numbers of long-term monitors were deployed initially or work is required urgently, time-resolved measurements in habitable and non-habitable rooms (on ground floor or basements) might also give useful information on the source and the pathway of radon. Time-resolved measurements can also be used to determine the effectiveness of any existing ventilation systems with time. In some cases, this information may be used to improve the ventilation system to reduce radon levels during occupancy [Reisbacka 2008].

Best practice is to seal obvious gaps around piping and other service entries (e.g. drainage and cables), but it is difficult to identify and seal all cracks. Grab sampling might provide additional information on significant pathways for radon infiltration.

If building materials are suspected to have a high concentration of $^{226}$Ra, gamma dose rate measurements are recommended to determine if the building material is an important source of radon. Likewise, if well water is used, measurements of radon concentration in the water can identify if the water is an important source of indoor radon.

Other diagnostic measurements that can be considered include radon in soil gas and soil permeability. Soil permeability can be useful input for the design and applicability of sub-slab depressurisation systems, e.g. [Jiránek 2014].

## Individual Monitoring

In workplaces where workers' exposure to radon is considered as occupational or is managed as a planned exposure situation, the determination of the individual exposure or dose is required to demonstrate compliance with reference levels and dose limits. As described above, area measurements of radon together with information on occupancy times can be used to assess workers' exposures. However, in situations where the exposure conditions are subject to considerable spatial and temporal fluctuations or if the individual frequently changes exposure sites with different exposure conditions, individual monitoring should be employed, if appropriate. For example, individual monitoring is recommended in underground mines where exposure conditions are highly variable.

Personal monitors that measure the radon or radon progeny activity concentrations in air have been developed and are used routinely in underground mines. The sampler is worn on the upper part of the trunk within the breathing zone of the worker. In mines with forced ventilation, measurements of the activity radon progeny concentrations in air (i.e. PAEC) are generally recommended. In addition doses from other sources, such as external gamma radiation and inhaled long-lived radionuclides, should be monitored and assessed. Further information regarding protection of workers against radon in the uranium mining industry is given by ICRP [ICRP 2015b].

In non-uranium mines in the UK, passive alpha track monitors are used for personal monitoring. It has been shown that the measured result is independent of the radon diffusion half-time of the passive monitor, provided it is short compared with the radioactive half-life of $^{222}$Rn of 91.7 h [Bartlett 1988]. These detectors are therefore

suitable for measuring average activity radon concentrations even in situations of short exposures or a series of short high-radon exposures. These passive detectors are typically worn on the upper trunk or can be attached to the workers' hard hat. Electronic personal devices have also been used in caves and underground spas.

If passive detectors are used for personal monitoring, they should be stored in a low radon area when not in use. A suitable storage area should be selected. To assess the exposure when not in use, control detectors are issued with the personal monitors and the control detectors should remain in the storage area throughout the issue period. All workers' personal monitors should be returned to the storage area when not being worn. The worker's radon gas exposure while working can be determined from the personal monitor, the control detectors and knowing the number of working hours.

*In vivo* measurements of $^{210}$Pb in bone or $^{210}$Pb in urine samples are not recommended for radon exposure estimates as they are difficult to interpret and the incorporated $^{210}$Pb could have originated from sources other than inhaled radon progeny. However, results of such measurements on underground miners have been used as an indicator of high radon exposures and to identify areas that need tighter control and further monitoring [Azeredo 1991; Dantas 2007]. *In vivo* measurements of $^{214}$Pb/$^{214}$Bi in lungs are only an indication of recent exposures because of their short biological half-lives in lungs and, therefore, also cannot be used for dose assessment of chronic exposures.

In the cases of high acute intakes of radon and radon progeny, whole body monitoring can be employed over about two days to measure $^{214}$Pb/$^{214}$Bi. Activity of $^{214}$Pb/$^{214}$Bi measured between ~5 h and 2 days after the intake arise from the decay of radon that has been absorbed in organs and tissues. These results may be interpreted by the application of the systemic biokinetic model for radon [ICRP 2017].

## Dosimetry

***Q7**: Which dose coefficients should be used?*

Two approaches have been used by ICRP to estimate effective doses arising from the inhalation of radon progeny. These are the dosimetry approach and the so-called epidemiological approach, also referred to as the dose conversion convention [ICRP 1993].

For the dosimetry approach, equivalent and effective doses, following inhalation of radon progeny, can be calculated with the ICRP reference biokinetic and dosimetric models including the Human Respiratory Tract Model (HRTM) [ICRP 1994; 2015b], the Human Alimentary Tract Model (HATM) [ICRP 2006] and the systemic biokinetic models for polonium, lead and bismuth [ICRP 2017]. A systemic biokinetic model for radon gas has also been developed so that effective doses arising from the inhalation of radon gas can be calculated [ICRP 2017].

Doses depend mainly on the radon progeny concentration in air, the duration of exposure, the breathing rate and the aerosols' properties, including the activity size distribution of the radon progeny aerosol and the unattached fraction. If the exposure is characterised by radon gas measurements then a value for the equilibrium factor, $F$, is required to estimate the radon progeny concentration in air. For radiological protection purposes, most of the parameters in the dosimetric models, such as breathing rate, correspond to values for the Reference Worker or Reference Person.

In the epidemiological approach, the dose conversion convention is derived by dividing the detriment per unit exposure to radon and its progeny with the total detriment associated with unit effective dose. The former was determined from miner epidemiology and the latter determined mainly from epidemiological studies of Japanese atomic bomb survivors exposed largely to gamma rays [ICRP 1993; Marsh 2010]. This comparison allowed the calculation of the dose conversion convention expressed in mSv per unit PAE exposure (i.e. mSv per WLM or mSv per J h m$^{-3}$).

The latest dose conversion factors recommended by ICRP in its OIR report series for the inhalation of radon progeny and thoron progeny should be used for radiation

protection purposes [ICRP 2017]. In general, the dose arising from the inhalation of radon or thoron gas may be ignored as this is only a small contribution to the effective dose compared with that from the inhalation of their airborne progeny.

ICRP recommends the use of a single dose coefficient of 3 mSv per mJ h $m^{-3}$ (approximately 10 mSv per WLM) for the calculation of doses following exposure to radon ($^{222}Rn$) progeny in underground mines and in building, in most circumstances [ICRP 2017]. This single dose coefficient is sufficient for the majority of circumstances and so no adjustment for aerosol characteristics is necessary to implement the system of radiation protection. However, for indoor workplaces where workers are engaged in substantial physical activities, and for workers in tourist caves, a dose coefficient of 6 mSv per mJ h $m^{-3}$ (approximately 20 mSv per WLM) is considered to be more appropriate by ICRP. Furthermore, specific dose coefficients should be calculated using the dosimetric data given by ICRP in cases where aerosol conditions are significantly different from typical conditions and where sufficient, reliable aerosol data are available and assessed doses warrant more detailed consideration [ICRP 2017]. In such cases, the specific dose coefficients would be used to calculate doses for radiation protection purposes if required by the regulatory authority.

In terms of measurements of $^{222}Rn$ gas exposure, the ICRP reference dose conversion coefficient of 3 mSv per mJ h $m^{-3}$ (approximately 10 mSv per WLM ) corresponds to $6.7 \times 10^{-6}$ mSv per Bq h $m^{-3}$, assuming an equilibrium factor, $F$ of 0.4. With an occupancy of 2000 h per year for a worker [ICRP 1993a; 2010a] and $F$=0.4, the effective dose corresponding to annual exposure at the upper references level of 300 Bq $m^{-3}$ recommended in ICRP Publication 126 [ICRP 2014] is 4 mSv.

If radon gas measurements are carried out in rooms or locations of a workplace, then the annual effective dose, $E$ (in mSv) can be calculated as follows:

$$E = DCF \cdot 1.57 \cdot 10^{-6} \sum_i C_{Rn_i} \cdot F_i \cdot O_i \qquad \text{mSv}$$

where

| | |
|---|---|
| $C_{Rn_i}$ | annual average radon concentration (Bq $m^{-3}$) |
| $F_i$ | equilibrium factor |
| $O_i$ | annual occupancy (h) in room or location *i* |
| DCF | dose conversion factor for radon progeny expressed in terms of mSv per WLM as given by ICRP for workers (i.e. 10 mSv per WLM). |

Long-term measurements of at least 3 months are required to determine $C_{Rn_i}$. However, if time resolved measurements are also performed then $C_{Rn_i}$ can be modified to obtain the annual average radon concentration in room or location *i* during occupancy.

Typically, the ICRP reference value of $F$=0.4 for indoor workplaces should be assumed for regulatory purposes. However, if there are circumstances where $F$ is likely to be significantly greater than 0.4, then a more appropriate value of $F$ should be determined based on measurement. High values of $F$ may occur in cases where the ventilation rate is not too high but the particle concentration is high because of additional aerosol sources arising from technical processes, dispersion activities and combustion, for example. However, the corresponding unattached fraction is low so the dose per unit radon gas exposure does not significantly change. Therefore, in most indoor workplaces the ICRP reference value of $F$ may be assumed for radiation protection purposes.

In cases where $F$ is low and has been determined by a sufficient number of measurements, it should only be adopted if sufficient and reliable measurements of the unattached fraction, $f_p$ has also been carried out. In such cases a specific dose coefficient should be calculated. Alternatively, the ICRP reference value of $F$=0.4 may be assumed with the reference dose coefficient.

Nevertheless, radon progeny measurements are recommended at workplaces where the equilibrium factor varies significantly because of large variations in the ventilation or significant fluctuations in the aerosol particle concentrations. Examples may include underground mines and NORM processing plants.

## Recommendations

| R# | G | Text of the recommendation |
|---|---|---|
| | | ***Q1**: How should workers be protected against radon exposure?* |
| H01 | M | As part of the national radon action plan, radon measurements in workplaces and mixed-use buildings must be carried out in radon prone areas to demonstrate compliance with national reference levels (NRLs) [EC 2014]. Initially, the aim is to ensure the overall protection of the users of the buildings rather than to control doses to specific individuals. An employer has responsibility towards its employees to ensure radon levels are as low as reasonably achievable.<br>If the appropriate measurement result is above the NRL then optimisation must be carried out to reduce exposures. Such actions include physical remediation measures (mitigation) to reduce radon concentrations, management actions to reduce occupancy, and measurements to investigate the activity concentration during working hours, if appropriate.<br>If mitigation is carried out, then repeat measurements should be made to confirm the effectiveness of the mitigation system and records of the measurements should be kept. Remediated premises should be re-measured periodically to ensure that radon levels remain low. Measurements should also be repeated after any significant building work or changes to an operational cycle affecting exposure conditions such as changes to the heating, ventilation and air conditioning operation.<br>If in spite of mitigation actions radon levels (as an annual average) remain above the NRL, the relevant regulator must be notified. A dose assessment is required taking account of actual parameters of the exposure situation such as occupancy patterns and, potentially, associated regular variations in radon levels. If doses are above 6 mSv per year then the workplace mustl be managed as a planned exposure situation whereas if below or equal to 6 mSv per year they must be kept under review. For some workplaces, such as thermal spas, caves, mines and other underground workplaces, competent authorities may consider from the outset that workers' exposure to radon is occupational [ICRP 2014]. |
| H02 | A | A national protocol/methodology should be developed for the determination of the annual average radon activity concentration in indoor workplaces and for the dose assessment of workers to ensure a consistent approach nationwide. |
| | | ***Q2**: What are the strategies for radon risk communication?* |
| H03 | I | As part of the national radon action plan, information about radon measurements, radon risk and remediation should be communicated to employers and employees. Core messages for employers and employees should be developed that are simple, brief and to the point [WHO 2009]. Employers should: find out if their workplace needs to be tested for radon, carry out appropriate tests, act on the results and share information with employees and building users as appropriate. It should be stressed that practical techniques for mitigation are available. |
| H04 | I | The synergistic effect of tobacco smoking and radon should be communicated to employers and employees [ICRP 2014]. |
| H05 | I | An assessment of the level of knowledge and the perceptions of radon risks of the target audience should be carried out both before and after a risk communication campaign [WHO 2009]. |
| | | ***Q3**: How should it be ensured that measurements are reliable?* |
| H06 | I | A quality assurance programme should be established and maintained by all those providing radon measurement services. It is preferable but not mandatory that radon measurement services, testing and calibration laboratories are accredited in accordance with ISO/IEC 17025:2005. |
| H07 | I | Regular calibrations, duplicate measurements, blind tests, laboratory and field background measurements should be part of the quality assurance programme. Radon services are also recommended to participate in intercomparison exercises or performance tests [WHO 2009; ICRU 2012]. |
| H08 | I | Measurements should be metrologically traceable. The measurement uncertainty should be estimated, taking account of both calibration and field measurement uncertainties, and should be in accordance with [ISO/IEC 2008]. |

| R# | G | Text of the recommendation |
|---|---|---|
| | | ***Q4**: What measurement strategies for workplace monitoring should be adopted to demonstrate compliance with reference levels and dose limits?* |
| H09 | I | The monitoring strategy for indoor workplaces should take account of the exposure conditions and the operation cycle. Typically, for indoor workplace monitoring, area radon gas measurements are recommended to investigate if the annual average radon concentration is below the NRL. Long-term measurements over a period of a year are advisable. However, if for practical reasons this is not feasible, then a measurement period of at least 3 months is recommended. Seasonal correction factors may be applied, if appropriate, to convert 3-month measurements to annual averages but these factors should be derived for a given climate or region. National or regional studies should, therefore, be undertaken to determine if there is an observable and reliable seasonal variation. An alternative approach is to use the heating season measurement without correction for a conservative estimate of the annual average radon concentration [ICRU 2012]. |
| H10 | I | The choice of the detector for radon gas measurements depends upon the purpose of the measurement, the detector's suitability and the cost. Alpha track detectors are recommended for long-term measurements although electret ionisation chambers are a suitable alternative. In situations of suspected high thoron activities, it is recommended to use radon-thoron discriminative detectors [ICRU 2012]. |
| H11 | I | Stationary devices for area measurements of radon gas should be installed at positions that are representative of the worker's exposure, i.e. within the breathing zone (generally 1-2 metres above floor level) of regularly occupied locations. The aim is to measure radon in relevant parts of the workplace that are regularly occupied including: a representative number of ground floor locations and all regularly occupied spaces that are below ground level [WHO 2009; ICRU 2012]. |
| H12 | I | For indoor workplaces, where the radon level (as an annual average) remain above the NRL and where significant cyclic variations in radon concentrations are likely, time-resolved measurements should be considered to explore the activity concentration during working hours. In such cases, devices with a maximum time resolution of one hour are recommended [ICRU 2012]. |
| | | ***Q5**: When should radon progeny measurements be employed?* |
| H13 | I | Radon progeny measurements are recommended at workplaces where the equilibrium factor varies significantly because of variation in the ventilation or fluctuations in aerosol particle concentration [ICRU 2012]. |
| | | ***Q6**: When should individual monitoring be employed?* |
| H14 | I | In workplaces where workers' exposure to radon is considered as occupational or is managed as a planned exposure situation, individual exposure or dose assessments are required to demonstrate compliance with reference levels and dose limits. Depending upon exposure conditions, individual as well as area monitoring may be applied. If the spatial and temporal conditions are very variable or if the individual frequently changes exposure sites with different exposure conditions then individual monitoring is generally recommended, if appropriate. For example, personal monitors are used in many underground workplaces, such as mines, where the exposure conditions are variable [ICRP 2014; ICRU 2012]. |
| | | ***Q7**: Which dose coefficients should be used?* |
| H15 | A | The latest dose conversion factors recommended by ICRP for the inhalation of radon progeny and thoron progeny should be used for radiation protection purposes, if a dose assessment is required. The Article 31 Group of Experts will continue to review updates of ICRP Publications, and the European Commission will make recommendations on dose coefficients for radon taking account of their opinions. |

G= Grade: M = Mandatory, I = International, A = Advisory

# Annexes

# ANNEX I – Reference Biokinetic and Dosimetric Models

## Introduction

This Annex presents the biokinetic and dosimetric models that were used in the dose calculations for doses to workers in ICRP Publication 68 [ICRP 1994b], as well as the revised models used in the OIR report series [ICRP 2015b].

## Biokinetic models

Biokinetic models describe the uptake of radionuclides to the body (via the gastro-intestinal (or alimentary) tract, the respiratory tract or via a wound), their retention, transfer to other body regions and their excretion. They are needed for the calculation of the time-integrated activity (number of nuclear transformations) in the source regions $r_S$ where the radionuclides accumulate.

There are compartmental biokinetic models for the gastro-intestinal and alimentary tracts, for the respiratory tract, for wounds, for radionuclides in the systemic circulation (systemic models), and for excretion.

A compartmental structure may be visualised as a series of boxes (compartments) connected with arrows (representing ransfer/exchange of material between compartments). An example of a generic four-compartment-model is given in Figure AI.1.

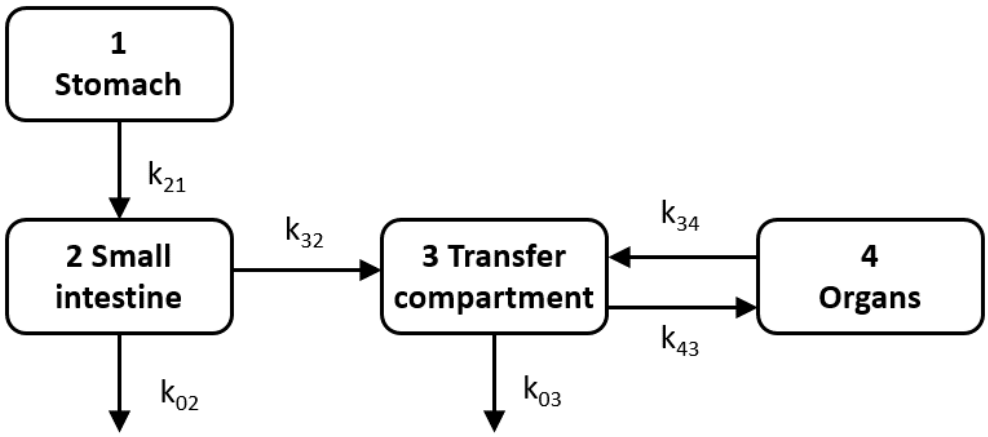



**Figure AI.1** A four-compartment model. The boxes represent the compartments, and the arrows the flow of materials between compartments

In the models used for internal dosimetry, compartments usually correspond to specific organs or tissues. One compartment can group together many organs/tissues, or conversely one organ/tissue can be described by many compartments. In a model for internal dosimetry, the compartments represent the organs or tissues where radionuclides are present and therefore correspond to the source regions $r_S$.

In general the exchange of material between the organs and tissues that the compartments represent is assumed to be regulated by first-order kinetics: the mass (activity) going from a given compartment i to another compartment j is proportional to the mass (activity) present in i. Therefore the equation governing the activity in the $i^{th}$ source region $A(r_{Si}, t)$ is given by:

$$\frac{dA(r_{Si},t)}{dt} = \sum_{j\neq i}\left(k_{ij}A(r_{Sj},t) - k_{ji}A(r_{Si},t)\right) - \lambda_R A(r_{Si},t) \qquad \text{(Eq. AI.1)}$$

with $k_{ji}$ being the transfer coefficient rate from compartment i (source region $r_{Si}$) to compartment j (source $r_{Sj}$) and $\lambda_R$ the radioactive decay constant.

## Respiratory Tract

The ICRP Human Respiratory Tract Model (HRTM) of ICRP Publication 66 [ICRP 1994a] (Figure AI.2) was used for the calculation of dose coefficients for ICRP Publication 68 [ICRP 1994b] and Publication 119 [ICRP 2012], as well as for the calculation of bioassay data for ICRP Publication 78 [ICRP 1997]. In this model, the respiratory tract is treated as two tissues: the extrathoracic airways and the thoracic airways. The extrathoracic tissues are sub-divided into the regions $ET_1$ (the anterior nasal passage), $ET'_2$ (the posterior nasal passage, the pharynx and the larynx) and the ET lymph nodes ($LN_{ET}$). The thoracic tissues (i.e. the lungs) are subdivided into the regions BB (the trachea and bronchi), bb (the bronchioles), AI (the alveolar interstitial region) and the thoracic lymph nodes ($LN_{TH}$).

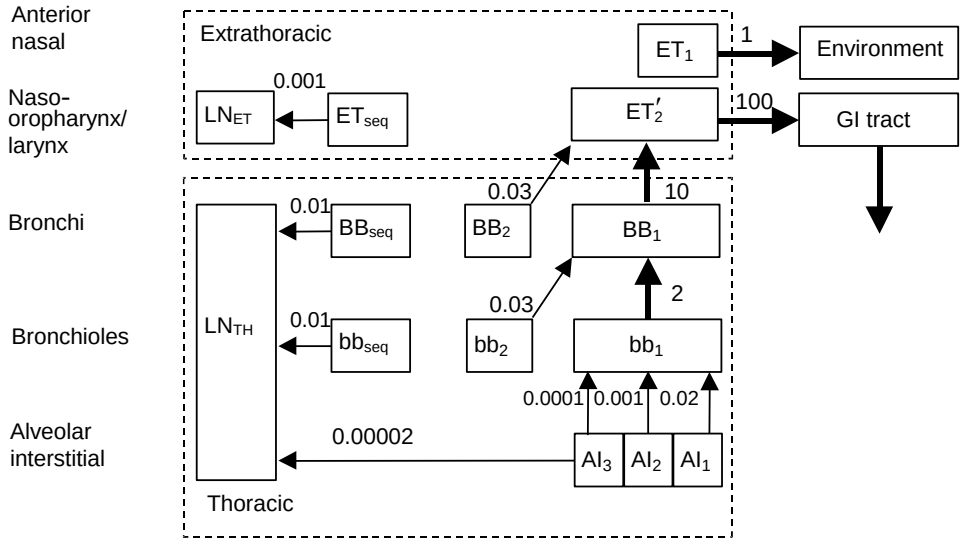



**Figure AI.2** ICRP Publication 66 [ICRP 1994a] biokinetic model of the human respiratory tract including particle transfer rates (in $d^{-1}$) (reproduced with kind permission of ICRP)

The deposition of aerosols depends on the physical properties of the aerosol, especially particle sizes, and on the age, sex and breathing behaviour of the individual who inhales the aerosol. The particle sizes are given in terms of the AMAD, the activity median aerodynamic diameter. The AMAD is a particle size such that half of the activity in the aerosol is associated with particles with an aerodynamic diameter greater than the AMAD and the other half with particles with a smaller aerodynamic diameter. The aerodynamic diameter of a particle is the diameter of a unit density sphere with the same terminal settling velocity in air as the particle considered. The AMAD is a suitable term for larger particles (> 0.1 μm) when the aerodynamic properties such as gravity and inertia are more relevant for the deposition processes. For smaller particles (up to 1 μm), for which the thermodynamic properties of the particles such as the Brownian motion dominate the deposition process, the activity median thermodynamic diameter, AMTD, is more appropriate. In the OIR report series the AMTD is used for aerosol sizes smaller than 0.3 μm, while the AMAD is used for aerosol sizes of 0.3 μm and larger.

In worker dose assessment cases, the AMAD is often not known. A default assumption of 5 μm is then made; this value is consistent with the reviews of workplace measurements by Dorrian and Bailey [Dorrian 1995].

Methods for deriving deposition values from the physical aerosol properties such as AMAD or AMTD, geometric standard deviation, density and shape factor are described in ICRP Publication 66. In Table AI.1 the default deposition values for workers are listed for various particle sizes. The fraction that is not deposited in any region of the respiratory tract is assumed to be exhaled again immediately.

The HRTM of ICRP Publication 66 was revised in Part 1 of the OIR report series, ICRP Publication 130 [ICRP 2015b] (Figure AI.3). The revised model has fewer compartments. The main changes are that material deposited in the $ET_1$ compartment can also be transferred to the $ET'_2$ compartment, modelling of slow clearance from the bronchial tree was simplified, and the modelling of deposition and clearance from the alveolar interstitial region was revised.

**Table AI.1** Reference deposition values for workers for various particle sizes; for computational purposes, these values are given to a higher precision than would be justified by the underlying knowledge (% of inhaled activity).

| HRTM compartment | AMAD 0.3 μm | AMAD 1 μm | AMAD 5 μm | AMAD 10 μm |
|---|---|---|---|---|
| $AI_1$ | 4.458 | 3.198 | 1.596 | 0.7104 |
| $AI_2$ | 8.916 | 6.396 | 3.191 | 1.421 |
| $AI_3$ | 1.486 | 1.066 | 0.5319 | 0.2368 |
| $bb_1$ | 1.523 | 0.8327 | 0.6569 | 0.4131 |
| $bb_2$ | 1.544 | 0.8087 | 0.4384 | 0.2099 |
| $bb_{seq}$ | 0.02162 | 0.01157 | 0.007721 | 0.004392 |
| $BB_1$ | 0.3260 | 0.6489 | 1.171 | 0.9436 |
| $BB_2$ | 0.3293 | 0.5844 | 0.5921 | 0.3116 |
| $BB_{seq}$ | 0.004619 | 0.008694 | 0.01243 | 0.008848 |
| $ET'_2$ | 5.820 | 21.11 | 39.89 | 38.36 |
| $ET_{seq}$ | 0.002912 | 0.01056 | 0.01996 | 0.01919 |
| $ET_1$ | 5.217 | 16.52 | 33.85 | 34.71 |

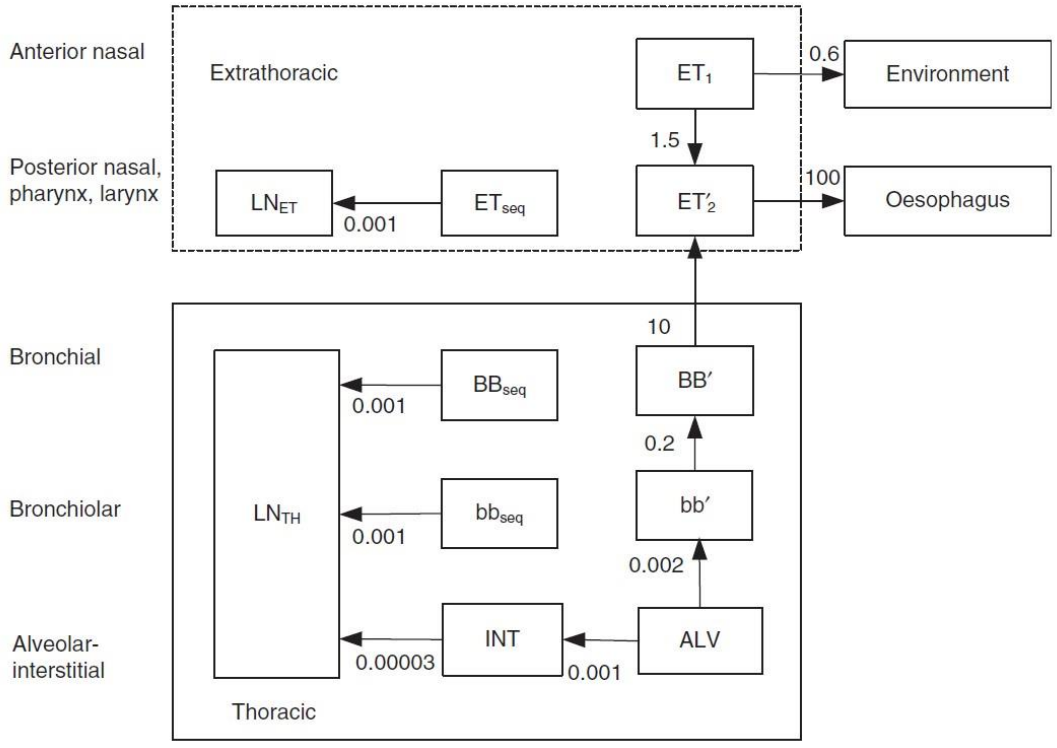



**Figure AI.3** ICRP Publication 130 [ICRP 2015b] biokinetic model of the human respiratory tract including particle transport rates (in $d^{-1}$) (reproduced with kind permission of ICRP))

Total deposition in the respiratory tract regions is identical for both models. However, in the revised model, a larger fraction of activity is deposited in the $ET_1$ region compared to the other extrathoracic compartments, thus allowing for the transfer of activity from $ET_1$ to $ET'_2$.

For material deposited in the respiratory tract there are three clearance processes. Material deposited in the anterior nose (the $ET_1$ compartment) is removed by extrinsic means (nose blowing, wiping, etc.). For all other material deposited in the respiratory tract, there are two other competing clearance processes, particle transport via the pharynx to the gastro-intestinal (or alimentary) tract and via the lymphatic system to the lymph nodes, and absorption into the blood.

The particle transport pathways and rates are shown in Figure AI.2 and Figure AI.3. A small fraction of material is retained in the airway walls. Specifically, it is deposited in the sequestration compartments of the ET, BB and bb regions from where it is transferred to the (extrathoracic or thoracic) lymph nodes. A small fraction is also removed from the AI region to the thoracic lymph nodes. Much more material is moved upwards by airway surface transport (mucociliary clearance) into the pharynx (included in the $ET'_2$ compartment) where it is swallowed and transferred into the alimentary tract (into the stomach when the gastro-intestinal tract model of ICRP Publication 30 [ICRP 1979] is used; into the slow clearance compartment of the oesophagus when the HATM [ICRP 2006] is used). For this particle transport to the pharynx, fast and slow components are represented by different compartments in the ICRP Publication 66 model [ICRP 1994a]. The distribution of activity between the fast compartment, the slow compartment and the sequestration compartment is defined by the deposition model.

In both the original (ICRP Publication 66) and the revised (ICRP Publication 130) HRTM, particle transport is considered to be independent of the material and independent of the age and sex of the person considered.

Absorption to blood is considered to operate in the same way from all compartments (except $ET_1$). The compartmental model representing absorption to blood "operates" on each compartment in the particle transport model (except for $ET_1$) and is shown in Figure AI.4 in two alternative configurations which are essentially equivalent.

In ICRP Publication 66 [ICRP 1994a], absorption parameter values were given for the model shown as (b) in Figure AI.4. From each compartment of the particle transport model (equivalent to the "Particles in initial state" compartment in the absorption model), there is direct absorption to blood with a transfer rate $s_p$. For a part of the material, however, there may be a slower absorption to blood. This part is transferred with a transfer rate $s_{pt}$ to the compartment "Particles in transformed state" from where it is absorbed to blood with the lower transfer rate $s_t$. Additionally, the absorption model allows for the possibility that the material may not be absorbed instantaneously into blood but may be retained within the tissue walls. For this, the compartment "Bound material" is included; a fraction of the material is transferred into this compartment with the same transfer rates $s_p$ and $s_t$ and is absorbed into blood from there with the transfer rate $s_b$. In the "Bound material" compartment, no particle transport takes place.

In the OIR report series, absorption parameters are given for the model shown as (a) in Figure AI.4 in almost all cases. A fraction $f_r$ of the deposit in each compartment of the particle transport model is assigned to the "Rapid dissolution" compartment, while the remainder of the deposit is assigned to the "Slow dissolution" compartment. Absorption to blood from these two compartments proceeds with transfer rates $s_r$ and $s_s$ respectively, and "Bound material" is modelled in a similar way to that in the alternative model.

Absorption rates depend on the chemical properties of the material. Because the material-specific absorption rates for a particular compound are in many cases not known, three default absorption Types are defined in ICRP Publication 66 for compounds which are soluble, less soluble, or insoluble. These default absorption Types are Types F, M, and S, for cases when the absorption is fast, moderate, or slow.

In some cases (for example for gases), the absorption Type V (very fast) is also used. For this, an instantaneous absorption into blood is assumed. The absorption rates for the default absorption Types F, M, and S specified in Publication 66 are listed in Table AI.2. These absorption rates were reviewed in [ICRP 2015b], and revised values were specified for the revised HRTM. These values are also shown in Table AI.2.

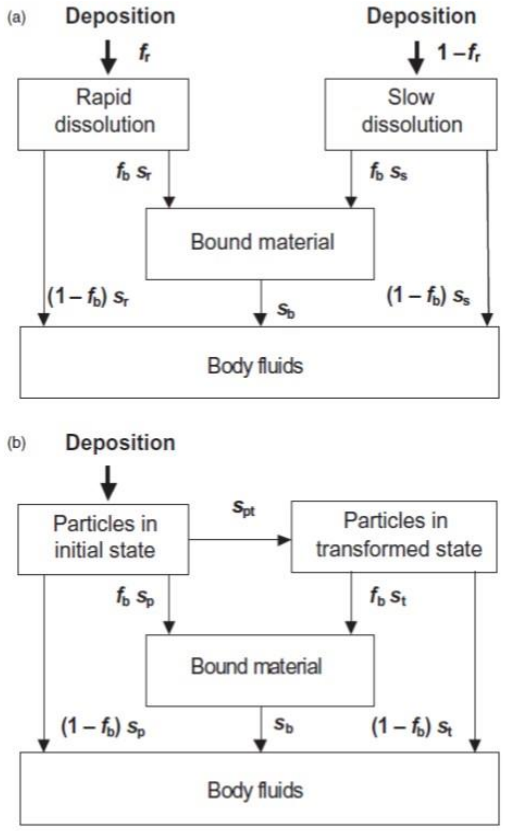



**Figure AI.4** Alternative compartment models representing time-dependent absorption to blood (dissolution and uptake) [ICRP 2015b] (reproduced with kind permission of ICRP)

**Table AI.2** Default absorption rates (in $d^{-1}$) and rapid dissolution fractions specified in ICRP Publication 66 [ICRP 1994a] and ICRP Publication 130 [ICRP 2015b]

| Absorption Type | F | | M | | S | |
|---|---|---|---|---|---|---|
| | ICRP 66 | ICRP 130 | ICRP 66 | ICRP 130 | ICRP 66 | ICRP 130 |
| $s_p$ | 100 | 30* | 10 | 6* | 0.1 | 0.03* |
| $s_{pt}$ | 0 | 0 | 90 | 24* | 100 | 3* |
| $s_t$ | - | | 0.005 | 0.005 | 0.0001 | 0.0001 |
| | | | | | | |
| $f_r$ | 1 | 1 | 0.1 | 0.2 | 0.001 | 0.01 |
| $s_r$ | 100 | 30* | 100 | 3* | 100 | 3* |
| $s_s$ | - | - | 0.005 | 0.005 | 0.0001 | 0.0001 |

* For some elements, specific values are recommended rather than the generic default values.

The bound state is not used in the default Types of the Publication 66 HRTM, and so is not included in the biokinetic data underlying the dose coefficients of ICRP Publications 68 and 119. However, in the OIR report series [ICRP 2016b; 2017], the bound state is used for some elements (for example cobalt and lead). In addition, in the OIR report series, specific absorption parameter values differing from those of the default Types are given for compounds of some specific elements. For uranium, for example, specific absorption parameter values are given for nine compounds [ICRP 2017].

Inhaled gases and vapours are exhaled again when they are not dissolved in, or in reaction with, the airway surfaces. Therefore their deposition is dependent on their solubility and reactivity. Three default classes are defined in ICRP Publication 66 for gases and vapours:

- Class SR-0 for insoluble and non-reactive material such as noble gases for which deposition in the respiratory tract is negligible. For these gases no deposition in the respiratory tract is assumed;
- Class SR-1 for soluble or reactive material like carbon monoxide or elemental iodine for which by default deposition values of 0.1, 0.2, 0.1, 0.2, and 0.4 are assumed for $ET_1$, $ET'_2$, BB, bb, and AI, respectively;
- Class SR-2 for highly soluble or reactive material like carbon dioxide or tritiated water for which a complete deposition in $ET'_2$ with immediate absorption to blood is assumed.

In the OIR report series, the standard assumption for gases and vapours is a fractional deposition of 0.2, 0.1, 0.2, and 0.5 in $ET'_2$, BB, bb, and AI, respectively, with absorption according to absorption Type F when there is no specific information on the element.

## Alimentary Tract

For the calculation of the dose coefficients published in ICRP Publications 68 and 119 and the bioassay data published in ICRP Publication 78, ICRP uses the gastro-intestinal tract model of its Publication 30 [ICRP 1979] (Figure AI.5). This is a simple four-compartment model (stomach, small intestine, upper large intestine and lower large intestine) based on [Eve 1966], which allows absorption to body fluids (blood) from the small intestine.

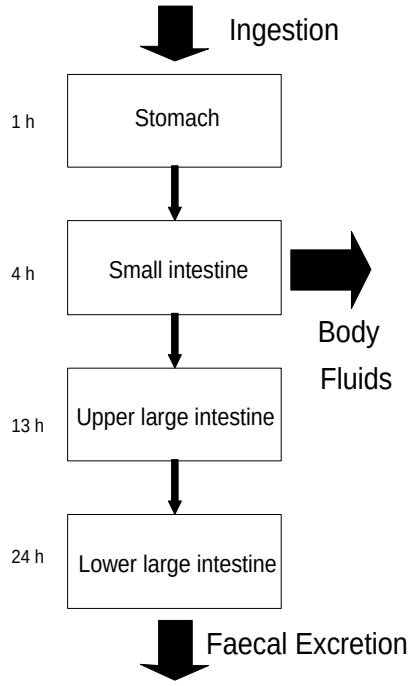



**Figure AI.5** ICRP Publication 30 [ICRP 1979] biokinetic model of the gastro-intestinal tract with mean transit times

In this model the mean transit times are 1 h for the stomach, 4 h for the small intestine, 13 h for the upper large intestine, and 24 h for the lower large intestine. These transit times are considered to be independent of the ingested material, and of age and gender of the person.

The fraction that is absorbed to body fluids from the small intestine is called $f_1$ and is dependent on the chemical properties (the solubility) of the material. In ICRP models

for workers, it ranges from 1.0E-05 for very insoluble material such as insoluble compounds of plutonium, up to 1 for very soluble material such as caesium compounds or iodine, which are considered to be completely absorbed to blood.

In its Publication 100 [ICRP 2006], ICRP published a new Human Alimentary Tract Model (HATM) (Figure AI.6); the HATM is used in the OIR report series.

In contrast to the Publication 30 gastro-intestinal model, the HATM also includes the oral cavity and the oesophagus, which has its own tissue weighting factor for the calculation of effective dose. Absorption to the systemic circulation is possible from (almost) all sites of the tract, and is not necessarily instantaneous as it was in the Publication 30 model. In the HATM, there may be retention in the walls of the tract with subsequent recycling of some of the material back into the contents of the tract. The total fraction of activity which is absorbed from the alimentary tract to the systemic circulation in the HATM is called $f_A$, which may in principle be the sum of the various local absorption fractions. For the elements covered by Parts 2 and 3 of the OIR report series, however, absorption in the HATM takes place only from the small intestine without retention in the small intestine wall, and so the meaning of $f_A$ is the same as that of $f_1$ in the Publication 30 gastro-intestinal tract model.

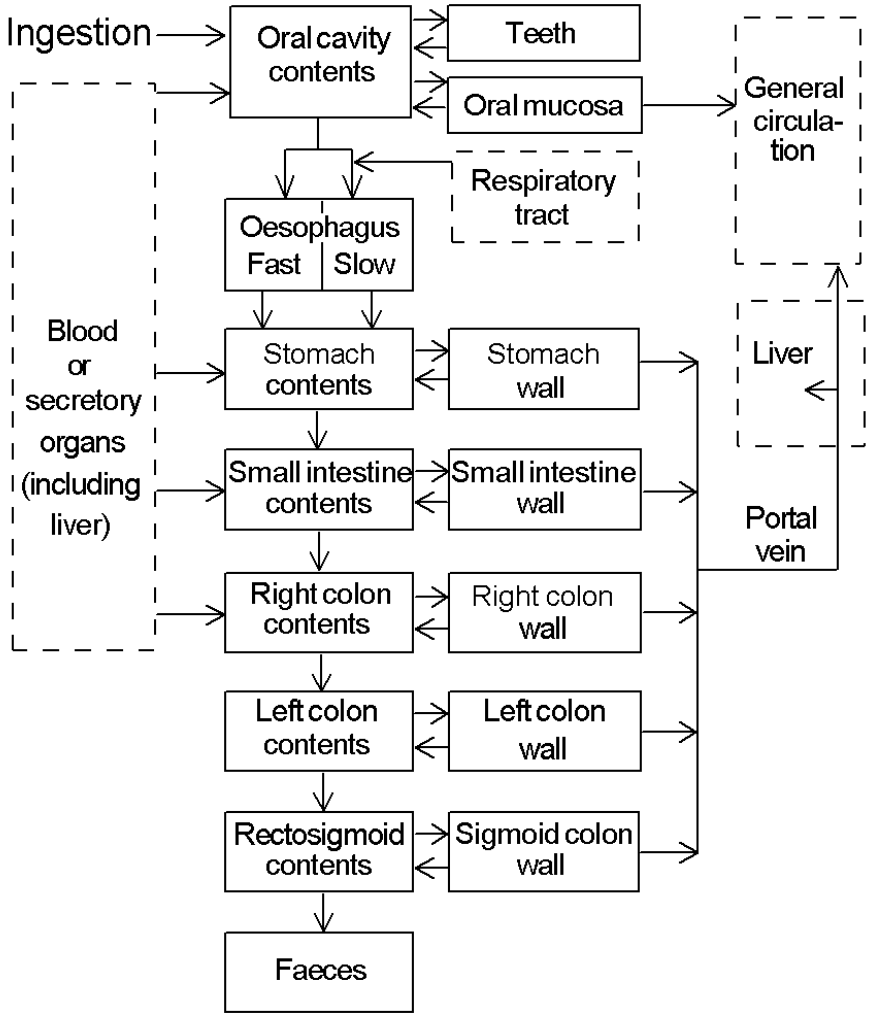



**Figure AI.6** ICRP Publication 100 [ICRP 2006] biokinetic model of the human alimentary tract (reproduced with kind permission of ICRP)

In the OIR report series only male biokinetic parameter values are used. The default mean transfer times of the HATM used in the OIR report series are shown in Table AI.3. For the oesophagus, two compartments with different mean transit times are given: the fast compartment (90%) representing the first swallowing and the slow compartment (10%) representing the residual activity after the first swallowing.

**Table AI.3** Default mean transfer times in the HATM compartments for male adults given in ICRP Publication 100

| HAT Region | mean transit time |
|---|---|
| Mouth | 12 s |
| Oesophagus | 7 s / 40 s |
| Stomach | 70 min |
| Small intestine | 4 h |
| Right colon | 12 h |
| Left colon | 12 h |
| Rectosigmoid | 12 h |

## NCRP Wound Model

For intakes of radionuclides via a wound, NCRP has developed a wound model [NCRP 2007] which is also presented in ICRP Publication 130 [ICRP 2015b]. It is a five-compartment model (Figure AI.7), which describes the wound retention and the subsequent transfer to lymph nodes and blood for soluble material, colloids, particles and fragments (large particles with a diameter > 20 μm). Default transfer rates are given for all forms entering the wound, with four different parameter sets for soluble material (weak, moderate, strong and avid). Most weak soluble material is cleared from the wound site within the first day while the retention of untreated fragments is mainly characterised by a biological half-time of almost 300 years.

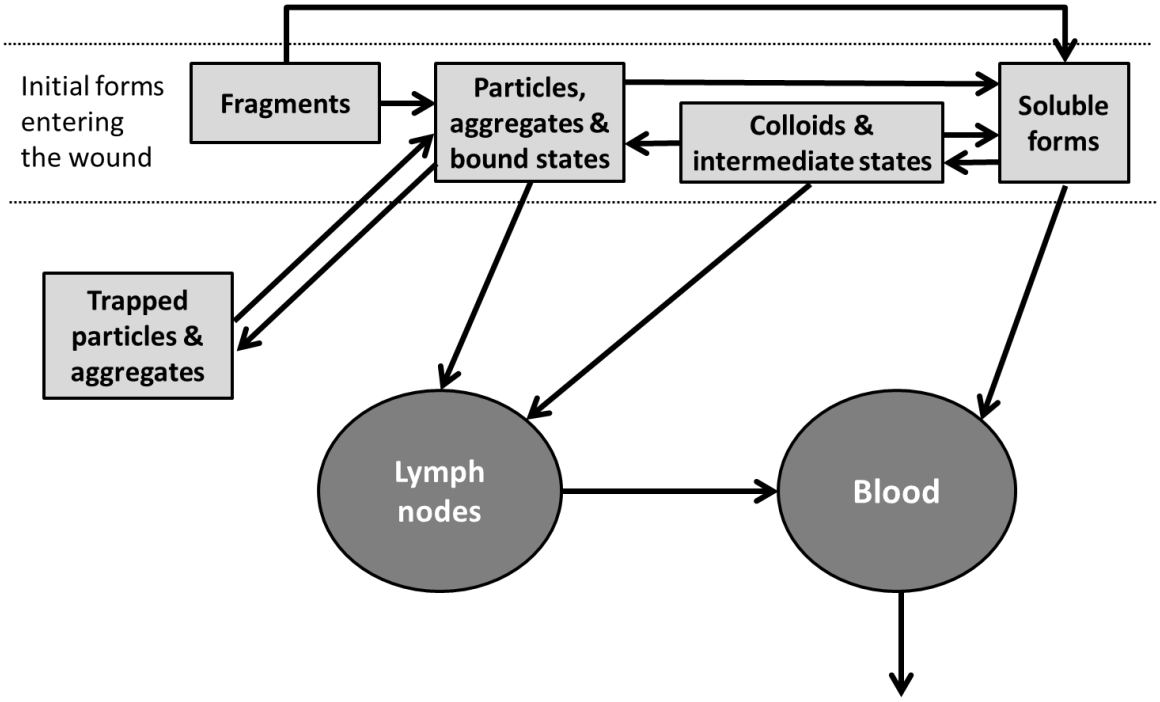



**Figure AI.7** Schematic representation of the NCRP wound model [NCRP 2007]

## Systemic Models

Activity injected or absorbed into blood from the respiratory tract, the gastro-intestinal (or alimentary) tract or from a wound is distributed to various organs according to the chemical properties of the substance, and may then be excreted. Figure AI.8 shows the generic model of ICRP Publication 67 [ICRP 1993b], which is an extension of the generic model given in the ICRP Publication 30 series [ICRP 1979-1988] for systemic

activity and which is used for the calculation of dose coefficients for most radionuclides published in ICRP Publication 119.

For the skeleton, the tissues trabecular bone, cortical bone and red marrow are considered as source regions. For the bone compartments, the biokinetic model distinguishes between surface and volume source regions.

In this model, activity is excreted directly from compartments representing the source organs instead of the physiologically more realistic assumption that activity is transported back into blood and is excreted from there. The excretion pathways are described in more detail below.

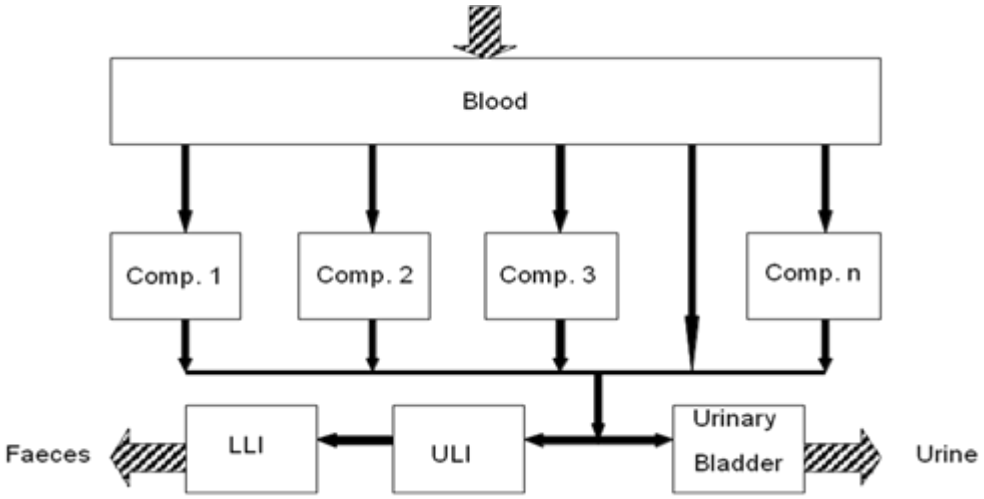



**Figure AI.8** Generic biokinetic model of ICRP Publication 67 [ICRP 1993b] for systemic activity; ULI and LLI are the upper large intestine and lower large intestine, respectively

ICRP Publications 67, 69, and 71 [ICRP 1993b; 1995a; 1995b] present more complex physiologically-based recycling models for actinides, for alkaline earth elements, and for iron; see for example Figure AI.9. These models describe in more detail the skeleton kinetics and result in more realistic doses and bioassay data.

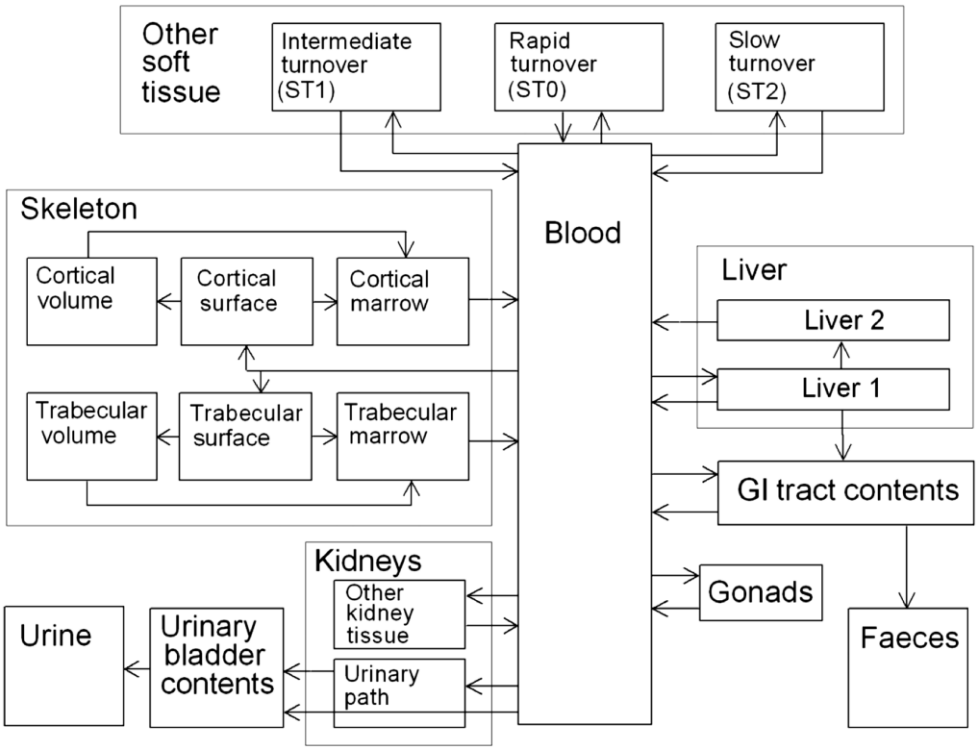



**Figure AI.9** Systemic biokinetic model for actinides [ICRP 1993b] (reproduced with kind permission of ICRP)

In the OIR report series, all systemic models are physiologically based recycling models. There are several model types for other groups of elements that are similar to the model framework for alkaline earths and actinides.

### Excretion Models

To model excretion in urine and faeces, the biokinetics of the excretion pathways must be considered. The OIR report series assumes that the urinary bladder empties every 4 h. For calculating dose coefficients and bioassay data, the simplifying assumptions of first-order kinetics with a urinary bladder clearance rate of 12 $h^{-1}$ are made.

For faecal excretion modelled using the Publication 30 GI tract model [ICRP 1979], the generic systemic model transfers activity to the upper large intestine from where it is excreted via the lower large intestine to faeces. With the HATM [ICRP 2006], activity is transferred to the right colon from where it is excreted via the left colon and rectosigmoid colon. These are simplifying assumptions, which avoid complications with re-absorption when considering a physiologically more realistic secretion into the small intestine. In some of the physiologically-based recycling models, however, secretion into the small intestine is also considered, for example for iron [ICRP 1995a]. Excretion via the gall bladder is not considered in ICRP's biokinetic models for workers.

### Biokinetic Behaviour of Daughter Radionuclides

For the calculation of dose coefficients, the contribution of daughter radionuclides produced within the body is taken into account. In the biokinetic models underlying the dose coefficients published in ICRP Publication 119, it is in general assumed that the daughter radionuclides have the same kinetics as the parent radionuclide (*shared kinetics*). Exceptions are iodine isotopes as decay products of tellurium isotopes and some isotopes of noble gases, for which it is assumed that they (partly) leave the body instantaneously without decay. Further exceptions are daughter radionuclides of lead, radium, thorium and uranium for which it is assumed that the daughter radionuclides follow their own kinetics independently of the parent radionuclide kinetics (*independent kinetics*). In the OIR report series independent daughter kinetics are implemented in most cases. In ICRP Publication 78, bioassay model predictions for daughter radionuclides are also given for the assessment of the intake of the parent radionuclide in some cases (for example bioassay model predictions for $^{214}$Pb and $^{214}$Bi as daughters of $^{226}$Ra).

## Dosimetric Models

The aim of the dosimetric models is to calculate the dose in a target tissue $r_T$ caused by a nuclear transformation in a source region $r_S$. For this, absorbed fractions $\phi(r_T \leftarrow r_S)$ for pairs of source regions $r_S$ and target tissues $r_T$ (i.e., the fraction of energy emitted in $r_S$ as a specified radiation which is absorbed in $r_T$) are needed.

Absorbed fractions for penetrating radiation (gamma radiation) are calculated with Monte Carlo methods which describe the photon transport within an anatomical phantom. In general, for non-penetrating radiation (alpha and, to a lesser extent, beta radiation) it is assumed that the absorbed fractions $\phi(r_T \leftarrow r_S)$ = 1 for $r_T = r_S$ and = 0 for $r_T \neq r_S$. This is an adequate approximation for larger regions $r_T$ and $r_S$. However, it is not adequate, for example, for small target regions as in the skeleton, the respiratory tract, the alimentary tract and in the case of the bladder wall with the source region bladder content. For these calculations it is assumed that the activity is homogeneously distributed within the source regions, and the average doses to target tissues are calculated.

The simplifying assumptions mentioned above were made for the dose coefficients of ICRP Publication 119 [ICRP 2012] for beta radiation. In addition, for the OIR report series [ICRP 2015b], Monte Carlo calculations with anatomical voxel phantoms [ICRP 2009b; 2016a] were performed for electrons.

## Anatomical Models

Anatomical phantoms were first developed as mathematical phantoms which describe the body and its organs using geometrical figures such as, for example, ellipsoids. Figure AI.10 shows a phantom family of the newborn, the 1, 5, 10, 15 year-old, and the adult [Cristy 1987] including cross-sections through the newborn and the adult.

These mathematical phantoms, of course, are only rough approximations of the human anatomy. With the increase in computer power, more realistic phantoms have been developed. These are Voxel (volume elements, actually an abbreviation of volume pixel) phantoms, which offer an improved anatomical representation of the human body compared to the mathematical phantoms. Voxel models are based on detailed anatomical data from humans of different age, sex, weight, height which can be obtained from CT or MRI images.

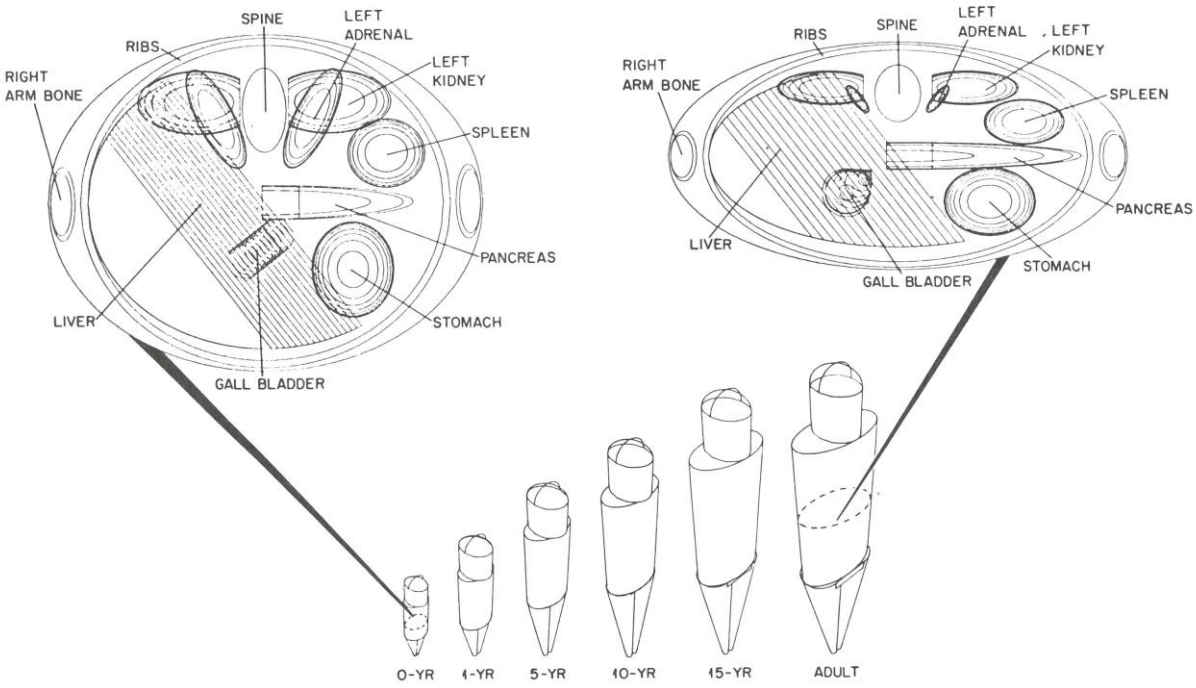



**Figure AI.10** External views of the phantoms and superimposed cross-sections within the middle trunk of the newborn and adult male phantoms [Cristy 1987]

These voxel phantoms describe an individual person. In radiation protection, however, doses to Reference Persons are needed, as described in ICRP Publication 89 [ICRP 2002]. For the adult Reference Male and Reference Female, ICRP developed such voxel phantoms (see Figure AI.11) on the basis of images of individuals who were similar in height and weight to the reference persons; the resulting voxel phantoms were then adjusted to characteristics such as the organ weights of the Reference Persons. These phantoms were published in ICRP Publication 110 [ICRP 2009b]. The number of voxels is 211427 for the male phantom (voxel size 36.54 $mm^3$) and 378204 for the female phantom (voxel size 15.25 $mm^3$), respectively. The OIR report series uses absorbed fractions for electrons and gamma radiation based on these voxel phantoms [ICRP 2016a].

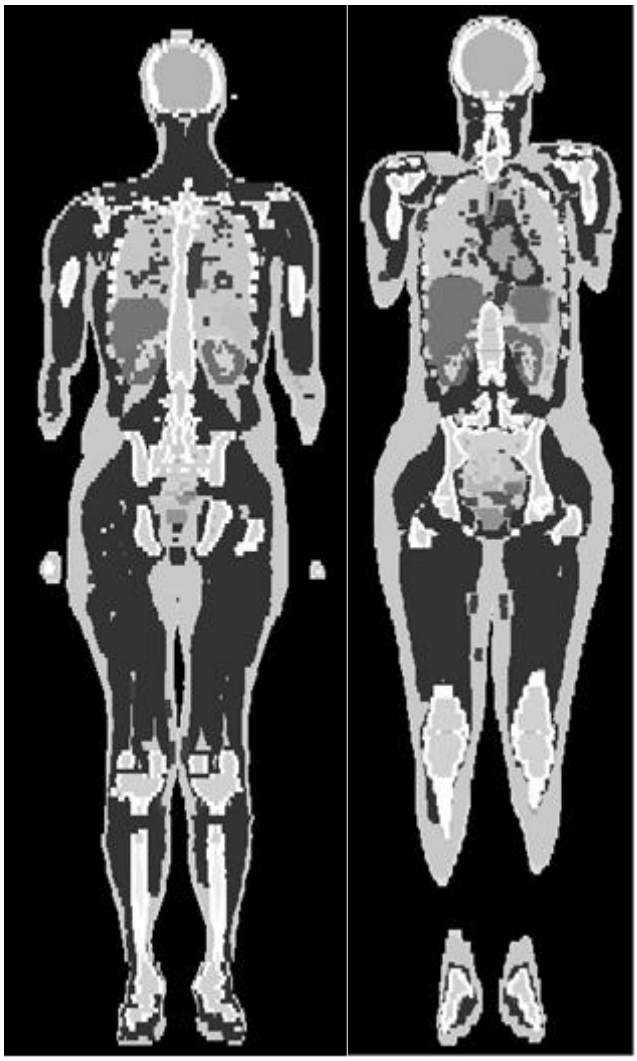


**Figure AI.11**

**Figure AI.11** Coronal image of the male (left) and female (right) adult reference computational phantoms as described in [ICRP 2009b] (courtesy of M.Zankl, Helmholtz Zentrum München)

## Models for the Skeleton

In the skeleton models underlying the dose coefficients of ICRP Publication 119, red bone marrow as a source and target region, trabecular bone and cortical bone as source regions, and bone surfaces as target tissues are all considered. In the description of source regions in the generic systemic model [ICRP 1993b], activity distributed on bone surfaces is distinguished from activity within the bone volume. The target tissue of bone surfaces is a 10 μm thin tissue layer at the surfaces.

In ICRP Publication 30 [ICRP 1979], constant absorbed fractions for non-penetrating radiation (alpha and beta radiation) are assumed, and for beta emitters on bone surfaces, two values are given, for low (< 0.2 MeV) and high mean energies.

In the OIR report series [ICRP 2015b] bone dosimetry is much more refined. The dosimetric model averages the endosteal dose within 50 μm of the surfaces. For the calculation of absorbed fractions to endosteal tissues and red bone marrow, micro-CT images of the various parts of the skeleton are used by coupling fluence-to-dose response functions with the particle fluence inside specific bone regions.

## Respiratory tract and alimentary tract

In the Human Respiratory Tract Model (HRTM) [ICRP 1994a], several target tissues within the extrathoracic and the thoracic tissues of the respiratory tract are defined. In the extrathoracic tissues, these are the anterior nasal passage ($ET_1$) and the posterior

nasal passage, the pharynx and the larynx ($ET'_2$). In the thoracic tissues, they are the trachea and bronchi (BB), the bronchioles (bb) and the alveolar interstitial region (AI). Additionally, both extrathoracic and thoracic lymph nodes are target tissues.

The target tissues are the cell layers within the airways walls that are considered to be radiosensitive. These are the basal cells of the epithelium in both of the extrathoracic regions, the basal cells and secretory cells in the bronchial epithelium, the Clara cells in the bronchiolar epithelium, and the endothelial cells, such as those of the capillary walls and type II epithelial cells, in the AI region.

ICRP Publication 66 gives absorbed fraction values for non-penetrating (alpha and beta) radiation for pairs of source regions and target tissues of the respiratory tract. For penetrating (gamma) radiation the lungs of the mathematical phantoms were used in the derivation of absorbed fractions for all thoracic source regions and target tissues, and the thyroid was used as a surrogate for the extrathoracic source regions and target tissues.

In the development of voxel models, the different sub-regions of the respiratory tract are considered and absorbed fraction values are calculated for gamma radiation. For non-penetrating radiation, the ICRP Publication 66 values continue to be used because the target regions are too small to be modelled by voxels.

Using the methods described above, regional doses to the respiratory tract can be calculated. Doses to the extrathoracic tissues and to the thoracic tissues (lungs) are given as weighted mean values of the regional doses. The weighting is performed with so-called partitioning factors which indicate the radiosensitivity of the regional tissues. In ICRP Publication 66, for the extrathoracic region, the apportionment factors used are 0.998:0.001:0.001 for $ET'_2$:ET1:extrathoracic lymph nodes, and for the lungs the partitioning factors are 0.333:0.333:0.333:0.001 for BB:bb:AI:thoracic lymph nodes. For the OIR calculations, the extrathoracic and thoracic lymph nodes contribute to the lymph dose (with fractions of 0.08 each and a fraction of 0.84 for other lymph nodes).

Similarly to the HRTM, the Human Alimentary Tract Model (HATM) considers only specified radiosensitive cell layers as target regions. The location of the sensitive epithelial stem cells in the various regions is different for all regions of the tract and ranges from 60-100 μm for the stomach wall to 280-300 μm for the colon walls.

Absorbed fraction values for electrons are given in Annex F of ICRP Publication 100 [ICRP 2006]. For alpha radiation the absorbed fractions are non-zero only when the source region and target tissue are the wall of the same site in the tract. In these cases the absorbed fraction is taken to be the fraction of the thickness of the layer of the radiosensitive cells and the thickness of the mucosa in the wall. For the small intestine (depth of the mucosa 200 μm, radiosensitive cells at a depth of 130-150 μm), for example, the absorbed fraction would be $\phi$(small intestine wall $\leftarrow$ small intestine wall) = 0.1.

The colon dose is calculated as the mass-weighted average of the doses calculated for the upper and lower large intestine for the gastro-intestinal tract model used in ICRP Publication 30, or the three colon segments right colon, left colon and rectosigmoid in the HATM.

# ANNEX II –Examples of monitoring programme design and internal dose assessment

## Introduction

In this Annex, examples of dose assessment of cases are given to demonstrate the application of the Technical Recommendations. The cases have been evaluated with the ICRP biokinetic and dosimetric models of ICRP Publications 66, 67 and 69. The corresponding numerical values of dose coefficients and bioassay quantities per unit intake for default parameter values are given in ICRP Publications 68 and 78 respectively. The method of evaluation is consistent with ISO 27048:2011 [ISO 2011] and with the IDEAS Guidelines [EURADOS 2013].

## EXAMPLE 1: Criteria for individual monitoring and selection of monitoring method

### Description of the case

A group of workers will handle $^{239}$Pu and $^{241}$Am during normal chemical operations in a fume hood. The activity ratio of $^{239}$Pu to $^{241}$Am is about 5:1. The maximum permissible activity handled in the fume hood is 60 kBq of $^{239}$Pu per year. Moderate solubility and the default AMAD of 5 μm can be assumed. Although in practice $^{238}$Pu, $^{240}$Pu and $^{241}$Pu are likely to be also present, it is assumed in this example for illustrative purposes and for simplicity that there are no other plutonium isotopes present.

For this example, it is also assumed that there are no available data from past monitoring programmes (individual or workplace monitoring).

*Is routine monitoring required?*

*Can any procedures be implemented to avoid the need for individual monitoring?*

*Which individual monitoring method should be selected for $^{239}$Pu and $^{241}$Am.*

*Does routine monitoring of $^{239}$Pu (Type M) by urinary and faecal analysis have adequate sensitivity and which monitoring intervals are the appropriate?*

*Does routine monitoring of $^{241}$Am by lung monitoring have adequate sensitivity?*

### Assessment

*Is routine monitoring required?*

As there are no available monitoring data, the approach described by IAEA Safety Standard Series RS-G-1.2 involving the calculation of "decision factors" $d_j$ is used to decide if individual monitoring should be performed [IAEA 1999]. This approach suggests criteria for individual monitoring which are based on the potential for annual committed effective doses of 1 mSv or more. Other factors are also considered, including the physical safety factor $f_{fs}$, the handling safety factor, $f_{hs}$ and the protection safety factor, $f_{ps}$. Tables AII.1 and AII.2 present values of $f_{hs}$ and $f_{ps}$ suggested in IAEA RS-G-1.2. In the majority of the cases the physical safety factor $f_{fs}$ should be assigned a value of 0.01 [IAEA 1999].

A specific radionuclide decision factor $d_j$ (mSv) for a specific practice is defined as follows:

$$d_j = 1000 \cdot A_j \cdot e_{inh,j}(50) \cdot f_{fs} \cdot f_{hs} \cdot f_{ps} \qquad \text{(Eq. AII.1)}$$

where $A_j$ is the cumulative activity in Bq of radionuclide j present in the workplace over a year and $e_{inh,j}(50)$ is the committed effective dose for inhalation of radionuclide j in Sv Bq$^{-1}$. The decision factor for all the radionuclides in the workplace is given by:

$$D = \sum_j d_j \qquad \text{(Eq. AII.2)}$$

**Table AII.1** Handling safety factors, $f_{hs}$

| Process | $f_{hs}$ |
|---|---|
| Storage (stock solution) | 0.01 |
| Very simple wet operations | 0.1 |
| Normal chemical operations | 1 |
| Complex wet operations with risk of spills | 10 |
| Simple dry operations | 10 |
| Handling of volatile compounds | 100 |
| Dry and dusty operations | 100 |

**Table AII.2** Protection safety factors, $f_{ps}$

| Protection measure | $f_{ps}$ |
|---|---|
| Open bench operations | 1 |
| Fume hood | 0.1 |
| Glove box | 0.01 |

All radionuclides for which $d_j \geq 1$ mSv must be monitored. If $D$ is 1 mSv or more, a need for individual monitoring is indicated but if less than 1 mSv individual monitoring may not be necessary. When $D \geq 1$ mSv, radionuclides for which $d_j \geq 0.3$ mSv should also be monitored. However, monitoring for radionuclides for which $d_j$ is much less than 0.1 mSv is unnecessary.

The decision factor is used to decide if individual monitoring should be performed. Table AII.3 gives the specific radionuclide decision factor, $d_j$ and the decision factor, $D$ for both plutonium and americium.

**Table AII.3** Calculated decision factors

| Nuclide | Activity [Bq] | Dose coefficient, $e_{inh,j}(50)$ [Sv Bq$^{-1}$] | Physical safety factor, $f_{fs}$ | Handling safety factor, $f_{hs}$ | Protection safety factor, $f_{ps}$ | Specific radionuclide decision factor, $d_j$ [mSv] |
|---|---|---|---|---|---|---|
| $^{239}$Pu | 6.0E4 | 3.2E-05 | 0.01[a] | 1[b] | 0.1[c] | 1.9 |
| $^{241}$Am | 1.2E4 | 2.7E-05 | 0.01[a] | 1[b] | 0.1[c] | 0.32 |
| | | | | | | |
| Decision factor, D [mSv] | | | | | | 2.2 |

(a) Default values given by [IAEA 1999]
(b) Normal chemical operations
(c) Fume hood

Because the decision factor, D is greater than 1 mSv, individual monitoring is required and both $^{239}$Pu and $^{241}$Am should be monitored because the condition on the specific radionuclide decision factor, $d_j \geq 0.3$ mSv, is met.

*Can any procedures be implemented to avoid the need for individual monitoring?*

The decision factor, $D$ can be reduced to below 1 mSv, in which case individual routine monitoring would not be necessary, by:

- Upgrading the containment (e.g. a glove box would provide a factor of 10 reduction in *D*)
- Reducing activity levels; maximum permissible activity level of $^{239}$Pu would need to be less than 27 kBq and the corresponding activity of $^{241}$Am would be less than 5.4 kBq.

It should be noted that if there is a failure of containment that may result in an intake, special monitoring of the persons involved in the incident should take place [IAEA 1999].

*Which individual monitoring method should be selected for $^{239}$Pu and $^{241}$Am?*

For individual routine monitoring of relative soluble forms of $^{239}$Pu and $^{241}$Am, the preferred methods are urine and faeces monitoring. In addition, for $^{241}$Am, lung measurements can also be applied [ISO 2006].

*Does routine monitoring of $^{239}$Pu (Type M) by urinary and faecal analysis have adequate sensitivity and which monitoring intervals are appropriate?*

The routine monitoring programme should be able to reliably detect all potential exposures per year which exceed an annual effective dose of 1 mSv [ICRP 2015b; ISO 2006]. Thus the following relation should be met:

$$1000 \cdot e(50) \cdot \frac{DL}{m(\Delta T)} \cdot \frac{365}{\Delta T} \leq 1\,mSv \qquad \text{(Eq. AII.3)}$$

Where

| | |
|---|---|
| e(50) | effective dose coefficient (Sv Bq$^{-1}$) |
| DL | detection limit of the measurement technique (e.g. Bq for retention or Bq d$^{-1}$ for excretion) |
| ΔT | monitoring interval (d) |
| m(t) | predicted measured quantity for unit intake at a time t after the intake. For retention it is Bq per Bq intake and for excretion it is Bq d$^{-1}$ per Bq intake. |

Equation AII.3 may be used to calculate the detectable annual doses $D_d$ in mSv:

$$D_d = 1000 \cdot e(50) \cdot \frac{DL}{m(\Delta T)} \cdot \frac{365}{\Delta T} \qquad \text{(Eq. AII.4)}$$

In addition, the uncertainties in the assessed doses resulting from an unknown time interval between intake and measurement are used to define the monitoring intervals [ICRP 2015b; ISO 2006]. The maximum underestimate of the dose resulting from a single intake should not exceed a factor of three, and therefore the following relation should be met:

$$\frac{m\left(\Delta T/2\right)}{m(\Delta T)} \leq 3 \qquad \text{(Eq. AII.5)}$$

It is acknowledged that Eq. AII.3 and AII.4 are conservative because it is assumed that the intake occurs at the beginning of the monitoring interval and that the residual activity from previous intakes is not considered. This is discussed in more detail in the section at the end of this example entitled 'Revision of calculation of detectable doses'.

Detectable annual doses and maximum potential underestimations of routine monitoring programmes with different monitoring periods for $^{239}$Pu (Type M) by urinary and faecal analysis were derived by applying equation AII.4 and are given in Tables AII.4 and AII.5. It can be seen that, for urine analysis with alpha spectrometry, the technique does not have adequate sensitivity to detect potential annual doses of less than 1 mSv arising from inhalation of $^{239}$Pu alone. However, with mass spectrometry, annual doses of less than 1 mSv could potentially be detected with

monitoring periods of 30, 60, 90 or 180 d. In comparison, faecal monitoring has better sensitivity and detecting annual doses of less than 1 mSv is achievable; the underestimation due to unknown time of intake is less than 3 for monitoring periods of 30, 60 and 90 days (Table AII.5).

**Table AII.4.** Detectable annual doses[a] and maximum potential underestimations[b] of a routine monitoring programme of $^{239}$Pu (Type M) by urine analysis

| *Monitoring Technique* | | | | *Alpha spectrometry* | | *TIMS* | |
|---|---|---|---|---|---|---|---|
| *Detection Limit DL (mBq L$^{-1}$)* [c] | | | | *Typical 0.3* | *Achievable 0.05* | *Typical 0.01* | *Achievable 0.004* |
| Monitoring interval, $\Delta T$ (d) | Urine excretion rate (Bq d$^{-1}$ per Bq intake) | | Maximum potential under-estimation [b] | Detectable annual doses[a] (mSv) | | | |
| | $m(\Delta T)$ | $m(\Delta T/2)$ | $m(\Delta T/2)/m(\Delta T)$ | | | | |
| 7 | 2.4E-05 | 6.3E-05 | 2.6 | 33 | 5 | 1.1 | 0.44 |
| 14 | 1.2E-05 | 2.4E-05 | 2.1 | 34 | 6 | 1.1 | 0.46 |
| 15 | 1.1E-05 | 2.2E-05 | 2.0 | 33 | 5 | 1.1 | 0.44 |
| 30 | 9.5E-06 | 1.1E-05 | 1.2 | 19 | 3 | 0.65 | 0.26 |
| 60 | 8.1E-06 | 9.5E-06 | 1.2 | 11 | 2 | 0.38 | 0.15 |
| 90 | 7.1E-06 | 8.7E-06 | 1.2 | 9 | 1.4 | 0.29 | 0.11 |
| 180 | 5.4E-06 | 7.1E-06 | 1.3 | 6 | 1.0 | 0.19 | 0.08 |

(a) Annual doses from intakes of $^{239}$Pu (Type M) only. Detectable annual dose is calculated with equation AII.4. Effective dose coefficient = 3.2E-05 Sv Bq$^{-1}$ for $^{239}$Pu (Type M, 5 µm AMAD). A reference 24-hour urinary excretion volume of 1.6 L for males is assumed [ICRP 2002].
(b) The maximum potential underestimation is recommended not to exceed a factor of 3.
(c) Typical and achievable detection limits are taken from the IDEAS Guidelines [EURADOS 2013].

The detectable annual doses given in Tables AII.4 and AII.5 for plutonium monitoring only take account of intakes of $^{239}$Pu. Taking account of intakes of $^{241}$Am and assuming an activity ratio of $^{239}$Pu to $^{241}$Am of 5:1 would increases the detectable annual doses by a factor of about 1.2. The ISO standard on monitoring, ISO 20553:2006 [ISO 2006], states that

> *in the case of mixtures where the radionuclide composition is well known, it is possible to use the measurement of a single radionuclide to infer the activities of the others. This approach is acceptable if the additional uncertainty (in terms of dose) arising from the incomplete knowledge of the radionuclide composition does not exceed 10 %.*

The establishment of an air-monitoring programme to determine if the potential annual doses are less than 1 mSv from the inhalation of actinides is an alternative approach to faecal and urine monitoring. Such a programme would use workplace static air samplers and personal air samplers as described by [Roberts 2007]. Air sampling can also be used as a routine monitoring method, provided that the sampling uncertainties have been characterised and/or a suitable confirmatory monitoring programme has been established.

**Table AII.5.** Detectable annual doses[a] and maximum potential underestimations[b] of a routine monitoring programme of $^{239}$Pu (Type M) by faecal analysis

| *Monitoring technique* | | | | *Alpha spectrometry* | |
|---|---|---|---|---|---|
| *Detection Limit DL (mBq/24h) [c]* | | | | *Typical 2* | *Achievable 0.2* |
| Monitoring interval, $\Delta T$ (d) | Faecal excretion rate (Bq d$^{-1}$ per Bq intake) | | Maximum potential under-estimation [b] | Detectable annual doses[a] (mSv) | |
| | $m(\Delta T)$ | $m(\Delta T/2)$ | $m(\Delta T/2)/m(\Delta T)$ | | |
| 7 | 2.3E-03 | 5.2E-02 | 22 | 1.4 | 0.14 |
| 14 | 4.4E-04 | 2.3E-03 | 5.3 | 3.8 | 0.38 |
| 15 | 4.3E-04 | 1.6E-03 | 3.8 | 3.6 | 0.36 |
| 30 | 2.8E-04 | 4.3E-04 | 1.5 | 2.7 | 0.27 |
| 60 | 1.3E-04 | 2.8E-04 | 2.2 | 2.9 | 0.29 |
| 90 | 6.7E-05 | 1.9E-04 | 2.9 | 3.8 | 0.38 |
| 180 | 1.7E-05 | 6.7E-05 | 3.9 | 7.5 | 0.75 |

(a) Annual doses from intakes of $^{239}$Pu (Type M) only. Detectable annual dose is calculated with equation AII.4. Effective dose coefficient = 3.2E-05 Sv Bq$^{-1}$ for $^{239}$Pu (Type M, 5 µm AMAD).
(b) The maximum potential underestimation is recommended not to exceed a factor of 3.
(c) Typical and achievable detection limits are taken from the IDEAS Guidelines [EURADOS 2013].

**Table AII.6.** Detectable annual doses[a] and maximum potential underestimations[b] of a routine monitoring programme of $^{241}$Am (Type M) by lung monitoring

| *Monitoring technique)* | | | | *Gamma spectrometry* | |
|---|---|---|---|---|---|
| *Detection Limit DL (Bq) [c]* | | | | *Typical 10* | *Achievable 4* |
| Monitoring interval, $\Delta T$ (d) | Lung retention (Bq per Bq intake) | | Maximum potential under-estimation [b] | Detectable annual doses[a] (mSv) | |
| | $m(\Delta T)$ | $m(\Delta T/2)$ | $m(\Delta T/2)/m(\Delta T)$ | | |
| 7 | 5.2E-02 | 5.5E-02 | 1.1 | 270 | 110 |
| 14 | 4.7E-02 | 5.2E-02 | 1.1 | 150 | 60 |
| 15 | 4.6E-02 | 5.1E-02 | 1.1 | 140 | 56 |
| 30 | 3.8E-02 | 4.6E-02 | 1.2 | 84 | 34 |
| 60 | 2.8E-02 | 3.8E-02 | 1.4 | 58 | 23 |
| 90 | 2.2E-02 | 3.3E-02 | 1.5 | 50 | 20 |
| 180 | 1.2E-02 | 2.2E-02 | 1.8 | 46 | 18 |

(a) Annual doses from intakes of $^{241}$Am (Type M) only. Detectable annual dose is calculated with equation AII.4. Effective dose coefficient = 2.7E-05 Sv Bq$^{-1}$ for $^{241}$Am (Type M, 5 µm AMAD).
(b) The maximum potential underestimation is recommended not to exceed a factor of 3.
(c) Typical and achievable detection limits are taken from the IDEAS Guidelines [EURADOS 2013].

*Does routine monitoring of $^{241}$Am by lung monitoring have adequate sensitivity?*

Table AII.6 shows that lung monitoring for $^{241}$Am does not have adequate sensitivity to detect potential annual doses of less than 1 mSv. However, as is the case for monitoring moderately soluble plutonium, urine monitoring with mass spectrometry or faecal monitoring may have adequate sensitivity.

## Monitoring insoluble forms of plutonium

Another group of workers will handle insoluble forms of plutonium. Again, for illustrative purposes and for simplicity, it is assumed that there are no other plutonium isotopes present, although in practice $^{238}$Pu, $^{240}$Pu and $^{241}$Pu would most likely be present.

*Does urine and faeces routine monitoring of insoluble forms of $^{239}$Pu (Type S) have adequate sensitivity?*

As can be seen from Table AII.7, routine monitoring of insoluble forms of plutonium by urine analysis does not in general have adequate sensitivity to detect potential annual doses of less than 1 mSv. However, for a monitoring period of 180 d, a detectable annual dose of 0.7 mSv is achievable with mass spectroscopy. In comparison, faecal monitoring has adequate sensitivity (Table AII.8).

**Table AII.7.** Detectable annual doses[(a)] and maximum potential underestimations[(b)] of a routine monitoring programme of $^{239}$Pu (Type S) by urine analysis

| *Monitoring Technique* | | | | *Alpha spectrometry* | | *TIMS* | |
|---|---|---|---|---|---|---|---|
| *Detection Limit DL (mBq L$^{-1}$) [(c)]* | | | | *Typical 0.3* | *Achievable 0.05* | *Typical 0.01* | *Achievable 0.004* |
| Monitoring interval, ΔT (d) | Urine excretion rate (Bq d$^{-1}$ per Bq intake) | | Maximum potential under-estimation [(b)] | Detectable annual doses[(a)] (mSv) | | | |
| | *m*(ΔT) | *m*(ΔT/2) | *m*(ΔT/2)/ *m*(ΔT) | | | | |
| 7 | 3.1E-07 | 6.9E-07 | 2.2 | 660 | 110 | 22 | 9 |
| 14 | 1.9E-07 | 3.1E-07 | 1.6 | 550 | 91 | 18 | 7 |
| 15 | 1.9E-07 | 2.9E-07 | 1.6 | 515 | 86 | 17 | 7 |
| 30 | 1.7E-07 | 1.9E-07 | 1.1 | 280 | 46 | 9.3 | 3.7 |
| 60 | 1.6E-07 | 1.7E-07 | 1.0 | 145 | 24 | 4.8 | 1.9 |
| 90 | 1.6E-07 | 1.7E-07 | 1.0 | 99 | 17 | 3.3 | 1.3 |
| 180 | 1.6E-07 | 1.6E-07 | 1.0 | 50 | 8.3 | 1.7 | 0.7 |

(a) Annual doses from intakes of $^{239}$Pu (Type S) only. Detectable annual dose is calculated with equation AII.4. Effective dose coefficient = 8.3E-06 Sv Bq$^{-1}$ for $^{239}$Pu (Type S, 5 μm AMAD). A reference 24-hour urinary excretion volume of 1.6 L for males was assumed [ICRP, 2002].

(b) The maximum potential factor for underestimation is recommended not to exceed a factor of 3.

(c) Typical and achievable detection limits are taken from the IDEAS Guidelines [EURADOS 2013].

**Table AII.8.** Detectable annual doses[a] and maximum potential underestimations[b] of a routine monitoring programme of $^{239}$Pu (Type S) by faecal analysis

| *Monitoring technique* | | | | *Alpha spectrometry* | |
|---|---|---|---|---|---|
| *Detection Limit DL (mBq/24h)* [c] | | | | *Typical 2* | *Achievable 0.2* |
| Monitoring interval, $\Delta T$ (d) | Faecal excretion rate (Bq d$^{-1}$ per Bq intake) | | Maximum potential under-estimation [b] | Detectable annual doses[a] (mSv) | |
| | $m(\Delta T)$ | $m(\Delta T/2)$ | $m(\Delta T/2)/\ m(\Delta T)$ | | |
| 7 | 2.5E-03 | 5.5E-02 | 22 | 0.35 | 0.035 |
| 14 | 5.1E-04 | 2.5E-03 | 4.9 | 0.85 | 0.085 |
| 15 | 4.9E-04 | 1.7E-03 | 3.5 | 0.81 | 0.081 |
| 30 | 3.5E-04 | 4.9E-04 | 1.4 | 0.57 | 0.057 |
| 60 | 1.9E-04 | 3.5E-04 | 1.9 | 0.53 | 0.053 |
| 90 | 1.1E-04 | 2.5E-04 | 2.4 | 0.62 | 0.062 |
| 180 | 3.7E-05 | 1.1E-04 | 2.9 | 0.89 | 0.089 |

(a) Annual doses from intakes of $^{239}$Pu (Type S) only. Detectable annual dose is calculated with equation AII.4. Effective dose coefficient = 8.3E-06 Sv Bq$^{-1}$ for $^{239}$Pu (Type S, 5 μm AMAD).
(b) The maximum potential underestimation is recommended not to exceed a factor of 3.
(c) Typical and achievable detection limits taken from the IDEAS Guidelines [EURADOS 2013].

## Revision of calculation of detectable annual doses

The annual detectable doses calculated with Eq. AII.4, as recommended by ISO [2006b], are conservative because:

- it is assumed that the intake occurs at the beginning of the monitoring interval, and
- the contributions (P) to the measured activity from intakes occurring in preceding monitoring intervals are not taken into account.

Assuming intakes occur only at the beginning of the monitoring interval and taking account of the residual activity from previous intakes, the following procedure may be used to calculate the detectable annual doses:

(i) Assume each measurement at the end of the monitoring interval corresponds to the limit of detection, DL.

(ii) Determine the magnitude of the intake, $I_1$ in the first monitoring interval.

(iii) Predict the contribution to all subsequent measurements from this intake. For example, the contributions to the next two measurements from intake $I_1$ are $I_1 \cdot m(2 \cdot \Delta T)$ and $I_1 \cdot m(3 \cdot \Delta T)$ respectively.

(iv) Subtract the contributions from this intake from all subsequent data. For example, $I_1\ m(2\Delta T)$ is subtracted from the data at the end of the second monitoring interval and $I_1 \cdot m(3 \cdot \Delta T)$ is subtracted from the data at the end of the third monitoring interval.

(v) Repeat (ii) to (iv) for the next monitoring interval.

(vi) After calculating all the intakes for the year, the detectable annual dose is given by: $e(50) \sum_{i=1}^{N} I_i$ where $N$ is the number of monitoring intervals in a year (i.e $365/\Delta T$).

Using this procedure, the detectable annual doses were recalculated for routine monitoring programmes of $^{239}$Pu by urinary and faecal analysis (Table AII.9), assuming typical detection limits for alpha spectrometry.

The detectable annual doses were also recalculated for routine monitoring of $^{241}$Am by lung counting (Table AII.10).

**Table AII.9**. Detectable annual doses of routine monitoring programmes of $^{239}$Pu by urinary and faecal analysis calculated using the above procedure[a]. Typical detection limits, DL for alpha spectrometry are assumed[b]

| *Monitoring Technique* | *Urine* | | *Faeces* | |
|---|---|---|---|---|
| *Detection Limit DL [b]* | *Typical: 0.3 mBq L$^{-1}$* | | *Typical: 2 mBq d$^{-1}$* | |
| Monitoring interval ΔT (d) | Detectable annual doses[a] (mSv) | | | |
| | Type M | Type S | Type M | Type S |
| 7 | 3.08 | 23.8 | 0.69 | 0.14 |
| 14 | 3.20 | 23.7 | 1.2 | 0.22 |
| 30 | 3.26 | 23.7 | 1.4 | 0.25 |
| 60 | 3.35 | 23.7 | 2.1 | 0.32 |
| 90 | 3.43 | 23.7 | 2.9 | 0.41 |
| 180 | 3.65 | 23.7 | 6.3 | 0.62 |

(a) Annual doses from intakes of $^{239}$Pu only. Detectable annual dose is calculated assuming intakes occur only at the beginning of the monitoring interval and the residual activity from previous intakes is considered. A reference 24-hour urinary excretion volume of 1.6 L for males is assumed [ICRP 2002].
(b) Typical detection limits for alpha spectroscopy are taken from the IDEAS Guidelines [EURADOS 2013]

**Table AII.10**. Detectable annual doses of routine monitoring programmes of $^{241}$Am (Type M) by lung counting using the above procedure[a]

| *Monitoring Technique* | *Lung measurements - Faeces* |
|---|---|
| *Detection Limit DL [b]* | *Typical: 10 Bq* |
| Monitoring interval ΔT (d) | Detectable annual doses[a] (mSv) |
| 7 | 22 |
| 14 | 22 |
| 30 | 23 |
| 60 | 26 |
| 90 | 29 |
| 180 | 38 |

(a) Annual doses from intakes of $^{241}$Am only. Detectable annual dose is calculated assuming intakes occur only at the beginning of the monitoring interval and the residual activity from previous intakes is included.
(b) Typical detection limit of $^{241}$Am for lung measurements by gamma ray spectroscopy are taken from the IDEAS Guidelines [EURADOS 2013].

## EXAMPLE 2: Determining intake and dose from single and multiple bioassay data

### Description of the case

Following a suspected intake by inhalation of $^{137}Cs$ by a worker, a whole body measurement was performed two days after intake. The measurement result *M* was 72 kBq. The chemical form was caesium chloride.

### Assessment

To assess this case, the ISO 27048:2011 procedure for special monitoring (Table E.2) is followed.

- STEP 1: Check if uptake via wound or if decorporation therapy can be ruled out

  As there has been no uptake via wound or intact skin and chelation therapy has not been used proceed to step 2.

- STEP 2: Check if the measured value is significant

  Value exceeds decision threshold, proceed to step 3.

- STEP 3: Standard dose assessment

  Pure inhalation and default parameter values were assumed: Type F absorption for caesium chloride with an activity median aerodynamic diameter (AMAD) of 5 µm. The intake, *I* is given by:

  $$I = \frac{M}{m(t)} = \frac{72000\ Bq}{0.5} = 144000\ Bq \qquad \text{(AII.6)}$$

  where m(t) is the predicted whole body activity for unit intake at day 2. Using the corresponding dose coefficient for $^{137}Cs$ (6.7E-09 Sv $Bq^{-1}$), the assessed dose is 0.96 mSv.

- STEP 4: Criterion for accepting the standard dose assessment

  It is assumed that the uncertainty on the measurements can be characterised by an overall scattering factor (*SF*) of 1.2, the default value given by the IDEAS Guidelines and ISO 27048:2011 for *in vivo* measurements of radionuclides emitting high photon energy radiation. It includes both Type A and Type B uncertainties.

  There is no need for further evaluation if the following relation is valid,

  $$E(50)\cdot SF^2 < 1\ \text{mSv} \qquad \text{(AII.7)}$$

  where

  $E(50)$ is the committed effective dose corresponding to the measured valued calculated in STEP 3.

  1 mSv = 5% of the annual dose limit of 20 mSv.

  With $E(50)$ = 0.96 mSv and $SF$ = 1.2, relation (AII.7) is not valid:

  $E(50)\ SF^2$ = 1.4 mSv

  and therefore further evaluation is required – proceed to step 5.

- STEP 5: Confirm assumptions by additional measurements

  ISO 20553:2006 recommends whole body and urine measurements for special monitoring programmes following inhalation of $^{137}Cs$. Table C.7 of **Chapter C** recommends two urine and two whole body measurements in cases when the assessed dose is greater than 1mSv but less than 6 mSv. However, in this case as the chemical form and the solubility of the material is known, urine measurements were not

requested and two more whole body measurements were carried out; results are given in Table AII.11 below.

**Table AII.11** Whole body measurements of $^{137}$Cs following an acute inhalation of caesium chloride

| Time of measurement after intake, $t$ (d) | Activity of $^{137}$Cs in total body, $M$ (Bq) | Predicted total body activity per unit intake, $m(t)$, (Bq per Bq intake)[(a)] |
|---|---|---|
| 2 | 72000 | 0.5 |
| 9 | 84000 | 0.41 |
| 23 | 44000 | 0.38 |

(a) Absorption Type F, AMAD= 5 μm.

- STEP 6: Comparison with dose limits: to check if the annual dose limit may potentially be exceeded

  Figure A.19 and Table A.20 of ISO 27048:2011 show the lower level (LL) and the upper level (UL) representing the predict range of measurements corresponding to a dose reference level of 20 mSv.

  As the number of measurements is less than 20, and M<LL and $M \cdot SF^2$<UL for all the measurement values (M), the annual dose limit is not potentially exceeded.

  The intake from multiple data is calculated using the maximum likelihood method by applying the following equation:

$$\ln(I) = \frac{\sum_{i=1}^{n} \frac{\ln(I_i)}{[\ln(SF_i)]^2}}{\sum_{i=1}^{n} \frac{1}{[\ln(SF_i)]^2}} \qquad \text{(AII.8)}$$

  where the point estimate, $I_i$ is the intake calculated from the $i^{th}$ measurement given by equation (AII.6) and $SF_i$ is the overall scattering value for measurement $i$. In this case the estimated intake using all 3 data points is 150 kBq and the corresponding dose is 1.0 mSv. The fit to the measurement data is shown in Figure AII.1. Although, there are only three data points the fit is not rejected by the chi squared ($\chi^2$) test or by eye. Chi squared = 4.7 and p-value = 0.10.

  The second measurement (84000 Bq) on day 9 after intake is greater than the first measurement (72000 Bq) on day 2, which may suggest further intakes. The estimated intake calculated from the first measurement is 144000 Bq. The predicted whole body activity, P at day 9 from this intake is 59040 Bq. As the measurement (84000 Bq) is less than $P \cdot SF2 = 59040 \cdot 1.22 = 85000$, this indicates that the measurement is consistent with the previous assessed intake and it can be assumed that no new intake has occurred. Furthermore, review of the workplace monitoring showed no evidence of further release of activity.

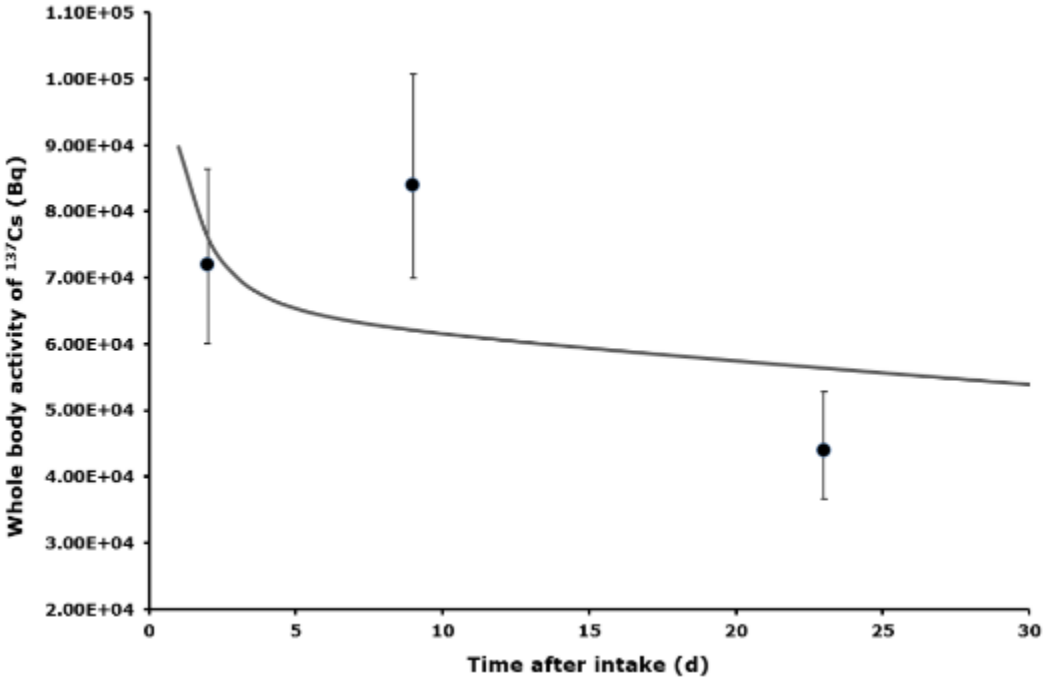



**Figure AII.1** Model fits to whole body data of $^{137}$Cs activity assuming Type F and 5 μm AMAD

## EXAMPLE 3: Routine and special monitoring for $^{131}I$

### Description of the case

A technician preparing and handling radiopharmaceuticals containing $^{131}I$ has the potential to be exposed to elemental $^{131}I$ as a vapour. A routine monitoring programme was set up using thyroid measurements with a 14 day interval. From previous experience with workers with similar exposure conditions, it is expected that, on a few occasions, intakes may occur in a given monitoring period that result in effective doses of less than 0.3 mSv. The results of the first three thyroid measurements are given in Table AII.12.

**Table AII.12** Routine thyroid monitoring of $^{131}I$

| Date | Time after start of work with radiopharmaceuticals (d) | Activity of $^{131}I$ in thyroid (Bq) | Uncertainty due to counting statistics, $1\sigma_A$ (Bq) |
|---|---|---|---|
| 18/09/2014 | 14 | 510 | 35 |
| 02/10/2014 | 28 | 170 | 12 |
| 16/10/2014 | 42 | 24500 | 1660 |

### Assessment – Routine monitoring

To assess this case, the ISO 27048:2011 procedure for routine monitoring (Table E.1) is followed.

*First measurement* (510 Bq, 14 days after start of work)

- STEP 1: Appropriateness of measurement

  Thyroid monitoring and a monitoring interval of 14 days is consistent with the recommendations of ISO 20553 [ISO 2006] – See Table C.3 of **Chapter C**.

- STEP 2: Check if the measured value is significant

  The measurement value is above the decision threshold (~12 Bq) of the measurement method. The critical monitoring value ($M_c$) for thyroid measurements of $^{131}I$ corresponding to a potential annual dose of 0.1 mSv for a monitoring period of 15 days is 30 Bq [EURADOS 2013; ISO 2011]. As the measurement value is above the $M_c$ value, an evaluation is required.

- STEP 3: Standard dose assessment, using default assumptions

  The ICRP Publication 68 model for iodine vapour (elemental iodine) is assumed with an absorption Type F. Assuming the intake occurred at the mid-point of the monitoring interval, the intake may be determined by:

  $$I = \frac{M}{m(\Delta T / 2)} = \frac{510}{0.14} = 3640\ Bq \qquad \text{(Eq. AII.9)}$$

  The monitoring interval, $\Delta T$ is 14 days. With the corresponding dose coefficient of 2.0E-08 Sv $Bq^{-1}$, the effective dose is calculated as 0.073 mSv.

- STEP 4: Criterion for accepting the standard dose assessment

  From Table AII.10 the scattering value ($SF_A$) due to counting statistics alone is calculated as $SF_A = \exp(\sigma_A/M) = 1.07$. Because $^{131}I$ emits a high energy photon that is measured, the default scattering factor value for

Type B uncertainties is $SF_B$ = 1.15 [EURADOS 2013; ISO 2011]. Combining these two types of uncertainties gives an overall scattering factor value of 1.2:

$$SF = \exp\left[\sqrt{(\ln(SF_A))^2 + (\ln(SF_B))^2}\right] \quad \text{(Eq. AII.10)}$$

No further evaluation is needed if the following condition is satisfied:

$$E(50)\cdot n\cdot SF^2 < 1 \text{ mSv} \quad \text{(Eq. AII.11)}$$

where

$E(50)$ committed effective dose calculated in Step 3 corresponding to the measured value

$n$ number of monitoring periods in a year ($n$= 365/$\Delta T$)

$SF$ overall scattering factor associated with the measurement used for intake estimation

1 mSv value of the 5% of the annual dose limit of 20 mSv.

With $SF$=1.2, n=365/14 = 26 and E(50) = 0.073 mSv, relation (AII.11) is not valid [$E(50)\cdot n\cdot SF^2$ = 2.7 mSv] and therefore further evaluation is required - proceed to step 5.

- STEP 5: Check if exposure is unexpected

  It is expected that, on a few occasions, some intakes may occur in a given monitoring period resulting in effective doses of less than 0.3 mSv for intakes in that period. Therefore, this is not an unexpected exposure.

- STEP 6: Comparison with dose limits: to check if the annual dose limit may *potentially* be exceeded

  A graph for $^{131}$I as a particulate (Type F, 5 µm AMAD) giving the predicted range of measurements of thyroid activity for a reference dose level of 20 mSv is given in Figure A.18 of ISO 27048:2011 [ISO 2011]. The corresponding graph for elemental $^{131}$I as a vapour is expected to be similar and therefore this graph may be used to determine if the annual dose limit may *potentially* be exceeded. The graph gives a lower level (LL) of about 7.1E+04 Bq of thyroid activity at 14 days after intake corresponding to a dose limit of 20 mSv. Because the measurement value (510 Bq) and $M\cdot SF^2 = 510\cdot 1.2^2 = 730$ are less than the LL (7.1E+04 Bq), it can be concluded that the annual dose limit has not been exceeded. The measurement result, the assessed dose (0.073 mSv) and the assumptions are documented.

  For comparison purposes, an alternative method, appropriate when the relevant graphs are not presented in ISO 27048:2011 is to use equation E.5 of **Chapter E** to decide if the annual dose limit could be exceeded. Equation E.5 is rewritten here:

  $$DIL_{\min} = \frac{0.02}{e(50)} \cdot 0.3 \cdot m(\Delta T) \cdot \frac{\Delta T}{365} \cdot \frac{1}{SF^2} \quad \text{(Eq. AII.12)}$$

  With e(50)= 2.0E-08 Sv Bq$^{-1}$, ΔT=14 d, m(ΔT) = 7.2E-02 (Bq per Bq intake) and SF=1.2 the lower level of the derived investigation level, $DIL_{\min}$ is 580 Bq. Because the measurement value (510 Bq) is less than $DIL_{\min}$ it can be concluded that the annual dose limit has not been exceeded. The measurement result, the assessed dose (0.073 mSv) and the assumptions are documented.

*Second measurement* (170 Bq, 28 days after the start of work)

- STEP 1: Appropriateness of measurement

  It has already been determined that the routine monitoring programme is appropriate – see above.

- STEP 2: Check if the measured value is significant

  The measurement value is above the $M_c$ of 30 Bq for a monitoring period of 15 days [EURADOS 2013; ISO 2011].

  To determine if the measured value indicates a new intake occurred in the second monitoring interval, the contribution of previous intakes to the measurement results, *P*, should be evaluated, taking account of the uncertainty in the measurement.

  The value of *P* at the time of the second measurement arising from the first intake is 140 Bq. As the second measurement (170 Bq) lies within the interval given by (AII.13):

  $$P/SF^2 < M < P \cdot SF^2 \qquad \text{(Eq. AII.13)}$$

  that is: $140/(1.2^2)$ Bq < 170 Bq < $140 \cdot (1.2^2)$,

  it may be concluded that the second measurement is consistent with the previous intake and no new intakes occurred in the second monitoring interval. The measurement is documented and it is stated that no new intake occurred in this monitoring interval.

*Third measurement* (24500 Bq, 42 days after the start of work)

- STEP 1: Appropriateness of measurement

  It has already been determined that the routine monitoring programme is appropriate – see above.

- STEP 2: Check if the measured value is significant

  The measurement value is above the $M_c$ of 30 Bq for a monitoring period of 15 days [EURADOS 2013, ISO 2011].

  The value of *P* at the time of the third measurement arising from the first intake is 37 Bq. As the third measurement (24500 Bq) is above $P \cdot SF^2 = 37 \cdot (1.2^2) = 53$, it can be concluded that a new intake occurred in the third interval.

- STEP 3: Standard dose assessment, using default assumptions

  Assuming the intake occurred at the mid-point of the third interval the estimated intake is given by:

  $$I = \frac{M - P}{m(\Delta T / 2)} = \frac{24500 - 37}{0.14} = 175000 \ Bq$$

  The corresponding effective dose is 3.5 mSv.

  Table AII.13 summarises the main results of the assessment.

**Table AII.13** Result of evaluation of routine thyroid monitoring of $^{131}I$

| Monitoring period | 4th Sep 2014 – 18th Sep 2014 | 18th Sep 2014 – 2nd Oct 2014 | 2nd Oct 2014– 16th Oct 2014 |
|---|---|---|---|
| Measurement, *M* at end of monitoring period (Bq) | 510 | 170 | 24500 |
| Value of contribution from previous intakes, P (Bq) | 0 | 140 | 37 |
| P / $SF^2$ (Bq) | | 95 | 26 |
| P * $SF^2$ (Bq) | | 200 | 53 |
| Assumed date of intake | 11/09/2014 | No intake | 09/10/2014 |
| Intake (Bq) | 3640 | | 175000 |
| E(50) (mSv) | 0.073 | | 3.5 |

- STEP 4: Criterion for accepting the standard dose assessment

  With $SF$=1.2, n=365/14 = 26 and E(50) = 3.5 mSv relation (AII.11) is not valid [i.e. $E(50)$. $n \cdot SF^2$ = 131 mSv > 1 mSv] and therefore further evaluation is required - proceed to STEP 5.

- STEP 5: Check if exposure is unexpected

  This exposure resulting in a dose of 3.5 mSv is unexpected and therefore special monitoring is required – go to STEP 5 of special monitoring procedure (Table E.2 of **Chapter E**).

## Assessment – Special monitoring

The procedure of ISO 27048:2011 is followed, commencing with STEP 5 of Table E.2 in **Chapter E**.

- STEP 5: Confirm assumptions by additional measurements

  ISO 20553:2006 recommends thyroid and urine measurements for special monitoring programmes following inhalation of $^{131}I$. Table C.7 of **Chapter C** recommends two urine and two thyroid measurements in cases when the assessed dose is greater than 1mSv but less than 6 mSv over a 7 day period [EURADOS 2013]. These measurements were requested and the monitoring data are given in Tables AII.14 and AII.15.

- STEP 6: Comparison with dose limits: to check if the annual dose limit may potentially be exceeded

  Figure A.18 and Table A.19 of ISO 27048:2011 [ISO 2011] show the lower level (LL) of the predicted thyroid measurements for $^{131}I$ (inhaled as a particulate) corresponding to a dose reference level of 20 mSv. The thyroid measurements are plotted on this graph (Figure AII.2) assuming the intake occurred at the beginning of the monitoring period (i.e. on 02/10/2014). As can be seen, the measurements are below the LL, indicating that the annual dose limit has not been exceeded. The intake and the dose are assessed using the thyroid and urine measurement data. This is decribed in the next sub-section; the procedure for the 'special evaluation for inhalation' of the IDEAS Guidelines is followed.

  For illustrative purposes only, the alternative approach to determining whether the annual dose limit could be exceeded may be followed by applying equation E.8 of **Chapter E**. Equation E.8 may be rewritten:

$$DIL_{\min SM}(i) = \frac{0.02}{e(50)} \cdot 0.3 \cdot m(t_i) \cdot \frac{1}{SF_i^2} \qquad \text{(Eq. AII.14)}$$

With e(50)= 2.0E-08 Sv Bq$^{-1}$, ΔT=14 d, m(ΔT) = 7.2E-02 (Bq in thyroid per Bq intake) and SF=1.2, the lower level of the derived investigation level, $DIL_{min,SM}$, is 15000 Bq. Because the thyroid measurement value (24500 Bq) is greater than $DIL_{min,SM}$, this would suggest that the annual dose limit may *potentially* be exceeded. This shows that this approach is more conservative than that using the graphs of ISO 27048:2011.

**Table AII.14** Special thyroid monitoring of $^{131}$I

| Date | Time after start of work with radiopharmaceuticals (d) | Activity of $^{131}$I in thyroid (Bq) | Uncertainty due to counting statistics, $1\sigma_A$ (Bq) |
|---|---|---|---|
| 18/10/2014 | 44 | 15400 | 1040 |
| 22/10/2014 | 48 | 9600 | 650 |

**Table AII.15** Special urine monitoring of $^{131}$I

| Date | Time after start of work with radiopharmaceuticals | Urinary excretion rate of $^{131}$I (Bq d$^{-1}$)[a,b] |
|---|---|---|
| 18/10/2014 | 44 | 31 |
| 22/10/2014 | 48 | 13 |

(a) These are simulated 24-hr urine measurements, creatinine normalised.
(b) Uncertainty due to counting statistics is 10% (1 σ)

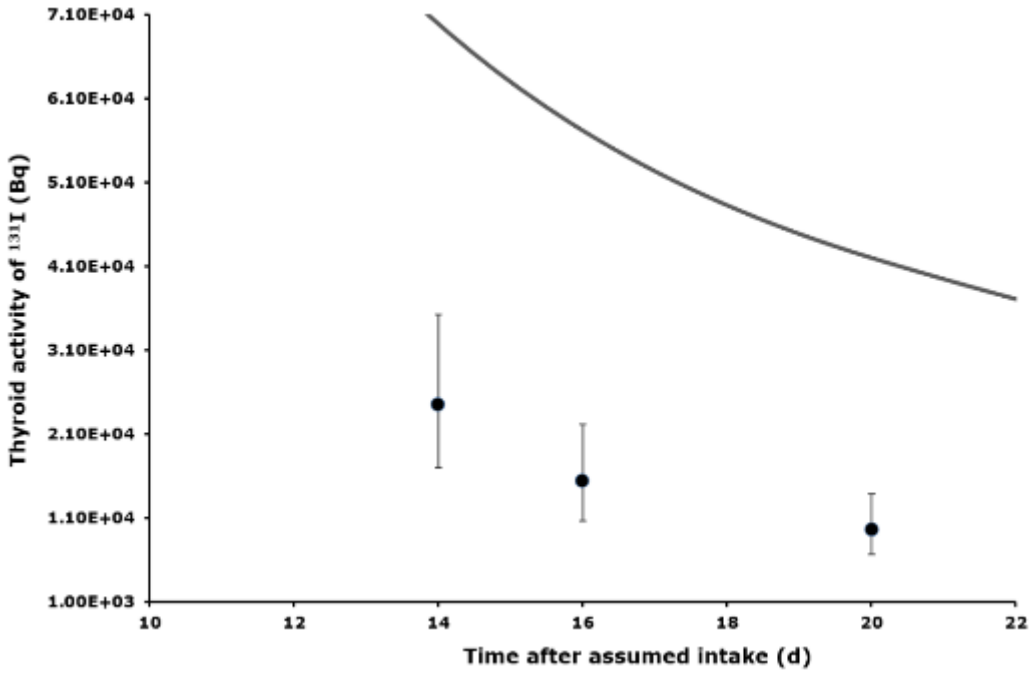



**Figure AII.2** Comparison of the measurement data and the lower level of the band of thyroid measurements for $^{131}$I (inhaled as a particulate) corresponding to an annual dose limit of 20 mSv. The error bars represent the 95% confidence interval. Data are plotted under the assumption that the intake occurred at the beginning of the third monitoring interval

## IDEAS Guidelines – Special evaluation for inhalation; Stage 5

The data of Tables AII.14 and AII.15 together with the thyroid measurement on the 16/10/2014 (Table AII.12) are used to re-assess the intake that occurred between the 2nd and 16th of October.

As calculated previously, the *SF* for the thyroid measurements is 1.2. For simulated 24-hour urine measurements, the default scattering factor value for Type B uncertainties is $SF_B$ = 1.6 [EURADOS 2013]. Given 10% uncertainty due to counting statistics (i.e. $SF_A$ = 1.1), the overall *SF* calculated with equation B4.2 is 1.62.

The contributions, P to the measured values (M) arising from the earlier intake of 11/9/2014 are subtracted from M to obtain the net value (N=M-P). However, as the contributions are less than 1% of the measured values, these subtractions are not strictly necessary. ICRP Publication 78 recommends that a correction should be made if P is more than 10% of M [ICRP 1997].

An assessment is made by simultaneously fitting the predicted bioassay functions to both the urine and thyroid datasets using the maximum likelihood method, assuming that the intake occurred at the mid-point of the monitoring interval (i.e. on 9/10/2014; 7 days before the measurement). The fit has a calculated chi-squared ( $\chi_0^2$ ) of 4.8 with a p-value of 0.31, indicating that it is not inadequate. The estimated intake is 137 kBq and the corresponding dose is 2.7 mSv. According to the Guidelines, this is the end of the evaluation and the result should be documented – see STEP 5.12 of the IDEAS Guidelines.

However, it is decided to continue the investigation in order to determine whether the activity ratio of urine/thyroid measurements could give some indication of the time of intake (IAEA, 2004). The expected ratios are given in Table AII.16.

The measured ratio on 18/10/2014 (day 44 after the start of work) is 2.0E-03 indicating that the intake occurred more than 3 days before the 18/10/2014.

By varying the time elapsed between the assumed intake and the measurements, the best fit to the data (i.e. the one with the lowest $\chi_0^2$ ) is found to occur when the date of intake is 14/10/2014 (day 40 after the start of work), giving a $\chi_0^2$ of 2.9 and a p-value of 0.58. The corresponding intake and dose are 87.6 kBq and 1.7 mSv (Figure AII.3).

**Table AII.16** Predicted values (Bq per Bq intake) for inhalation of $^{131}$I vapour

| Time after intake (d) | Thyroid activity (Bq) | Daily urine excretion (Bq $d^{-1}$) | Expected urine/thyroid ratio |
|---|---|---|---|
| 1 | 2.27E-01 | 5.18E-01 | 2.29 |
| 2 | 2.23E-01 | 5.12E-02 | 0.23 |
| 3 | 2.04E-01 | 3.06E-03 | 0.015 |
| 4 | 1.86E-01 | 3.00E-04 | 1.6E-03 |
| 5 | 1.69E-01 | 1.68E-04 | 1.0E-03 |
| 6 | 1.54E-01 | 1.80E-04 | 1.2E-03 |
| 7 | 1.40E-01 | 1.94E-04 | 1.4E-03 |
| 8 | 1.27E-01 | 2.03E-04 | 1.6E-03 |
| 9 | 1.16E-01 | 2.08E-04 | 1.8E-03 |
| 10 | 1.05E-01 | 2.09E-04 | 2.0E-03 |

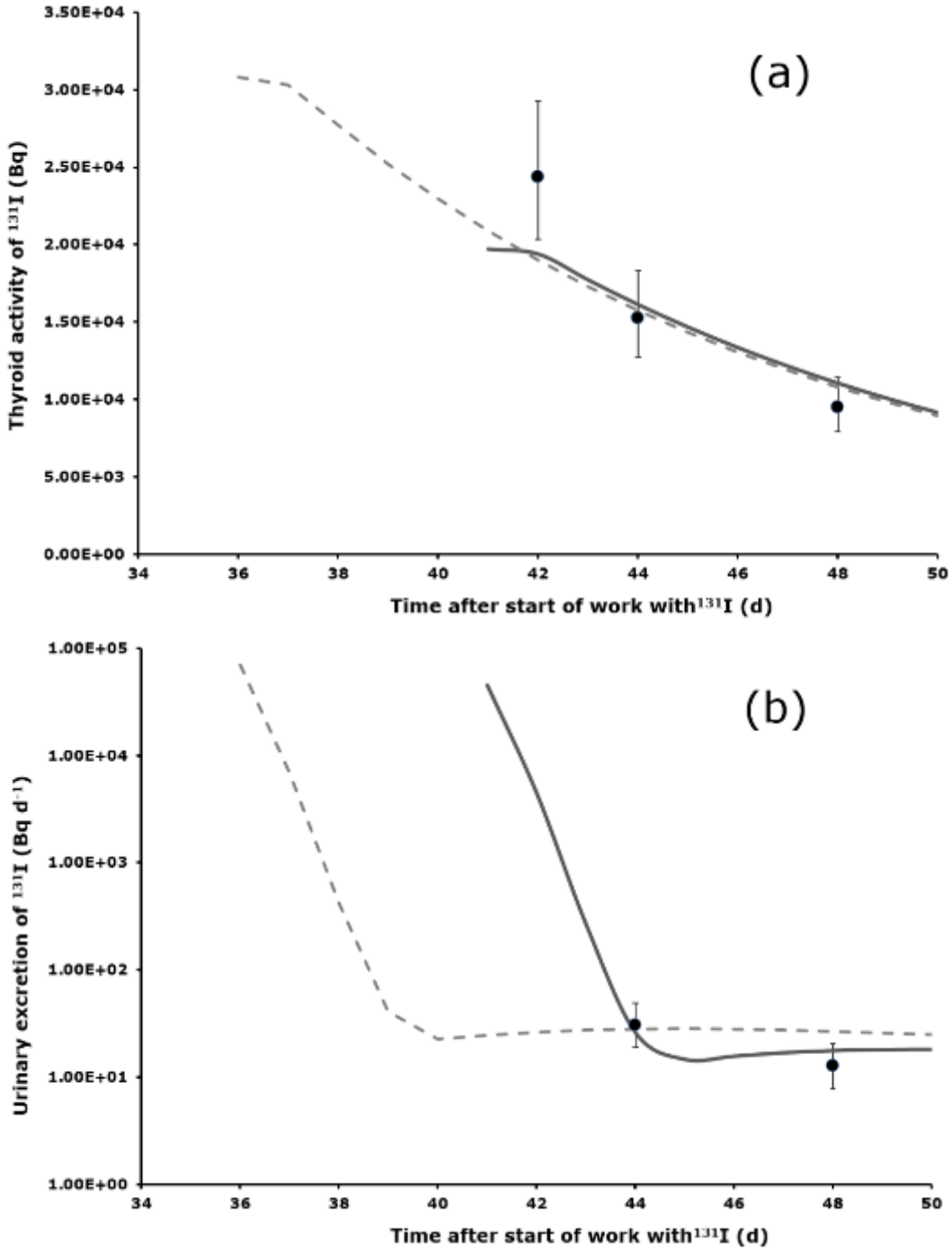



**Figure AII.3** Model fits to (a) thyroid and (b) urine data, assuming different times of intake of $^{131}$I vapour. Dashed line: mid-point of the monitoring interval (i.e. on 9/10/2014, which is 35 days after start of work and 7 days before the end of the monitoring interval); solid line: 14/10/2014, i.e. 40 days after start of work, which is 2 days before the end of the monitoring interval.

## EXAMPLE 4: Determining intake and dose in the presence of DTPA treatment

### Description of the case

An incident occurred (on day 0) in a nuclear fuel recycling facility under decommissioning. A worker dressed in protective clothing with clean air ventilation hit a metal string with his hand. The string pierced his protective glove and caused a puncture wound. Local spectrometry indicated alpha and beta contamination. The wound was washed with DTPA and 0.5 g of DTPA dry powder was immediately administered to the worker by inhalation. Decorporation treatment was carried on later by slow intravenous injection of 1 g DTPA on days 0, 1, 4, 6, 8, 11, 13, 15, 18, 20, 22, 25, 28, 32, 39, 46, 70 and 88 post-event.

For wound cases, the term intake refers to the intial activity deposited in the wound.

### Initial assessment

In accordance with recommendation E17: "*Wound cases should be treated on a case-by-case basis. Monitoring of the local activity around the wound site, the sharp object, dressings and compresses and excised tissue should be implemented to evaluate the equivalent dose to the area of wounded skin.*", the isotopic composition of surface contamination at the workplace was measured (Table AII.17). The occlusive compress was analysed by alpha spectrometry (Table AII.18) and measurement of local activity at the wound site was performed with the results indicated in Table AII.19.

**Table AII.17** Relative isotopic composition of radionuclides measured above detection limit by alpha and beta spectrometry of surface wipe at the workplace

| Radionuclide (measured emission) | Relative activity |
|---|---|
| $^{238}$Pu (alpha) | 1 |
| $^{239+240}$Pu (alpha) | 0.6 |
| $^{241}$Am (alpha) | 1.2 |
| $^{241}$Pu (beta) | 16 |

**Table AII.18** Result of alpha spectrometry analysis of occlusive compress

| Time after intake (day) | $^{238}$Pu (mBq) | $^{239+240}$Pu (mBq) | $^{241}$Am (mBq) |
|---|---|---|---|
| 0 | 1520 | 1140 | 1390 |

**Table AII.19** Results of individual monitoring by local gamma/X wound spectrometry

| Time after intake (day) | $^{238}$Pu (mBq) | $^{239+240}$Pu (mBq) |
|---|---|---|
| 0 | 80 | 41 |

Since activity was detected on the worker's skin, on the object that caused the wound and on the compress, following the initial gradation of Table E.4, the event was considered to be significant.

**Chapter C** indicates that "*special monitoring* […] *is performed either to better quantify significant exposures or following actual or suspected* accidental *intakes.*" Recommendation E18 states that "*a special monitoring programme should be*

*implemented for wound cases by a combination of in vivo and in vitro measurements in order to estimate the systemic uptake* […]". Recommendation E20 states that "*In the case of decorporation therapy, special monitoring should be performed […]*". So special monitoring is clearly required in this case.

Recommendation C15 states that "*Non-routine (special, task-related and confirmatory) monitoring programmes should be specified in such a way that sufficient information for the subsequent dose assessment is provided. A combination of several monitoring methods may be specified.*." Recommendation D17 states that, where urine samples are collected, "*A 24-hour urine sample is preferred, as no correction for sample duration is then needed*". Recommendation D19 states that "*Faeces bioassay should be used to assess inhalation intakes of insoluble radionuclides where urine bioassay does not provide adequate sensitivity; the representativeness of reference values for daily faecal mass excretion is an important source of uncertainty. Collection of 3-day total voids should be made to reduce such uncertainty, especially just after the time of the intake*". Recommendation D31 states that "*Alpha spectrometry is nevertheless recommended as the default method for measurements of alpha emitters in bioassay samples, on the basis of cost, versatility, throughput and availability*". Accordingly, 24-hour urine sample collection for day 1 and faeces sample collection for days 1 to 3 was performed. The samples were analysed by alpha spectrometry and the results were obtained on day 22 (Tables AII.20 and Table AII.21). The local wound monitoring was updated as indicated in Table AII.22.

**Table AII.20** Results of urine bioassay monitoring in terms of alpha activity

| Time after intake (day) | $^{238}$Pu (mBq d$^{-1}$) | $^{239+240}$Pu (mBq d$^{-1}$) | $^{241}$Am (mBq d$^{-1}$) |
|---|---|---|---|
| 1 | 7460 | 6170 | 13900 |

**Table AII.21** Results of faecal bioassay monitoring in terms of alpha activity

| Time after intake (day) | $^{238}$Pu (mBq d$^{-1}$) | $^{239+240}$Pu (mBq d$^{-1}$) | $^{241}$Am (mBq d$^{-1}$) |
|---|---|---|---|
| 1 | 9.2 | 3.7 | 12 |
| 2 | 7.4 | 6.6 | 11 |
| 3 | 24.4 | 21 | 24 |

**Table AII.22** Results of individual monitoring by local gamma/X wound spectrometry

| Time after intake (day) | $^{239}$Pu (Bq) | $^{241}$Am (Bq) |
|---|---|---|
| 0 | 80 | 41 |
| 1 | 83 | 39 |
| 4 | 68 | 28 |
| 6 | 56 | 26 |
| 15 | 40 | 16 |

Recommendation E18 states that "… *In order to evaluate the committed effective dose; to a first order of magnitude, the assessment should be made assuming a direct injection into blood*". Doing so with the IMBA software (PHE, UK) and implementing the biokinetic models from ICRP Publication 67, the available urine and faeces measurements provides the preliminary values of Table AII.23. The intake of $^{241}$Pu is

estimated on the basis of isotopic composition of Table AII.17 as ten times the total intake of $^{238}$Pu plus $^{239+240}$Pu. The dose from $^{241}$Pu is then calculated by multiplying the intake by the injection dose coefficient calculated with IMBA.

**Table AII.23** Initial committed effective dose assessment

| Radionuclide | $^{238}$Pu | $^{239+240}$Pu | $^{241}$Am | $^{241}$Pu | Total |
|---|---|---|---|---|---|
| Intake (Bq) | 808 | 665 | 205 | 14730 | |
| Dose (mSv) | 361 | 328 | 82 | 140 | 910 |
| Goodness of fit (p) | 8.0E-16 | 6.0E-17[7] | 2.0E-08 | | |

The provisionally estimated committed effective dose is 910 mSv, so the annual dose limit of 20 mSv may well be exceeded. Recommendation E22 states that "*Dose assessments after decorporation therapy require an expert assessment and need to be case-specific*". This is "*…because reference models cannot be applied due to the altered biokinetic behaviour of the radionuclide…*" (**Chapter E, Section E5**). As expected, the goodness of fit is very low. Further urine, faeces and wound monitoring is conducted, meeting the requirements of Table C.7 when dose is above 6 mSv.

## Regulatory assessment

At the end of the on-going calendar year, a dose assessment is required for regulatory purposes. According to Recommendation E08, "*The recommended approach comprises the the ISO 27048:2011 approach…*". STEP 1 of the ISO 27048:2011 procedure for assessment of doses on the basis of individual measurement performed for special monitoring, and of Table E.2 in this report, is to "*check if an intake via wound, intact skin or influenced by decorporation therapy can be ruled out*". This is obviously not the case, so it is recommended by ISO 27048:2011 to "*go to expert assessment*" and by the present report (Table E.2) to "*Go to EURADOS-IDEAS-Guidelines, Stage 4 and follow wound route* […]" at Stage 8.

STEP 8.1 is the identification of all measured data representing the case. At this point, results from bioassay monitoring are available up to day 23, as indicated in Tables AII.24 and AII.23.

The recommended values of scattering factors (SF) are 1.1 for 24-hour urine and 3 for 24-hour faecal samples (Table F.1). However, in this example, expert judgement (justified by Recommendation E22) indicates that the DTPA therapy causes significant uncertainty in the systemic model. To account for this increased uncertainty, SF values of 2 and 5 are used here for urine and faeces data respectively.

Recommendation E25 states that "*In the case of DTPA treatment, the plutonium intake may be estimated from urine measurements obtained more than 20 days after DTPA administration, and/or from urine excretion measured on the day following DTPA administration after correction with a DTPA enhancement factor. This factor may be taken to have a nominal value of 50 or adjusted to an individual-specific value determined after a therapeutic window. The application of the enhancement factor is only valid if the DTPA administrations are separated at least by 2 days*". Therefore only urine sampled on the days following each DTPA injection, at least 2 days after the previous injection, is considered further. The corresponding plutonium and americium measurement results are divided by the nominal DTPA enhancement factor of 50, as recorded in Table AII.26. The faecal monitoring values of Table AII.25 are used without application of a factor. On the basis of expert judgement, the same DTPA enhancement factor is applied here to the $^{241}$Am in urine data.

**Table AII.24** Results of urine bioassay monitoring in terms of alpha activity. Samples were collected over 24 hours.

| Time after intake (day) | $^{238}$Pu (mBq d$^{-1}$) | $^{239+240}$Pu (mBq d$^{-1}$) | $^{241}$Am (mBq d$^{-1}$) |
|---|---|---|---|
| 1 | 7460 | 6170 | 13900 |
| 2 | 1340 | 1030 | 1250 |
| 3 | 941 | 664 | 926 |
| 4 | 531 | 363 | 562 |
| 5 | 3450 | 2470 | 2680 |
| 6 | 437 | 308 | 520 |
| 7 | 2030 | 1440 | 2190 |
| 8 | 282 | 210 | 330 |
| 9 | 1080 | 925 | 1260 |
| 10 | 256 | 198 | 300 |
| 11 | 170 | 126 | 200 |
| 12 | 1220 | 1010 | 1430 |
| 13 | 236 | 188 | 277 |
| 14 | 861 | 710 | 1010 |
| 15 | 265 | 207 | 311 |
| 16 | 781 | 632 | 915 |
| 17 | 160 | 120 | 187 |
| 18 | 156 | 121 | 183 |
| 19 | 728 | 588 | 852 |
| 20 | 191 | 152 | 224 |
| 21 | 486 | 399 | 568 |
| 22 | 155 | 121 | 181 |
| 23 | 447 | 360 | 523 |

**Table AII.25** Results of faecal bioassay monitoring in terms of alpha activity. Samples were collected over 24 hours.

| Time after intake (day) | $^{238}$Pu (mBq d$^{-1}$) | $^{239+240}$Pu (mBq d$^{-1}$) | $^{241}$Am (mBq d$^{-1}$) |
|---|---|---|---|
| 1 | 9.2 | 3.7 | 12 |
| 2 | 7.4 | 6.6 | 11 |
| 3 | 24.4 | 21 | 24 |
| 9 | 60 | 45.4 | 53 |
| 17 | 32.9 | 25.1 | 30.5 |

**Table AII.26** Results of urine bioassay monitoring for samples collected during the 24-hour period following a DTPA injection. The values were divided by the nominal DTPA enhancement factor of 50.

| Time after intake (day) | $^{238}$Pu (mBq d$^{-1}$) | $^{239+240}$Pu (mBq d$^{-1}$) | $^{241}$Am (mBq d$^{-1}$) |
|---|---|---|---|
| 1 | 149 | 123 | 278 |
| 5 | 69 | 49 | 54 |
| 7 | 41 | 29 | 44 |
| 9 | 21 | 19 | 25 |
| 12 | 24 | 20 | 29 |
| 14 | 17 | 14 | 20 |
| 16 | 16 | 13 | 18 |
| 19 | 15 | 12 | 17 |
| 21 | 9.7 | 8.0 | 11 |
| 23 | 8.9 | 7.2 | 10 |

STEP 8.2 is the assessment of contribution of previous intakes. The worker's exposure to actinides has been routinely monitored before the event and no former contamination has been detected.

STEP 8.3 is to assign *a priori* a NCRP Report 156 wound model category on the basis of the behaviour over time of the monitored quantity. It is consistent with recommendation E18 that "*depending on circumstances, a more precise wound model may be used. The excretion and retention functions of the NCRP Publication 156 wound model and dose coefficients for radionuclides using a wound model combined with systemic models ... could be used*". The IDEAS Guidelines indicate that "*for example, for plutonium isotopes, choose 'Soluble Strong' for decreasing urinary excretion behaviour*". This is the present case and the Soluble Strong wound category is therefore used.

STEP 8.4 is the assessment of dose with *a priori* parameters. The dose assessment is conducted by fitting the NCRP Report 156 wound model with the Soluble Strong category, together with the ICRP Publication 67 systemic models for plutonium and americium, to the faecal and urinary bioassay data of tables AII.25 and AII.26 with SF values of 5 and 2 respectively. The fits are shown in Figures AII.4 to AII.9 and the corresponding results are recorded in Table AII.27. The intake of $^{241}$Pu is estimated as ten times the total intake of $^{238}$Pu plus $^{239+240}$Pu. The dose from $^{241}$Pu is the intake multiplied by the dose coefficient calculated for the Soluble Strong wound category.

**Table AII.27** Provisional committed effective dose assessment with a nominal enhancement factor of 50 for DTPA

| Radionuclide | $^{238}$Pu | $^{239+240}$Pu | $^{241}$Am | $^{241}$Pu | Total |
|---|---|---|---|---|---|
| Intake (Bq) | 65 | 51 | 25 | 1160 | |
| Dose (mSv) | 29 | 25 | 10 | 11 | **75** |
| Goodness of fit (p) | 0.98 | 0.98 | 0.86 | - | |

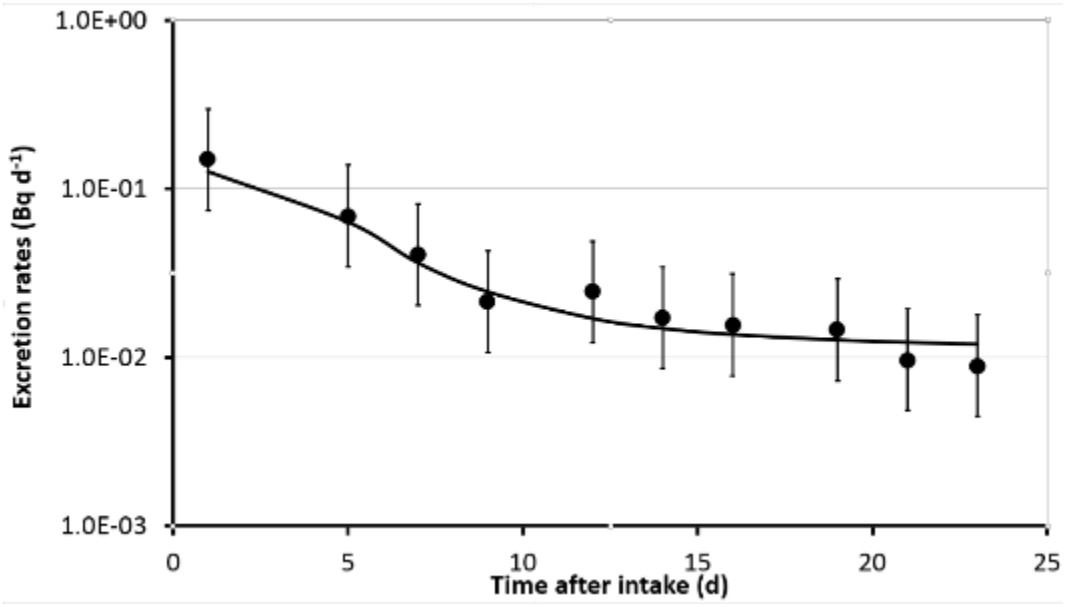



**Figure AII.4** Fit of NCRP Report 156 wound model with Soluble Strong category and ICRP Publication 67 Pu model to measurements of $^{238}$Pu in daily urine excretion up to day 23, divided by a nominal DTPA enhancement factor of 50

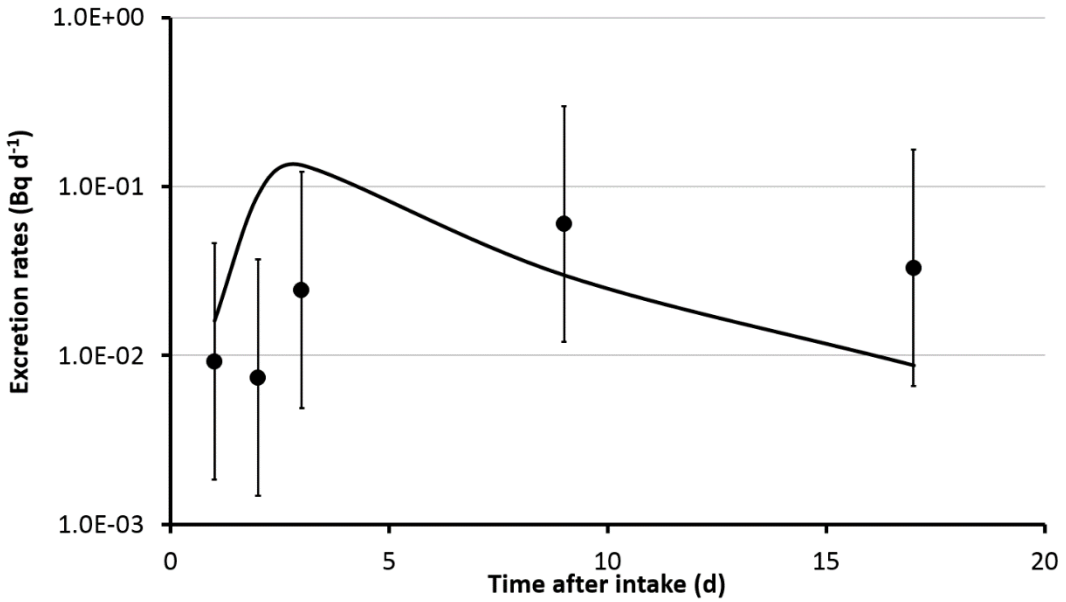



**Figure AII.5** Fit of NCRP Report 156 wound model with Soluble Strong category and ICRP Publication 67 Pu model to measurements of $^{238}$Pu in daily faecal excretion up to day 23

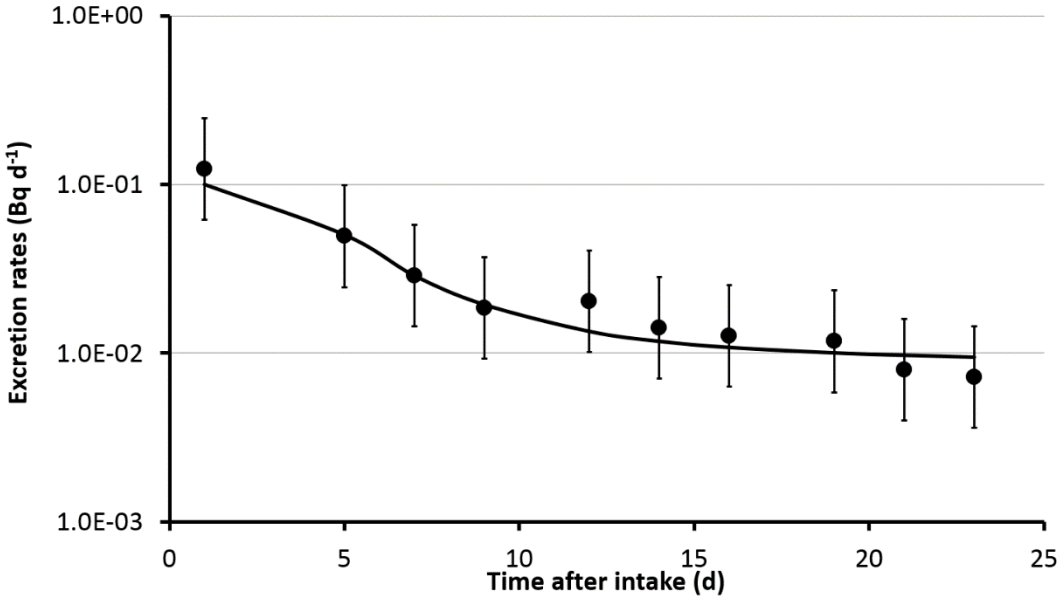



**Figure AII.6** Fit of NCRP Report 156 wound model with Soluble Strong category and ICRP Publication 67 Pu model to measurements of $^{239+240}$Pu in daily urine excretion up to day 23, divided by a nominal DTPA enhancement factor of 50

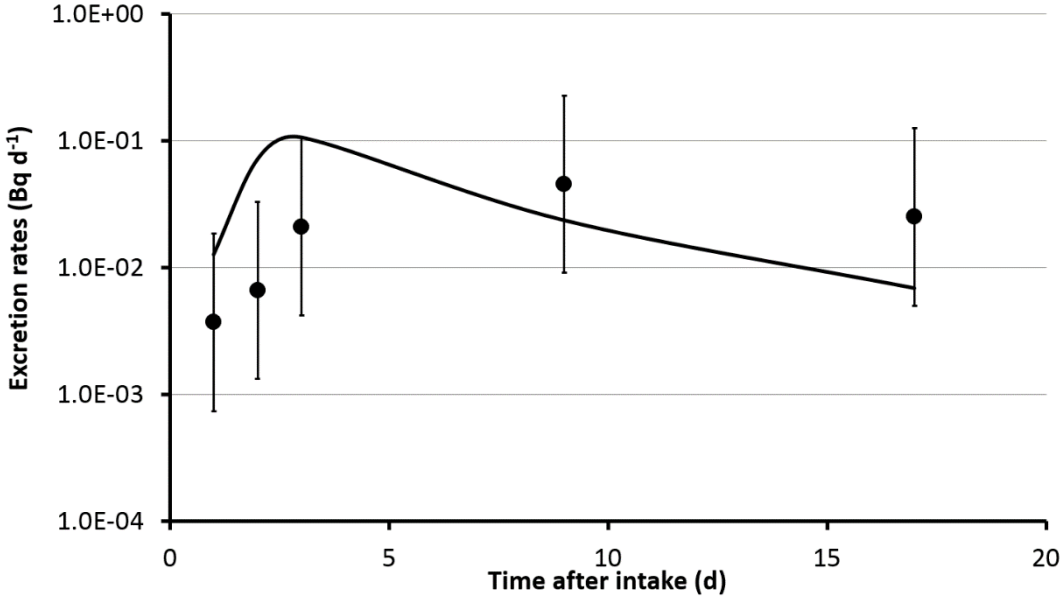



**Figure AII.7** Fit of NCRP Report 156 wound model with Soluble Strong category and ICRP Publication 67 Pu model to measurements of $^{239+240}$Pu in daily faecal excretion up to day 23

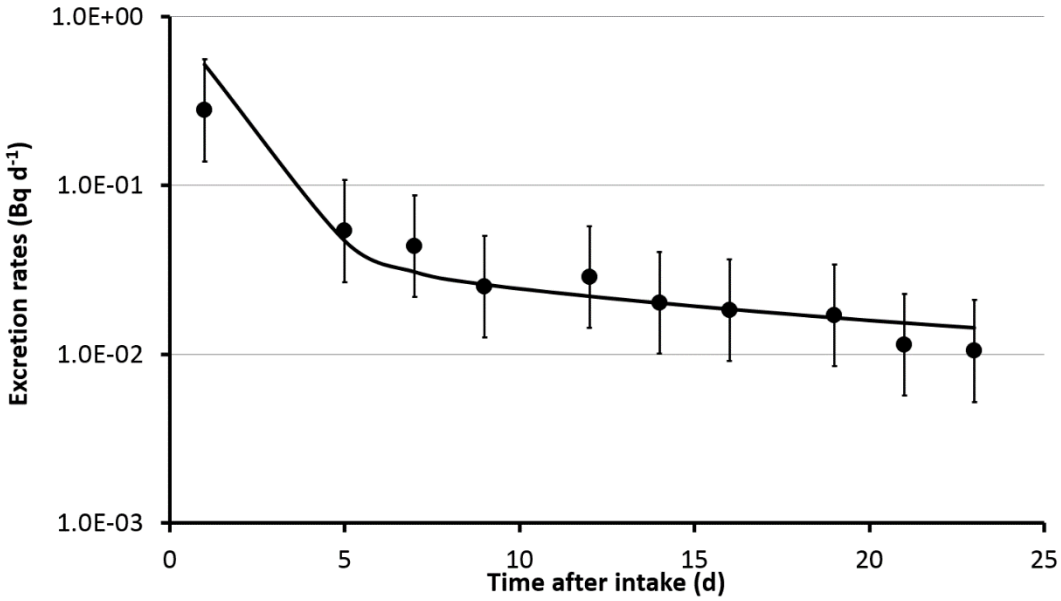



**Figure AII.8** Fit of NCRP Report 156 wound model with Soluble Strong category and ICRP Publication 67 Am model to measurements of $^{241}$Am in daily urine excretion up to day 23, divided by a nominal DTPA enhancement factor of 50

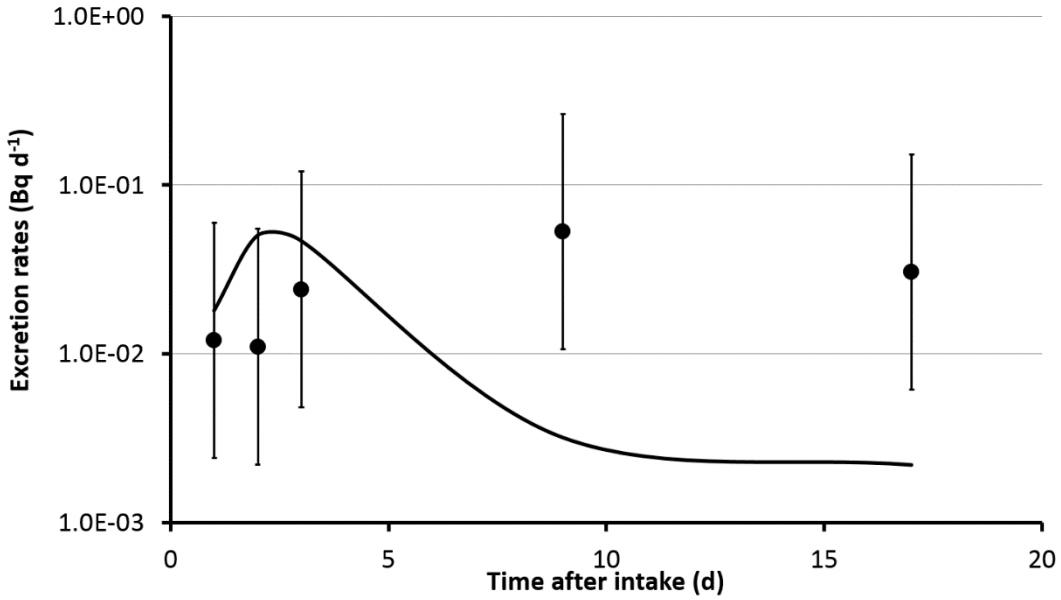



**Figure AII.9** Fit of NCRP Report 156 wound model with Soluble Strong category and ICRP Publication 67 Am model to measurements of $^{241}$Am in daily faecal excretion up to day 23

STEP 8.5: The provisionally assessed dose of 75 mSv is more than 1 mSv, so further special procedures (Stage 8B of IDEAS Guidelines) are needed for more detailed evaluation of the case.

## Individual-specific assessment

STEP 8.6: There are sufficient data (more than five measurements for both urine and faeces) according to Table C.7. Nevertheless, the special monitoring is carried on for three months after the incident to improve the accuracy of the dose assessment and verify the effectiveness of the treatment. The updated results are shown in Tables AII.28, AII.29 and AII.30. From day 47 to day 70, the medical practitionner takes advantage of the worker's vacation to break off the DTPA treatment, opening a therapeutic window.

**Table AII.28** Results of individual monitoring by local gamma/X wound spectrometry

| Time after intake (day) | $^{239}$Pu (Bq) | $^{241}$Am (Bq) |
|---|---|---|
| 0 | 80 | 41 |
| 1 | 83 | 39 |
| 4 | 68 | 28 |
| 6 | 56 | 26 |
| 15 | 40 | 16 |
| 50 | 29 ± 15 | 9 ± 1.2 |
| 71 | 26 ± 10 | 6.4 ± 1 |

**Table AII.29** Results of faecal bioassay monitoring in terms of alpha activity. Samples were collected over 24 hours

| Time after intake (day) | $^{238}$Pu (mBq d$^{-1}$) | $^{239+240}$Pu (mBq d$^{-1}$) | $^{241}$Am (mBq d$^{-1}$) |
|---|---|---|---|
| 1 | 9.2 | 3.7 | 12 |
| 2 | 7.4 | 6.6 | 11 |
| 3 | 24.4 | 21 | 24 |
| 9 | 60 | 45.4 | 53 |
| 17 | 32.9 | 25.1 | 30.5 |
| 31 | 38 | 26 | 20 |
| 63 | 15 | 10 | 13.1 |

**Table AII.30** Results of urine bioassay monitoring in terms of alpha activity. Samples were collected over 24 hours

| Time after intake (day) | $^{238}$Pu (mBq d$^{-1}$) | $^{239+240}$Pu (mBq d$^{-1}$) | $^{241}$Am (mBq d$^{-1}$) |
|---|---|---|---|
| 1 | 7460 | 6170 | 13900 |
| 2 | 1340 | 1030 | 1250 |
| 3 | 941 | 664 | 926 |
| 4 | 531 | 363 | 562 |
| 5 | 3450 | 2470 | 2680 |
| 6 | 437 | 308 | 520 |
| 7 | 2030 | 1440 | 2190 |
| 8 | 282 | 210 | 330 |
| 9 | 1080 | 925 | 1260 |
| 10 | 256 | 198 | 300 |
| 11 | 170 | 126 | 200 |
| 12 | 1220 | 1010 | 1430 |
| 13 | 236 | 188 | 277 |
| 14 | 861 | 710 | 1010 |
| 15 | 265 | 207 | 311 |
| 16 | 781 | 632 | 915 |
| 17 | 160 | 120 | 187 |
| 18 | 156 | 121 | 183 |
| 19 | 728 | 588 | 852 |
| 20 | 191 | 152 | 224 |
| 21 | 486 | 399 | 568 |
| 22 | 155 | 121 | 181 |
| 23 | 447 | 360 | 523 |
| 26 | 447 | 360 | 523 |
| 29 | 411 | 353 | 481 |
| 33 | 410 | 323 | 480 |
| 39 | 26 | 16.5 | 30 |
| 40 | 307 | 234 | 359 |
| 47 | 344 | 267 | 403 |
| 60 | 13.4 | 7.6 | 15.6 |
| 70 | 7.8 | 4.3 | 12.7 |
| 71 | 332 | 216 | 363 |
| 88 | 4.5 | 3.1 | 9.4 |
| 89 | 118 | 76 | 160 |

STEP 8.8 indicates that the Soluble Weak category of NCRP Report 156 should be assumed.

STEP 8.9 involves calculation of the dose with this NCRP default category. Following recommendation E25, the DTPA enhancement factor "*may be* […] *adjusted to an individual-specific value determined after a therapeutic window*". An individual-specific DTPA enhancement factor is determined at the end of the therapeutic window as the ratio of urine excretion on day 71 (just after DTPA treatment) to urine excretion on day 70 (just before DTPA treatment). This gives DTPA enhancement factors of 45 for plutonium and 30 for americium. The urine data of Table AII.30, collected on the days following a DTPA injection and divided by the individual-specific DTPA enhancement factor, are used for this dose assessment. Only the urine data of day 70 is used without correction with the DTPA enhancement factor since the sample was collected more than 20 days after the previous DTPA administration.

The dose assessment is conducted by fitting the NCRP report 156 wound model for Soluble Weak category and the ICRP Publication 67 systemic models for plutonium and americium to the faecal and urinary bioassay data of Tables AII.29 and AII.31 with SF values of 5 and 2 respectively. The fits are shown in Figures AII.10 to AII.15 and the corresponding results are recorded in Table AII.32. The intake of $^{241}$Pu is estimated as ten times the total intake of $^{238}$Pu plus $^{239+240}$Pu. The dose from $^{241}$Pu is the intake multiplied by the dose coefficient calculated for the Soluble Weak wound category.

**Table AII.31** Results of urine bioassay monitoring divided by an individual-specific DTPA enhancement factor of 45 (or 30) for Pu (for Am) for samples collected 24 hours following a DTPA injection. The measurements at day 70 were obtained more than 20 days after the DTPA administration on day 46 and so are not corrected by any DTPA enhancement factor.

| Time after intake (day) | $^{238}$Pu (mBq d$^{-1}$) | $^{239+240}$Pu (mBq d$^{-1}$) | $^{241}$Am (mBq d$^{-1}$) |
|---|---|---|---|
| 1 | 166 | 137 | 464 |
| 5 | 77 | 55 | 89 |
| 7 | 45 | 32 | 73 |
| 9 | 24 | 21 | 42 |
| 12 | 27 | 23 | 48 |
| 14 | 19 | 16 | 34 |
| 16 | 17 | 14 | 30 |
| 19 | 16 | 13 | 28 |
| 21 | 11 | 8.9 | 19 |
| 23 | 9.9 | 8.0 | 17 |
| 26 | 9.9 | 8.0 | 17 |
| 29 | 9.1 | 7.8 | 16 |
| 33 | 9.1 | 7.2 | 16 |
| 40 | 6.8 | 5.2 | 12 |
| 47 | 7.6 | 5.9 | 13 |
| 70 | 7.8 | 4.3 | 13 |
| 71 | 7.4 | 4.8 | 12 |
| 89 | 2.6 | 1.7 | 5.3 |

**Table AII.32** Committed effective dose assessment with Soluble Weak wound category and an individual-specific action factor for DTPA

| Radionuclide | $^{238}$Pu | $^{239+240}$Pu | $^{241}$Am | $^{241}$Pu | Total |
|---|---|---|---|---|---|
| Intake (Bq) | 57 | 43 | 49 | 1002 | |
| Dose (mSv) | 26 | 21 | 19 | 9.4 | **76** |
| Goodness of fit (p) | 0.80 | 0.75 | 0.47 | | |

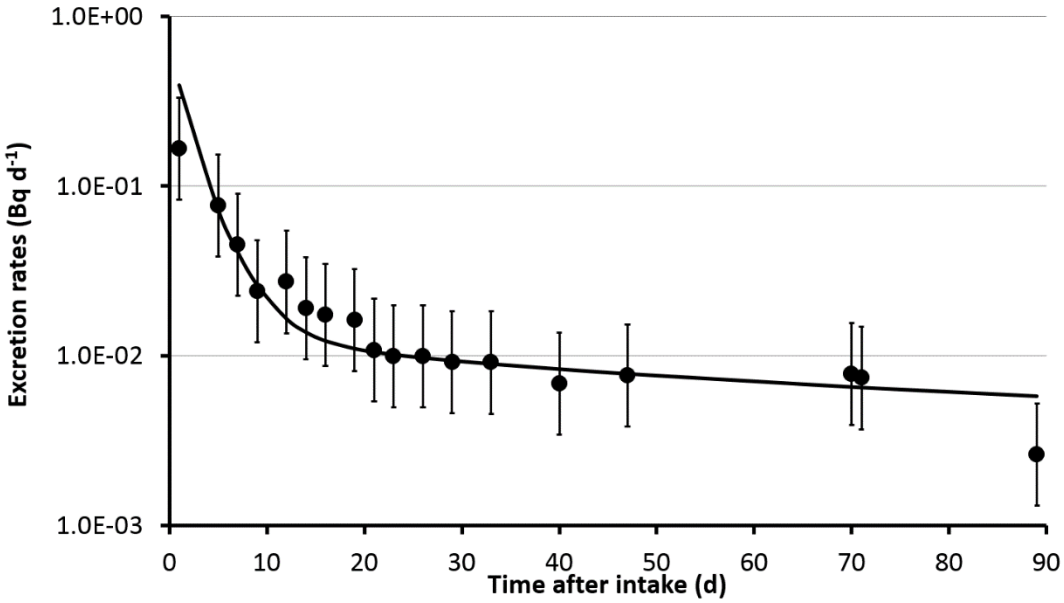



**Figure AII.10** Fit of NCRP Report 156 wound model with Soluble Weak category and ICRP Publication 67 Pu model to measurements of $^{238}$Pu in daily urine excretion up to day 89, divided by an individual-specific DTPA enhancement factor of 45

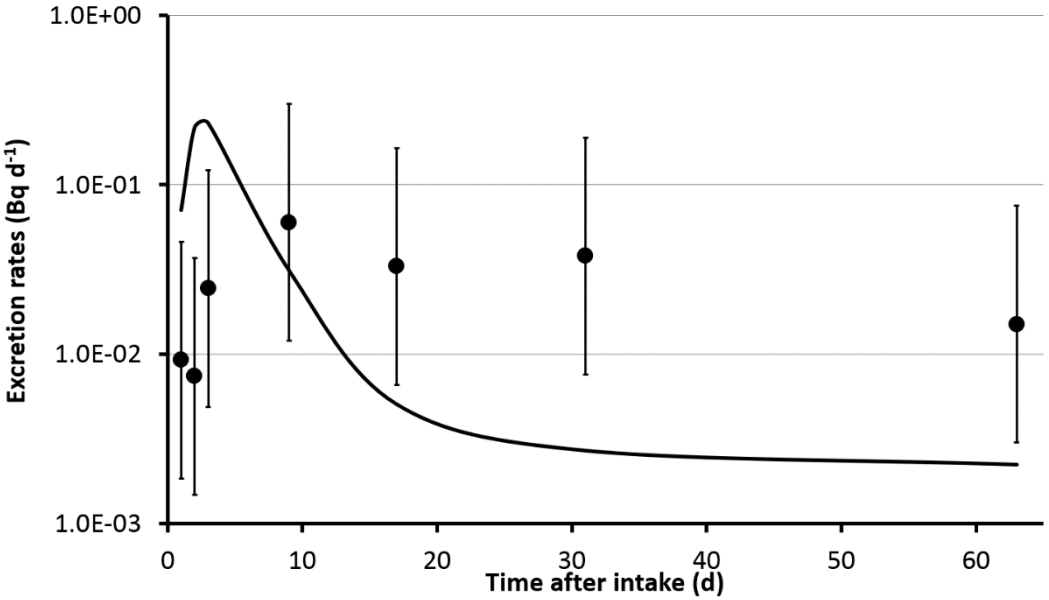



**Figure AII.11** Fit of NCRP Report 156 wound model with Soluble Weak category and ICRP Publication 67 Pu model to measurements of $^{238}$Pu in daily faecal excretion up to day 89

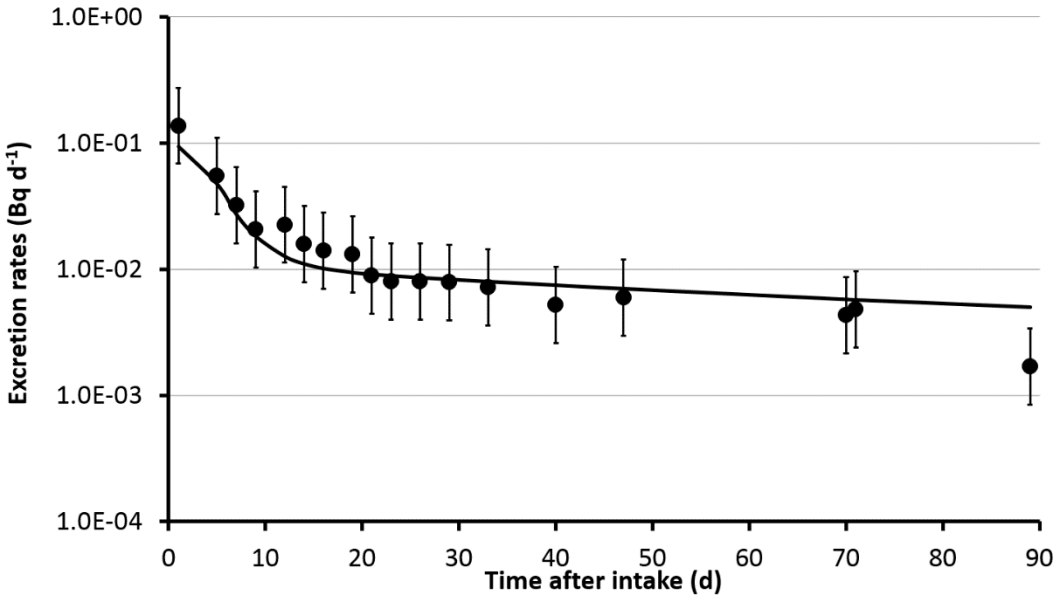



**Figure AII.12** Fit of NCRP Report 156 wound model with Soluble Weak category and ICRP Publication 67 Pu model to measurements of $^{239+240}$Pu in daily urine excretion up to day 89, divided by an individual-specific DTPA enhancement factor of 45

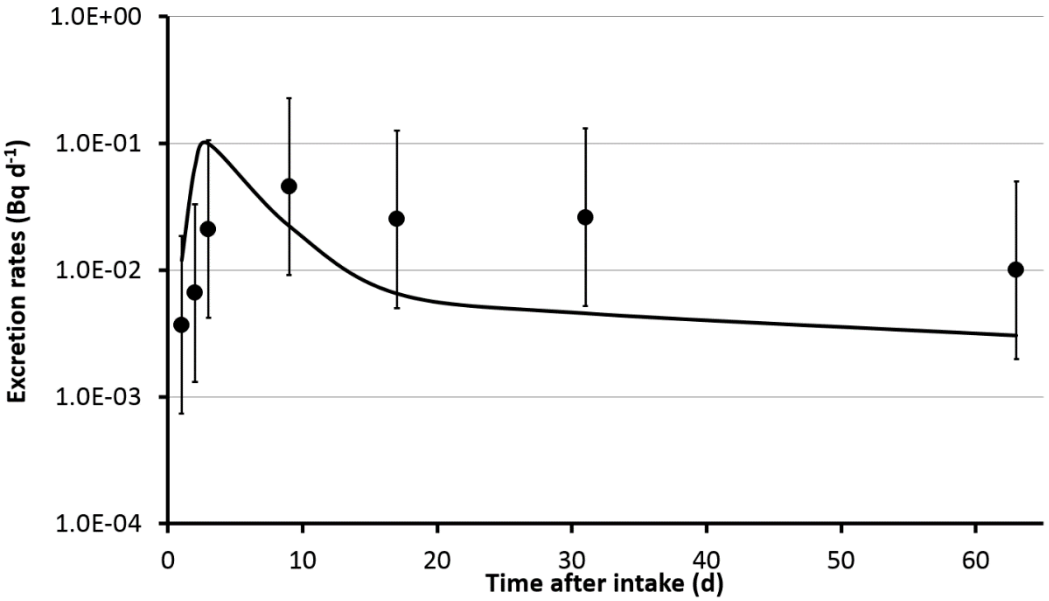



**Figure AII.13** Fit of NCRP Report 156 wound model with Soluble Weak category and ICRP Publication 67 Pu model to measurements of $^{239+240}$Pu in daily faecal excretion up to day 89

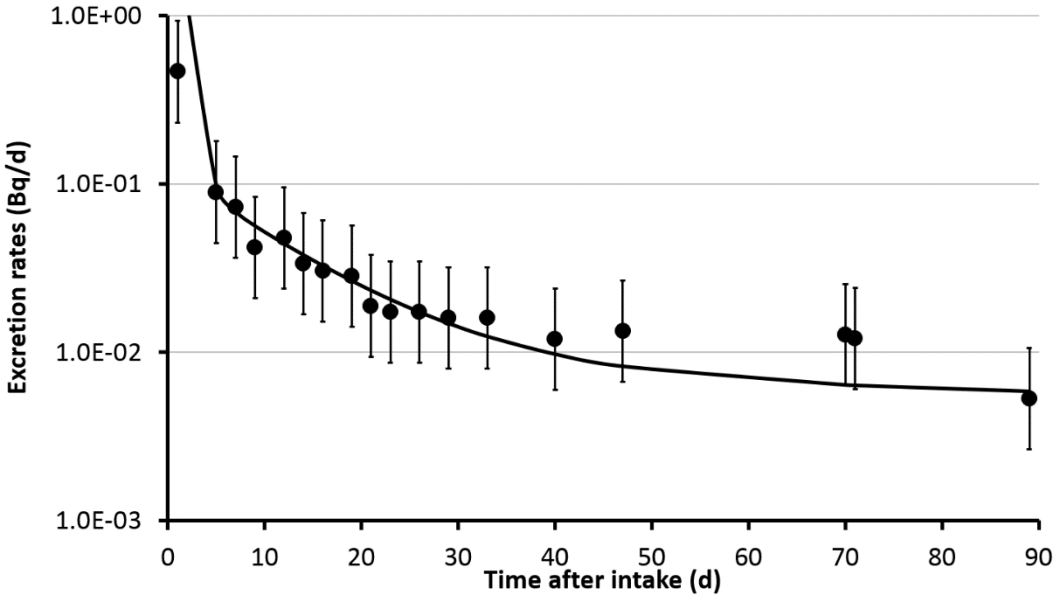



**Figure AII.14** Fit of NCRP Report 156 wound model with Soluble Weak category and ICRP Publication 67 Am model to measurements of $^{241}$Am in daily urine excretion up to day 89, divided by an individual-specific DTPA enhancement factor of 45

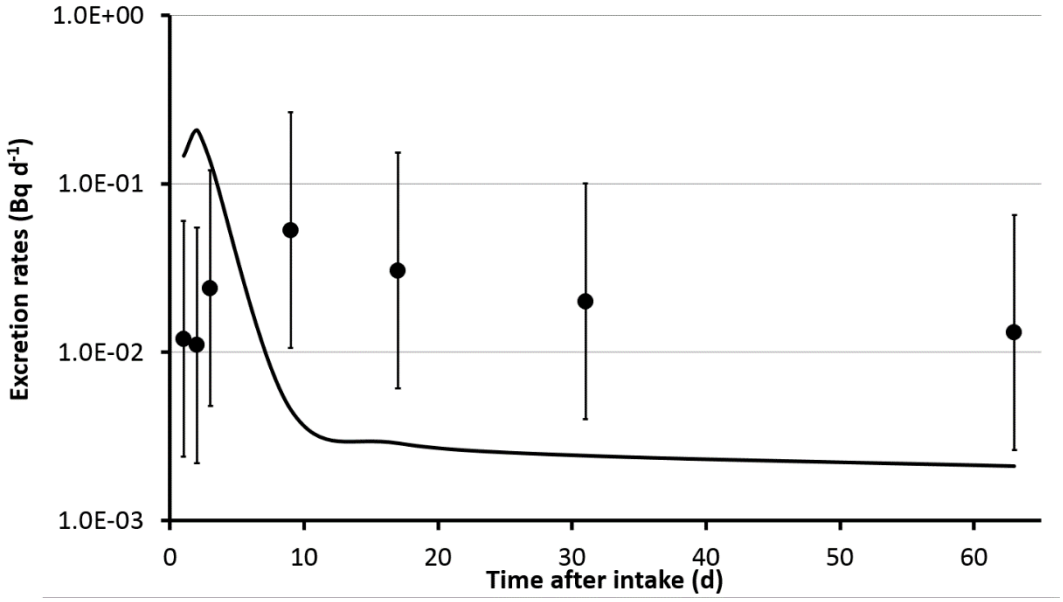



**Figure AII.15** Fit of NCRP Report 156 wound model with Soluble Weak category and ICRP Publication 67 Am model to measurements of $^{241}$Am in daily faecal excretion up to day 89

STEP 8.10: The goodness of fit is acceptable ($p>0.05$, and the fit looks reasonable by eye).

STEP 8.11: The assessed total committed effective dose is 76 mSv, which is more than 6 mSv, so further special procedures are needed (Stage 8C of IDEAS-Guidelines).

STEP 8.14: The number of data is sufficient.

STEP 8.15: A mixture of Soluble Weak and Soluble Strong categories is assumed. The best fit (greatest p-value) is obtained for 100% Soluble Strong and the corresponding results are indicated in Table AII.33.

**Table AII.33** Committed effective dose assessment with Soluble Strong wound category and individual-specific action factor for DTPA

| Radionuclide | $^{238}$Pu | $^{239+240}$Pu | $^{241}$Am | $^{241}$Pu | Total |
|---|---|---|---|---|---|
| intake (Bq) | 63 | 48 | 41 | 1115 | |
| dose (mSv) | 28 | 23 | 16 | 11 | **78** |
| goodness of fit (p) | 0.99 | 0.99 | 0.99 | | |

STEP 8.16: The goodnes of fit is acceptable.

STEP 8.16.1: The committed effective dose of 78 mSv is recorded.

This dose is reported as the final result of the assessment.

## EXAMPLE 5: Acute inhalation of fission products

This contamination scenario is taken from the case description presented in the IDEAS/IAEA Intercomparison Exercise on Internal Dose Assessment [Hurtgen 2005] and [IAEA 2007].

### Description of the case

During the reprocessing of graphite used in a reactor, a dust explosion containing fission products occurred. A 46 year old worker was involved and inhaled the dust. Measurement of a nasal swab, taken immediately after the accident, revealed the presence of 1.9 kBq of $^{90}$Sr. External decontamination, nose swab, and monitoring were immediately undertaken. No medical intervention was performed for the worker (e.g. blocking or chelating, etc.). The only information available relating to the chemical form of the dust was that it mainly contained graphite with fission products, indicating that strontium was likely to be insoluble. Follow up measurements began immediately with a whole body measurement for $^{137}$Cs and the collection of 24-hour urine samples for measurement of the $^{90}$Sr urinary daily excretion. Special monitoring was set up. Whole body and urine measurements were performed on a regular basis, and faeces measurements were also performed in parallel with the urine measurements.

The final database of measurements is composed of 9 whole body measurements for$^{137}$Cs (up to 595 d post-accident), and 11 and 5 measurements respectively of urinary and faecal daily excretion for $^{90}$Sr (up to 634 d post-accident).

All available data are reported in Table AII.34.

**Table AII.34** Whole body $^{137}$Cs measurement results and $^{90}$Sr daily urine and faeces excretion measurement results

| Time after accident (d) | WBC $^{137}$Cs activity (Bq) | Time after accident (d) | $^{90}$Sr daily urine excretion (Bq d$^{-1}$) | Time after accident (d) | $^{90}$Sr daily faecal excretion (Bq d$^{-1}$) |
|---|---|---|---|---|---|
| 0[(a)] | 7.0E+04 | 1 | 65 | 76 | 5.9 |
| 2 | 6.5E+04 | 4 | 13 | 227 | 2.2 |
| 7 | 5.0E+04 | 7 | 7.1 | 314 | 1.4 |
| 29 | 4.0E+04 | 29 | 1.2 | 492 | 2.0 |
| 62 | 3.5E+04 | 47 | 1.4 | 634 | 0.47 |
| 106 | 2.0E+04 | 76 | 1.0 | | |
| 226 | 6.2E+03 | 202 | 0.66 | | |
| 468 | 9.4E+02 | 227 | 0.64 | | |
| 595 | 8.0E+02 | 314 | 0.47 | | |
| | | 492 | 0.78 | | |
| | | 634 | 0.45 | | |

(a) It is assumed that the first measurement was made at 0.1 d.

### Dose assessment

STEP 1: Check if uptake via wound, intact skin or influenced by decorporation therapy can be ruled out

As there has been no uptake via wound or intact skin and chelation therapy has not been used, proceed to step 2

STEP 2: Check if the measured value is significant

Considering as a first approximation a value of the decision threshold (DT) equal to half the value of detection limit (DL) [ISO 2010a], and the values of DT evaluated on the basis of the Tables 3.1 and 3.4 of IDEAS Guidelines [EURADOS 2013], the DT value for the $^{137}$Cs measurement is 30 Bq while the DT value for $^{90}$Sr in urine is 0.2 Bq L$^{-1}$. Using a total daily excretion of 1.6 L d$^{-1}$ [ICRP 2002] in a male subject, this gives a value of DT = 0.32 Bq d$^{-1}$.

The initial values of the $^{137}$Cs and $^{90}$Sr measurements are both well above the respective DT values, so proceed to STEP 3.

STEP 3: Standard dose assessment

Pure inhalation and default parameter values were assumed: an activity median aerodynamic diameter (AMAD) of 5 µm, absorption Type F for caesium and, on the basis of the information on the chemical form, absorption Type S for strontium.

The values of retention or excretion are taken from the NIRS MONDAL3 software [Ishigure 2004].

The time of the first whole body measurement is assumed to be 0.1 d. The intake of $^{137}$Cs, $I$ is therefore based on a predicted whole body retention at 0.1 d equal to 0.787 Bq per Bq intake (the first available):

$$I = \frac{M}{m(t)} = \frac{70000}{0.787} = 8.9\text{E}04\ Bq \qquad \text{(Eq. AII.15)}$$

Using the corresponding dose coefficient for $^{137}$Cs (6.7E-09 Sv Bq$^{-1}$), the assessed dose is 0.60 mSv.

For $^{90}$Sr the intake value is based on a predicted value for the first day total urine excretion equal to 8.1E-04 Bq d$^{-1}$ per Bq intake:

$$I = \frac{M}{m(t)} = \frac{65}{8.1 \times 10^{-4}} = 8.0\,\text{E}04\ Bq \qquad \text{(Eq. AII.16)}$$

Using the corresponding dose coefficient for $^{90}$Sr (7.7E-08 Sv Bq$^{-1}$), the assessed dose is 6.2 mSv.

The total effective dose from intakes of both radionuclides is $E_{tot}(50)$ = 0.6 mSv + 6.2 mSv =6.8 mSv.

STEP 4: Criterion for accepting the standard dose assessment

It is assumed that the uncertainty on the measurement of $^{137}$Cs can be characterised by a total scattering factor (*SF*) of 1.2, the default value given by Table F.1 for *in vivo* measurements of radionuclides emitting high photon energy radiation. It includes both Type A and Type B uncertainties.

A total scattering factor (*SF*) of 1.7 is calculated for the daily urinary excretion measurements assuming a $SF_A$ component of 25% together with the $SF_B$ value of 1.6 as reported for simulated 24-hour urine in Table F.1.

There is no need for further evaluation if the following relation is valid:

$$E(50)\ SF^2 < 1\ \text{mSv} \qquad \text{(Eq. AII.17)}$$

where

$E(50)$ is the total committed effective dose calculated in Step 3 corresponding to the measured value,

For $^{137}$Cs with $E(50)_{Cs}$ = 0.6 mSv and *SF* = 1.2, the inequality (Eq. AII.17) is valid: $E(50)\ SF^2$ = 0.86 mSv).

For $^{90}$Sr, however, the value of $E(50)_{Sr}$ = 6.2 mSv and *SF* = 1.7, which means that the inequality (Eq. AII.17) is not valid ($E(50)_{Sr}\ SF^2$ = 17.9 mSv).

Therefore, further evaluation is required – proceed to Step 5.

STEP 5: Confirm assumptions by additional measurements

It is decided to perform the evaluation of $^{137}$Cs intake with all available monitoring data.

All the collected data are reported in Table AII.34. The total SF value associated with $^{137}$Cs whole body measurement data is 1.2. For $^{90}$Sr daily urinary excretion, a value of 1.7 is used. For faecal excretion of $^{90}$Sr, it was assumed that Type B errors dominate and a total SF value of 3.0 is assumed. This is the default value for Type B errors given in Table F.1 for 24-hour faecal samples.

STEP 6: Comparison with dose limits: to check if the annual dose limit may potentially be exceeded

Figure A.19 and Table A.20 of ISO 27048:2011 show the lower level (LL) and the upper level (UL) for $^{137}$Cs, representing the predicted range of WBC measurements corresponding to a dose reference level of 20 mSv.

As can be seen in Figure AII.16, $M_i < DIL_{min}(i) < LL$ for all measurements i= 1 to 9, where $M_i$ are the measurement values (empty circles), $DIL_{min}$ are the values of the lower derived investigation level calculated by means of (Eq. E.8) (solid squares) and LL is the lower level of the band reported in Figure A.19 of ISO 27048:2011 (dashed line). In the dashed line the values of table A.20 of ISO 27048:2011 column 2, for times after intake from day 1 to day 180, are reported..

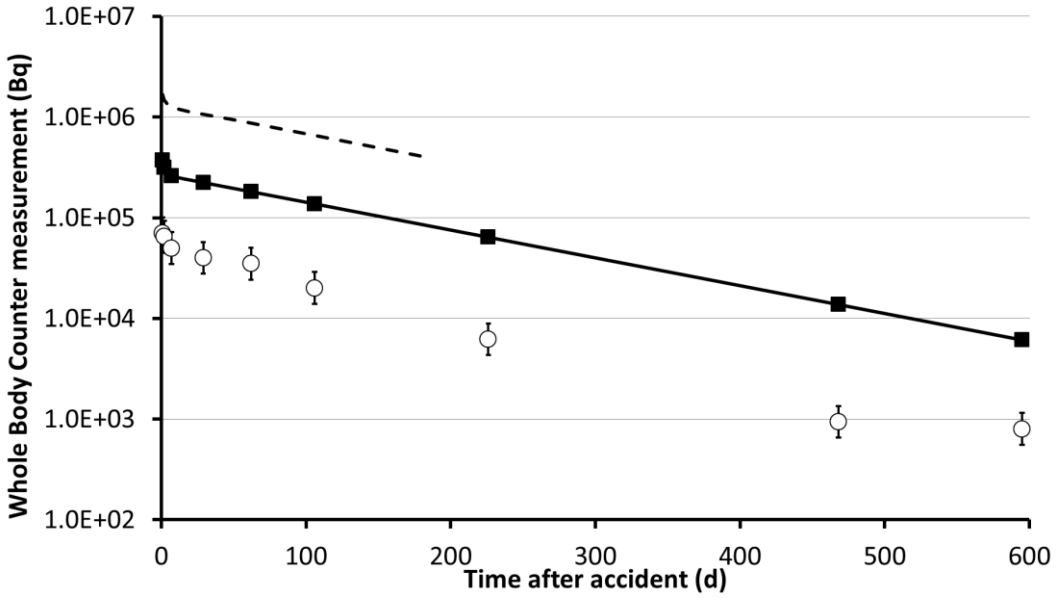



**Figure AII.16** Comparison between measured data (empty circles), lower level of the band (dashed line) and values of $DIL_{min}$ for whole body counter measurements of $^{137}$Cs (full line)

As can be seen, the comparison indicates that the annual dose limit is not exceeded, so the assessed dose should be documented and the assessment ended.

To make the final assessment of dose, the intake is calculated from the dataset of bioassay measurements, using the maximum likelihood method by applying the following equation:

$$\ln(I) = \frac{\sum_{i=1}^{n} \frac{\ln(I_i)}{[\ln(SF_i)]^2}}{\sum_{i=1}^{n} \frac{1}{[\ln(SF_i)]^2}} \qquad \text{(Eq. AII.18)}$$

where the point estimate, $I_i$ is the intake calculated from the $i^{th}$ measurement given by equation (Eq. B.9) and $SF_i$ is the overall scattering value for measurement $i$.

This equation is similar to equation E.9 of **Chapter E**. In this case all SF values are the same so the calculation may be simplified using equation (19) of ISO 27048:2011, which determines the geometric mean of the single intake estimates. In this case, the intake assessed using all nine data points is 88.7 kBq and the corresponding committed effective dose is 0.59 mSv. The calculated chi squared ($\chi_0^2$) value = 32 with 8 degrees of freedom (DoF) and a P-value = 9.3E-05. As the P-value is less than 0.05 the fit is rejected [EURADOS 2013].

Figure AII.17 shows the fit to the data.

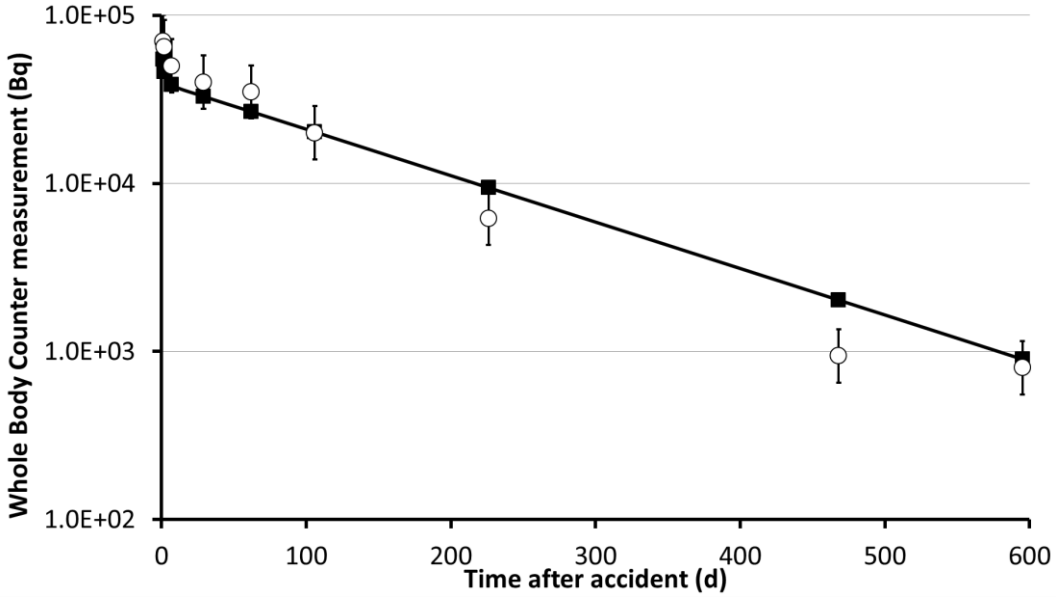



**Figure AII.17** Graph of the initial fitting of $^{137}$Cs whole body data (empty circles, uncertainty confidence interval of 68 %)

Two data points provide the greater contribution to the observed chi squared value, at days 226 and 468. These points may be considered as possible outliers (as they lie below the trend of the data). The procedure of paragraph 6.1 of the IDEAS Guidelines may be followed to test whether they are outliers.

First, consider the measurement that has the greatest influence on assessed intake, which is the measurement at 468 d post-accident. Its exclusion results in an increase of 9.6% in the assessed intake and dose, which cannot be considered as negligible.

Assessment of intake using the remaining 8 data values results in an assessment of intake of 97.3 kBq and E(50)= 0.65 mSv, an observed chi squared = 16, and P-value = 0.0278. So there is an increase in the P-value but the fit is also rejected (P-value < 0.05). The predicted value at 468 d is 2150 Bq and the measured value is 940 Bq. The ratio of these values is 2.287 which is more than a factor of $SF^3$ = 1.728. So the measurement at 468 d should be considered as outlier and discarded for the dose assessment.

Next, consider the exclusion of the second possible outlier, that at 226 d post-accident, its exclusion results in a further increase of 7.8% in the assessed intake and dose, which cannot be considered as negligible. A similar analysis indicates that also this measurement should be considered as outlier and discarded for the dose assessment.

The final assessed dose is therefore based on seven data values. The assessed intake is 104 kBq, and E(50) = 0.70 mSv.

A summary of this evaluation of rogue data is presented in Table AII.35.

The final fitting of the $^{137}$Cs WBC data is reported in Figure AII.18.

The dose evaluation for $^{137}$Cs ends here.

**Table AII.35** Identification of rogue data and fitting procedure

| N. of data | Excluded data at day(s) | Intake and E(50) percentage variation respect to all data (%) | Outlier datum | Evaluated Intake (kBq) | E(50) (mSv) | Observed chi squared | P-value | Fit rejected (YES / NO) |
|---|---|---|---|---|---|---|---|---|
| 9 (all) | none | - | - | 88.7 | 0.59 | 32 | 9.3E-05 | YES |
| 8 | 468 | 9.6 | YES | 97.3 | 0.65 | 16 | 0.0287 | YES |
| 7 | 468 and 226 | 17.4 | YES | 104 | 0.70 | 11 | 0.083 | NO |

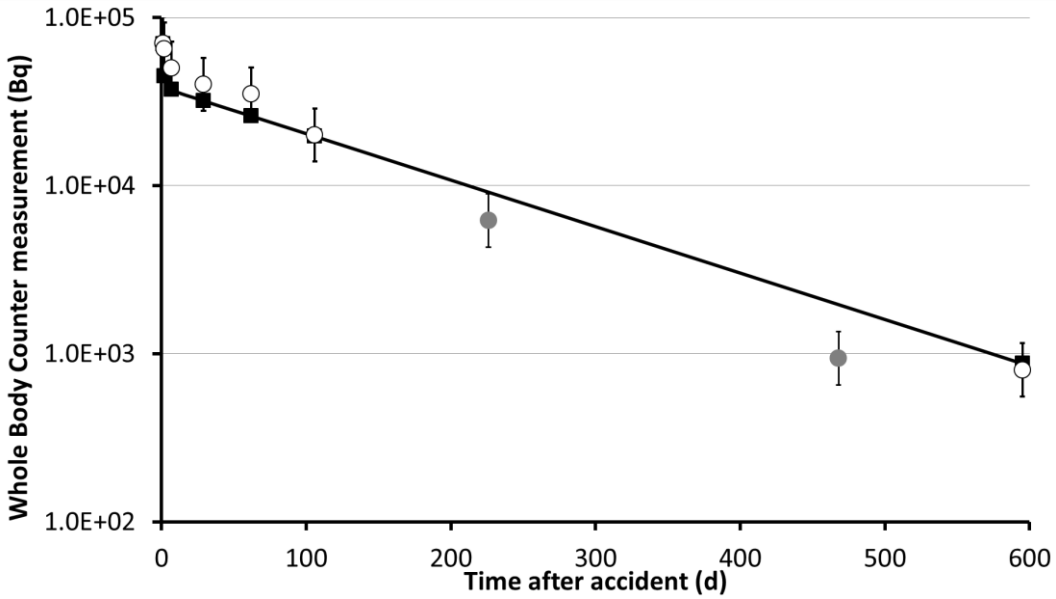



**Figure AII.18** Final fitting of the data of $^{137}$Cs WBC measurements. The outliers are indicated as grey symbols.

Regarding the $^{90}$Sr evaluation, a comparison with dose limits is performed using the data reported in Figure A.15 and in Table A.16 of ISO 27048:2011 for urine daily excretion up to 180 d post-accident.

In Figure AII.19, the measurement values are presented together with the values of the lower level (LL) of the band, taken from column 2 of Table A.16 of ISO 27048:2011. The $DIL_{min}$ data evaluated by means of (Eq E.8) using the $m(t_i)$ values calculated for 5 μm AMAD, absorption Type S and the corresponding e(50) value, are also presented.

As can be seen, the first measurement (65 Bq $d^{-1}$) is above the corresponding value of the LL (64 Bq $d^{-1}$). All the data, and especially the five data above 180 days, are well above the corresponding $DIL_{min}(i)$ values. So, it may be concluded that there is a possibility that the dose limit of 20 mSv may potentially be exceeded. So, proceed to Stage 4 of IDEAS Guidelines.

STAGE 4 – Step 4.1: Identification of intake route

On the basis of the case scenario,"pure inhalation" is selected. Go to Stage 5.

STAGE 5 - STEP 5.1: Identification of all measurement data

All the $^{90}$Sr urine and faeces data are used in the assessment. The SF values used are 1.8 for urine and 3 for faeces measurements.

STEP 5.2 : No contribution from previous intake(s) needs to be calculated.

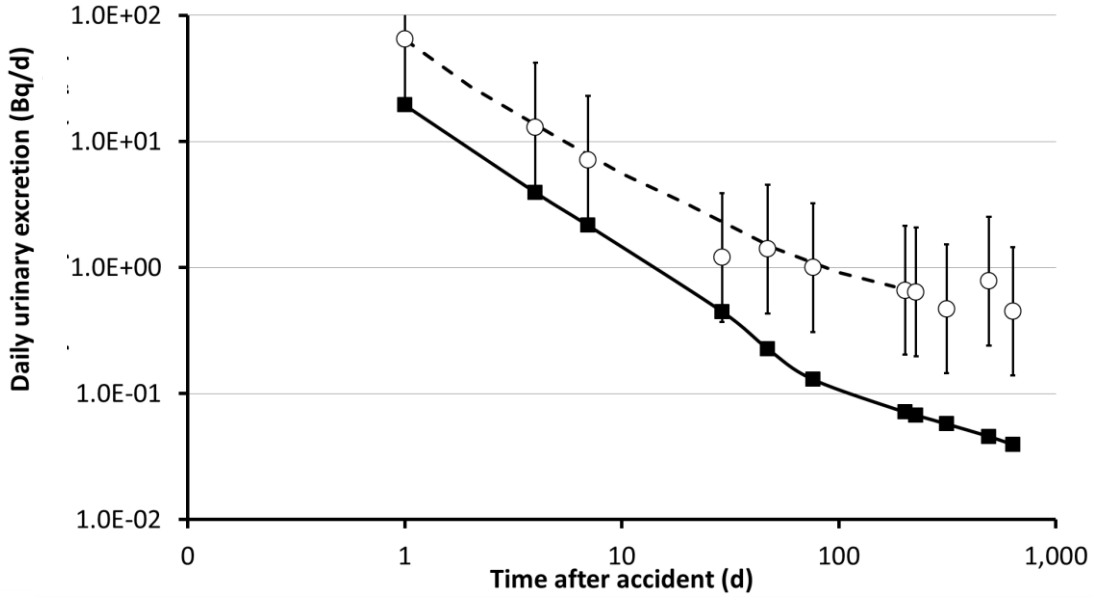



**Figure AII.19** Comparison between measured data (empty circles), lower level of the band (dashed line) and values of DILmin (filled squares and full line) for urine measurements of $^{90}$Sr

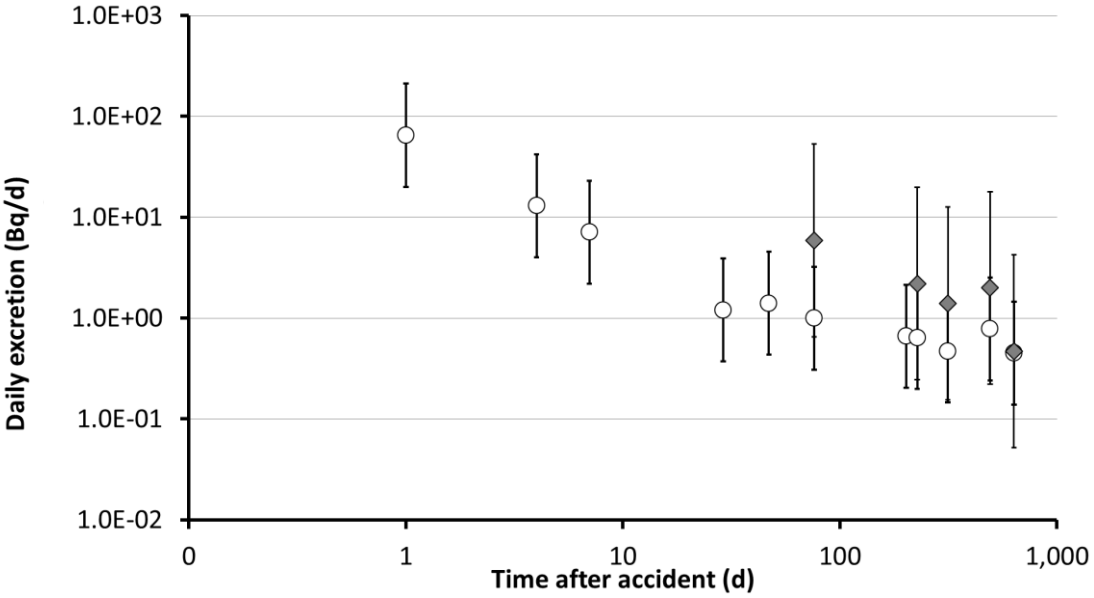



**Figure AII.20** $^{90}$Sr data with relative measurement uncertainty (C.I. 68%). Open circles: urine; Grey diamonds: faeces.

STEP 5.3: Assign *a priori* parameters

The following assumptions are adopted: Single intake at time 0, AMAD = 5 μm, absorption Type S, on the basis of the chemical form.

STEP 5.4: Time of intake is known. Go to Step 5.5.

STEP 5.5: Calculate dose with *a priori* parameters.

The equation to be used for the intake evaluation is:

$$\ln(I) = \frac{\sum_{i=1}^{n_u} \frac{\ln(I_i)}{(\ln(SF_{u,i}))^2} + \sum_{j=1}^{n_f} \frac{\ln(I_j)}{(\ln(SF_{f,j}))^2}}{\sum_{i=1}^{n_u} \frac{1}{(\ln(SF_{u,i}))^2} + \sum_{j=1}^{n_f} \frac{1}{(\ln(SF_{f,j}))^2}} \qquad \text{(Eq. AII.19)}$$

while the following equation is used for the evaluation of observed chi squared.

$$\chi_0^2 = \sum_{i=1}^{n_u} \left( \frac{\ln(M_i) - \ln(I \cdot m(t_i))}{\ln(SF_{u,i})} \right)^2 + \sum_{j=1}^{n_f} \left( \frac{\ln(M_j) - \ln(I \cdot m(t_j))}{\ln(SF_{f,j})} \right)^2 \qquad \text{(Eq. AII.20)}$$

The parameter $n_u$ is the number of urine data and $n_f$ is the number of faeces data, $I_i=M_i/m(t_i)$ is the estimate of intake based on urine datum of measurement $M_i$ , and $m(t_i)$ the predicted excretion value at time $t_i$; $I_j = M_j/m(t_j)$ is the estimate of intake based on faeces measurement $M_j$ , and $m(t_j)$ the predicted excretion value at time $t_j$; $SF_{u,i}=SF_u=1.7$ is the total scattering factor related to each urine measurement $M_i$ and $SF_{f,j}=SF_f=3$ is the total scattering factor related to each faecal measurement $M_j$.

The fitting procedure results in the following assessment: Intake= 138.4 kBq, E(50)= 10.7 mSv, observed chi squared = 17.8, P-value= 0.276. On the basis of the chi-squared test the fit is not rejected at the 5% level of significance (as P-value > 0.05).

However, inspection of the data in Figures AII.21 and AII.22 indicates that the fit looks unreasonable by eye. This is because the model predictions for faeces (continuous lines) present systematic overestimation over the whole time period, while the model predictions for urine present systematic overestimation before day 47 and then systematic underestimation afterwards. Thus, the fit is rejected on the basis of the "fit by eye" criterion of paragraph 6.3 of the IDEAS Guidelines.

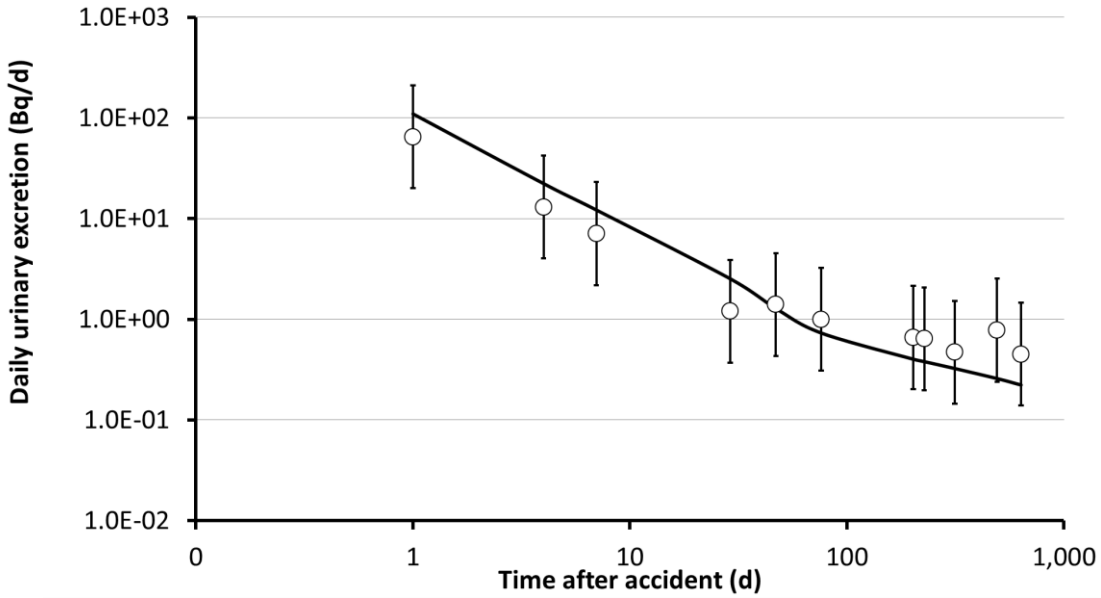



**Figure AII.21** Fitting of $^{90}$Sr urine data with default parameters

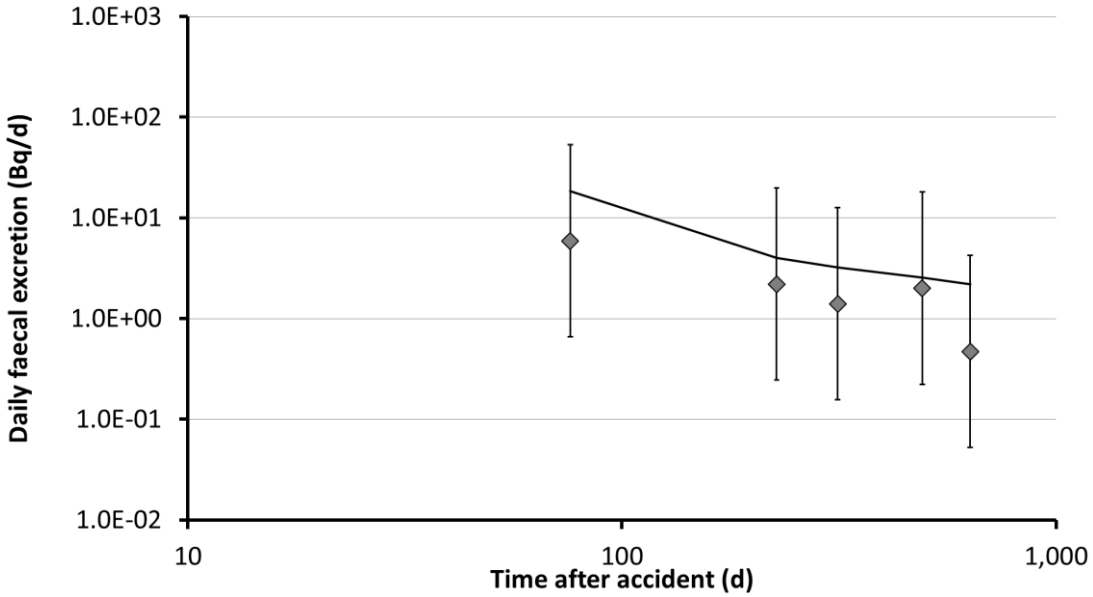



**Figure AII.22** Fitting of $^{90}$Sr faecal data with default parameters

STEP 5.6: Dose < 1 mSv ? As the evaluated E(50)= 10.7 mSv , go to Stage 5B.

STAGE 5B - STEP 5.7: Are there sufficient relevant data ?
Table 6.2 of the IDEAS Guidelines related to $^{90}$Sr in the 1 to 6 mSv range of doses indicates that the requirement is two urine and two faeces measurements. More than that is available for the present case. Go to Step 5.8.

STEP 5.8: Time of intake is known.

STEP 5.9: Early lung and faecal data are not available, go to Step 5.11.

STEP 5.11: Assessment of the dose by fitting of the absorption Type.
The choice of absorption Type F (the alternative available absorption Type) does not improve the fit as the observed chi squared value increases up to a value of 133.

STEP 5.13: Assessment of dose by fitting the mixture of default absorption Types.
As indicated in [Hurtgen 2005] and [IAEA 2007], no improvement can be achieved by mixing different percentages of Type F and Type S materials. Go to Stage 5C.

STEP 5.16: Determine specific HRTM absorption parameter values.
A trial has been performed in respect of default Type S material to increase the slow dissolution rate of the inhaled material in order to increase the late urinary excretion. As presented in [Hurtgen 2005] and [IAEA 2007], the late dissolution rate $S_t$ (with a default value of 1.0E-04 $d^{-1}$ for absorption Type S) was increased from 3.0E-04 $d^{-1}$ to 1.0E-03 $d^{-1}$, while maintaining the other two parameters $S_p$ and $S_{pt}$ at their original Type S default values (namely 0.1 and 100 $d^{-1}$). Each dose assessment was performed, by means of the IMBA™ code [Birchall 2003] with a different value of $S_t$, increasing it step by step and evaluating the observed chi squared value and the criterion "by eye". The best fit is reached for a value of 5.0E-04 $d^{-1}$.
The fitting procedure results in the following assessment: Intake= 67.2 kBq, e(50)= 5.3E-08 Sv/Bq, E(50)= 3.56 mSv, observed chi squared= 3.23, P-value = 0.999. So the fit is not rejected by both criteria. As can be seen in Figures AII.23 and AII.24, the systematic under- or over-estimation of the data is no longer present.

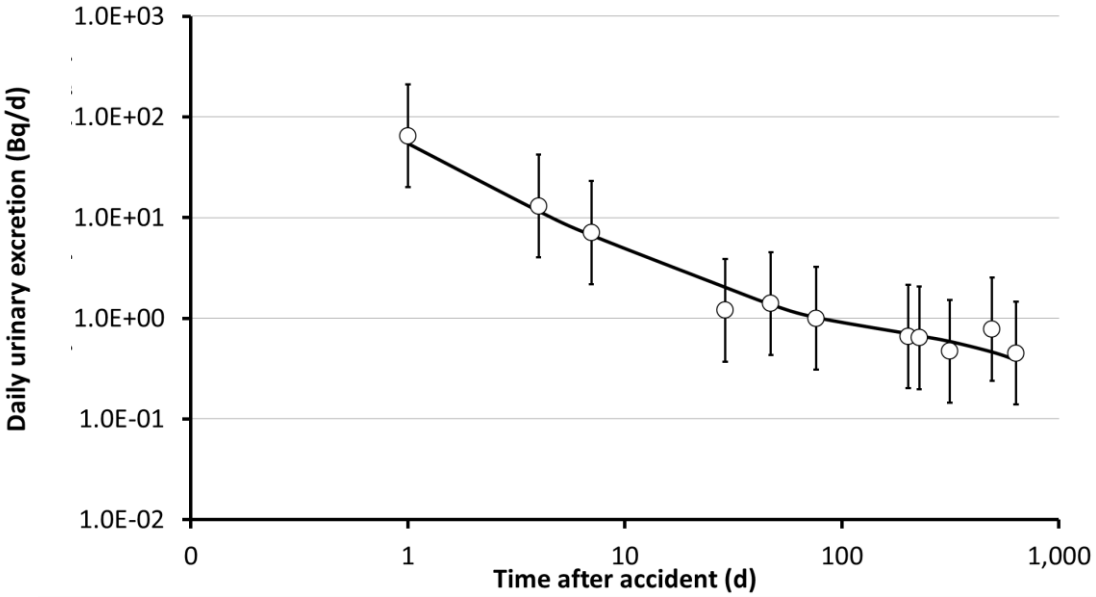



**Figure AII.23** Fitting of $^{90}$Sr urine data with modified absorption parameters

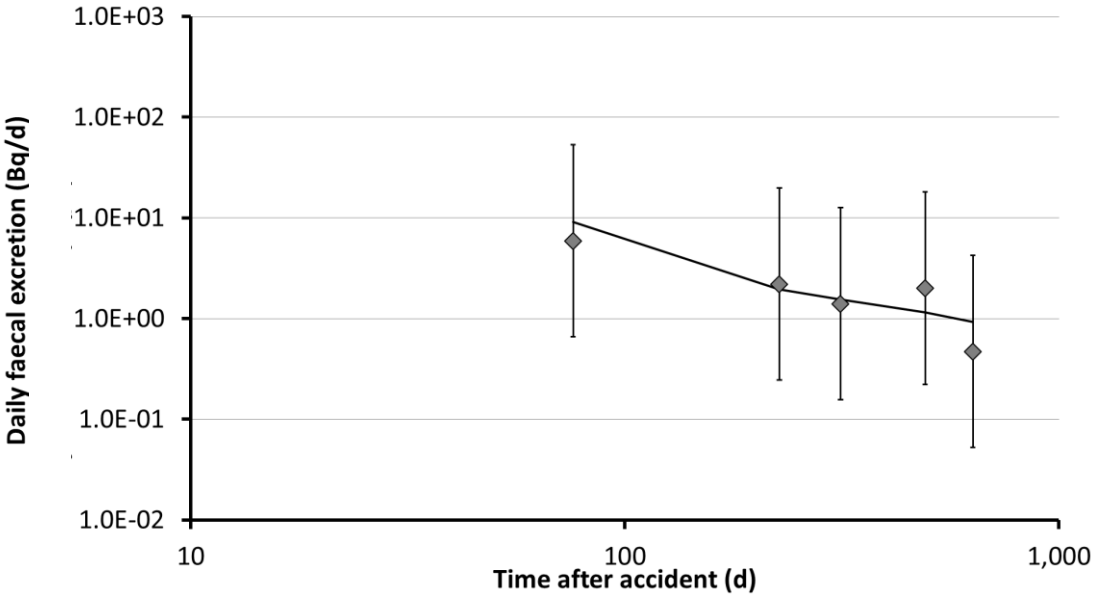



**Figure AII.24** Fitting of $^{90}$Sr faecal data with modified absorption parameters

The final result of the assessment is reported in Table AII.36, where the final step of the evaluation is also reported.

**Table AII.36** Final results of the internal dose assessment

| Radio-nuclide | Excluded data | Absorption Type | Evaluated Intake (kBq) | E(50) (mSv) | P-value | Final step of evaluation |
|---|---|---|---|---|---|---|
| $^{137}$Cs | 2 | F | 104 | 0.70 | 0.083 | 6 (ISO 27048:2011) |
| $^{90}$Sr | none | Modified S | 67.2 | 3.56 | 0.99 | 5.16 (IDEAS Guidelines) |

## EXAMPLE 6: Routine monitoring for intakes of natural uranium

### Description of the case

A male worker who handles natural uranium has been placed on a routine monitoring program of urine and faecal measurements with a monitoring interval of 90 d for both types of measurements.

The first urine measurement 90 days after start of work was carried out using Inductively Coupled Plasma Mass Spectrometry (ICP-MS). The mass concentration of $^{238}U$ and $^{235}U$ measured in the urine sample were 0.485 µg $L^{-1}$ and 0.003 µg $L^{-1}$ respectively. The volume of the sample was 1 L and the creatinine content was 1 g.

The first faecal measurement 90 days after start of work was carried out with alpha spectroscopy. The activity of $^{238}U$ and $^{234}U$ measured in the sample were 0.015 Bq and 0.014 Bq respectively. The mass of the faecal sample was 110 g.

The estimated daily excretions of natural uranium due to dietary intakes were 0.03 µg $d^{-1}$ for urine and 0.02 Bq $d^{-1}$ for faecal, which were based on previous measurements carried out before start of work. Urine measurements of other workers not exposed to uranium ranged from 0 to 0.24 µg $d^{-1}$.

The chemical form of the material is likely to be uranium trioxide.

The data provided is summarised in Table AII.37.

Assess the dose resulting from any intakes in the first monitoring period.

From previous experience with workers with similar exposure situations, it is expected that, on a few occasions, some intakes of natural uranium via inhalation may occur in a given monitoring period that result in annual effective doses of less than about 1 mSv.

**Table AII.37** Final results of the internal dose assessment

| Urine | | Faecal | |
|---|---|---|---|
| Method of measurement | ICP-MS | | Alpha spectrometry |
| $^{238}U$ | 0.485 µg $L^{-1}$ | $^{238}U$ | 0.015 Bq |
| $^{235}U$ | 0.003 µg $L^{-1}$ | $^{234}U$ | 0.014 Bq |
| Volume of sample | 1 L | Mass of sample | 110 g |
| Mass of creatinine | 1 g | | |
| Dietary excretion of natural uranium | 0.03 µg $d^{-1}$ | | 0.02 Bq $d^{-1}$ |

It can be assumed that only the uranium nuclides were present in the material with activity ratios typical for natural uranium (Table AII.38). The isotopic composition of natural uranium is given below and is taken from the IDEAS Guidelines [EURADOS 2013].

**Table AII.38** Isotopic composition of natural uranium [Berglund 2011; EURADOS 2013]

| Isotope | % Isotopic composition, [a] | % Alpha activity | Alpha activity, [b] Bq/g |
|---|---|---|---|
| $^{238}U$ | 99.2837 | 49.03 | 1.23E+04 |
| $^{235}U$ | 0.7110 | 2.26 | 5.68E+02 |
| $^{234}U$ | 0.005329 | 48.72 | 1.23E+04 |
| Total alpha activity, Bq/g | 2.51E+04 | | |
| Dietary excretion of natural uranium | 0.03 µg $d^{-1}$ | | 0.02 Bq $d^{-1}$ |
| Alpha activity ratio, $^{234}U/^{238}U$ | | | 0.994 |
| Alpha activity ratio, $^{235}U/^{238}U$ | | | 0.046 |

[a] Composition is given as weight % of total U isotopes
[b] Alpha activity per gram of natural uranium

## Confirmation of natural uranium

The mass concentration of $^{238}U$ and $^{235}U$ measured in the urine sample was 0.485 µg $L^{-1}$ and 0.003 µg $L^{-1}$ respectively. The specific activities of $^{238}U$ and $^{235}U$ are 1.24E+04 Bq $g^{-1}$ and 7.99E+04 Bq $g^{-1}$ respectively [EURADOS 2013]. This gives an alpha activity ratio of $^{235}U/^{238}U$ = (0.003 × 7.99E+04)/(0.485×1.24E+04) = 0.04, which is consistent with the isotopic ratio of natural uranium (Table AII.38).

The activity of $^{238}U$ and $^{234}U$ measured in the faecal sample were and 15 mBq and 14 mBq respectively. The uncertainty ($1\sigma$) due to counting statistics (i.e. Type A uncertainty) is about 18% as indicated by Figure 4.1 of the IDEAS Guidelines [EURADOS 2013]. This gives an activity ratio of $^{234}U/^{238}U = 0.93 \pm 0.24$ ($1\sigma$), which is consistent with the isotopic ratio of natural uranium (Table AII.38).

## Processing of data before use

The mass concentration of $^{238}U$ measured in the urine sample was 0.485 µg $L^{-1}$. As the volume of the sample was 1 L, the mass of $^{238}U$ in the sample is 0.485 µg. Normalisation to a 24 hour excretion was carried out based on the reference daily excretion of creatinine; 1.7 g $d^{-1}$ for males [ICRP 2002]. As the sample creatinine content was 1 g, the normalised 24 h excretion is 0.485 µg × 1.7 g $d^{-1}$/ 1.0 g = 0.825 µg $d^{-1}$. Thus, the mass of natural uranium in the normalised 24 h excretion sample is 0.830 µg $d^{-1}$ because 99.2837% of the mass of natural uranium is $^{238}U$, (Table AII.36). The corresponding daily urinary excretion of activity of natural uranium is 0.830 µg $d^{-1}$ × 1.0E-06 g $\mu g^{-1}$ × 2.51E+04 Bq $g^{-1}$ = 0.0208 Bq $d^{-1}$ (Table AII.38).

The activity of $^{238}U$ measured in the faecal sample was 0.015 Bq and mass of the faecal sample was 110 g. Normalising this to the daily reference mass of 150 g $d^{-1}$ for adult male faecal excretion [ICRP 2002] gives a daily excretion of 0.015 mBq × 150 g $d^{-1}$/110 g = 0.0205 Bq $d^{-1}$. Because 49.03% of the alpha activity of natural uranium is $^{238}U$, the activity of natural uranium in the normalised faecal example is 0.0205/0.4903 = 0.042 Bq $d^{-1}$.

Based on the information given in the case description the dietary background for daily urinary excretion of natural uranium can be assumed to be 0.03 µg $d^{-1}$ (7.5E-04 Bq $d^{-1}$) and 0.02 Bq $d^{-1}$ for faecal.

The processed data is summarised in Table AII.39.

**Table AII.39** Isotopic composition of natural uranium [Berglund 2011; EURADOS 2013]

| Sample type | Daily excretion of natural uranium | |
|---|---|---|
| | Normalised measurement at 90 days after start of work | Dietary excretion |
| Urine (Bq $d^{-1}$) | 0.0208 | 0.00075 |
| Faecal (Bq $d^{-1}$) | 0.042 | 0.020 |

## Assessment – Routine monitoring

To assess this case the ISO 27048 procedure for routine monitoring (Table E.1) is followed.

Urine measurement of 0.485 µg $L^{-1}$ of $^{238}U$ at 90 d after start of work. This corresponds to a daily urinary excretion of natural uranium of 0.0208 Bq $d^{-1}$ (see above).

- STEP 1: Appropriateness of measurement.

  Urine monitoring and a monitoring interval of 90 days for moderately soluble forms of uranium is consistent with the recommendations of the ISO standard 20553 [ISO 2006b] – See Table C.4 of chapter C.

- STEP 2: Check if the measured value is significant.

  The measurement value is above the detection limit (0.0015 µg $L^{-1}$) for ICP-MS of U-238. The critical monitoring value ($M_c$) for urine measurements of natural uranium (Type M) corresponding to a potential annual dose of 0.1 mSv for a monitoring period of 90 days is 0.003 Bq $d^{-1}$ [EURADOS 2013; ISO 2011]. As the measurement value is above the $M_c$ value, an evaluation is required.

  The overall uncertainty associated with the urine measurement is assumed to be dominated by Type B errors, which has a default $SF_u$ value of 1.6 for simulated 24 h urine, creatinine normalised values [EURADOS 2013].

  No previous intakes are assumed to occur apart from dietary intakes. The measured urine value, $M$ (0.0208 Bq $d^{-1}$) is significantly greater than the dietary excretion (i.e. M > $(SF_u)^2$ x 0.00075 Bq $d^{-1}$ = 0.002 Bq $d^{-1}$, with $SF_u$=1.6). The measured value, M is also greater than the range of urine measurements of other workers not exposed to uranium (range 0 – 0.006 Bq $d^{-1}$). Thus it can be concluded that a new intake has occurred.

- STEP 3: Standard dose assessment, using default assumptions.

  Pure inhalation and default parameters are assumed: Type M for uranium trioxide with an activity median aerodynamic diameter (AMAD) of 5 µm. The intake is assumed to occur at the mid-point of the monitoring interval and the predicted bioassay quantities, $m(\Delta T/2)$ are calculated with IMBA Professional Plus [Birchall 2007 a], which are consistent with the values given in ICRP Publication 78 [ICRP 1997].

  The urine and the faecal measurements are used to estimate the intake and dose (Table AII.39). The estimated dietary excretion, $B$ is subtracted from the measurement value, $M$. The overall $SF_f$ for the faecal measurement is assumed to be dominated by Type B errors, which has a default value of 3 [EURADOS 2013].

The estimated intake of natural uranium based on the urine measurement is given by:

$$I_u = \frac{M_u - B_u}{m_u(T/2)} = \frac{0.0208 - 0.00075}{2.02E-4} = 99\ Bq \qquad \text{(Eq. AII.21)}$$

The monitoring interval, $T$ is 90 days.

The estimated intake of natural uranium based on the faecal measurement is given by:

$$I_f = \frac{M_f - B_f}{m_f(T/2)} = \frac{0.042 - 0.020}{1.83E-4} = 120\ Bq \qquad \text{(Eq. AII.22)}$$

The monitoring interval, $\Delta T$ is 90 days.

The intake, $I$ is calculated by fitting the predicted values to both the urine and faecal measurements simultaneously using the maximum likelihood method by applying equation E.9 of chapter E:

$$\ln(I) = \frac{\sum_{i=1}^{n_u} \frac{\ln(I_i)}{(\ln(SF_{u,i}))^2} + \sum_{j=1}^{n_f} \frac{\ln(I_j)}{(\ln(SF_{f,j}))^2}}{\sum_{i=1}^{n_u} \frac{1}{(\ln(SF_{u,i}))^2} + \sum_{j=1}^{n_f} \frac{1}{(\ln(SF_{f,j}))^2}} \qquad \text{(Eq. AII.23)}$$

This gives an estimated intake of 102 Bq of natural uranium with $I_u$ = 99 Bq, $SF_u$=1.6, $I_f$= 120 Bq and $SF_f$=3.0. With the dose coefficient of 1.85E-06 Sv Bq$^{-1}$ for natural uranium (Table AII.38), the effective dose is calculated as 0.19 mSv.

**Table AII.40** Isotopic composition of natural uranium [Berglund 2011; EURADOS 2013]

| Isotope | % Alpha activity | Effective dose coefficient $e_{inh}(50)$; Sv Bq$^{-1}$ (a) | Fraction of activity × $e_{inh}(50)$; Sv Bq$^{-1}$ |
|---|---|---|---|
| $^{238}$U | 49.03 | 1.60E-06 | 7.84E-07 |
| $^{235}$U | 2.26 | 1.80E-06 | 4.07E-08 |
| $^{234}$U | 48.72 | 2.10E-06 | 1.02E-06 |
| Effective dose coefficient for inhalation of natural uranium (AMAD = 5 μm; Type M); Sv Bq$^{-1}$ | | | 1.85E-06 |

(a) Dose coefficients taken from ICRP Publication 68 [1994].

- STEP 4: Criterion for accepting the standard dose assessment

There is no need for further evaluation if the following relation is valid,

$E(50).\ n.\ SF^2 <$ 1 mSv (Eq. AII.24)

where

$E(50)$ the committed effective dose corresponding to the measured value calculated in Step 3.

$n$ number of monitoring periods in a year ($n$= 365/$\Delta T$)

$SF$ overall scattering factor associated with the measurement used for intake estimation

1 mSv value of the 5% of the annual dose limit of 20 mSv.

In this step, the *SF* associated with the urine measurement is used as greater weighting was given to the urine measurement in the intake estimation because of its smaller uncertainty. With *SF*=1.6, n=365/90 = 4 and E(50) = 0.19 mSv relation (AII.6.4) is not valid [$E(50)\cdot n\cdot SF^2$ = 1.95 mSv] and therefore further evaluation is required - proceed to step 5.

- STEP 5: Check if exposure is unexpected

  It is expected that, on a few occasions, some intakes of natural uranium via inhalation may occur in a given monitoring period resulting in annual effective doses less than about 1 mSv. Therefore, this is not an unexpected exposure.

- STEP 6: Comparison with dose limits: to check if the annual dose limit may *potentially* be exceeded.

  Figure A.24 and Table A.24 of ISO 27048 show the lower level (LL) and the upper level (UL) giving the predicted range of daily urinary excretion values of natural uranium corresponding to a dose reference level of 20 mSv. The urinary measurement value of 0.02 Bq $d^{-1}$ is greater than the LL (~ 0.005 Bq $d^{-1}$ ) at 90 days after intake indicating that the dose limit could potentially be exceeded - proceed to step 7.

- STEP 7: Application of case-specific information.

  One of the main reasons why the dose limit could potentially be exceeded is that if the material is more insoluble than expected (e.g., Type S rather than Type M).

  Previous in-vitro solubility measurements of the material that the workers are handling (expected to be uranium trioxide) suggests Type M behaviour. However, the ratio of the faecal to urine measurement should confirm whether it is closer to Type M or to Type S. The predicted ratio of faecal to urine measurement values for Type M and Type S materials are given in Table AII.41 for different times after intake. As the measured ratio (after background subtraction for dietary intakes) is (0.042-0.020)/(0.0208-0.00075) = 1.1, this indicates Type M behaviour rather than Type S. Furthermore, the fit to the urine and faecal data assuming the intake occurred at the mid-point gives good fits if Type M is assumed ($\chi_o^2$ =0.03 with 1 degree of freedom and the p-value = 0.9). However, if Type S is assumed then the fit is rejected ($\chi_o^2$ =9 with 1 degree of freedom and the p-value = 0.002) indicating that the material is not Type S.

  **Table AII.41** Predicted ratio of faecal to urine measurement values for Type M and Type S materials

| Time after intake, d | Predicted faecal to urine ratio | |
|---|---|---|
| | Type M | Type S |
| 1 | 4.6 | 162 |
| 45 | 0.9 | 42 |
| 90 | 0.5 | 25 |

As no additional graphs have been generated assuming Type M behaviour only, the alternative approach has been used to decide if the dose limit could potential be exceeded by calculating the lower level of derived investigation level, $DIL_{min}$ for urine excretion. This is carried out

by using equation E.5 of chapter E but with e(50) and m(T) for Type M. Equation E.5 is rewritten here:

$$DIL_{\min} = \frac{0.02}{e(50)} \cdot 0.3 \cdot m(\Delta T) \cdot \frac{\Delta T}{365} \cdot \frac{1}{SF^2} \qquad \text{(Eq. AII.25)}$$

With e(50)= 1.85E-06 Sv $Bq^{-1}$, T=90 d, m(T) = 1.25E-04 (Bq $d^{-1}$ per Bq intake) and SF=1.6 the lower level of the derived investigation level, $DIL_{min}$ is 0.039 Bq $d^{-1}$. Because the measurement value (0.020 Bq $d^{-1}$) is less than $DIL_{min}$ it can be concluded that the annual dose limit has not been exceeded. The measurement result, the assessed effective dose (0.19 mSv) and the assumptions are documented.

## Chemical toxicity

The ISO standard 16638-1 [ISO 2015d] gives derived investigation levels (DILs) in urine to assess the chemical risk for uranium compounds (Table AII.42). The DILs are based on a maximum kidney concentration of 3 µg $g^{-1}$ or an effective dose of 6 mSv for natural uranium [Stradling 2002]. The effective dose and the maximum kidney concentration were calculated assuming an acute intake occurred at the beginning of a single monitoring interval. The DIL for Type F is determined by chemical toxicity whereas for Type M or S it is determined by radiotoxicity (Table AII.42).

**Table AII.42**. Derived investigation levels[(a)] in urine for natural uranium compounds based on a maximum kidney concentration of 3 µg $g^{-1}$ or an effective dose of 6 mSv [Stradling 2002; ISO 2015d].

| Absorption Type | Monitoring interval (d) | Derived investigation level for urine (µg $d^{-1}$) | Maximum effective dose (mSv) | Maximum kidney concentration (µg $g^{-1}$) |
|---|---|---|---|---|
| F | 30 | 20 | 1.4 | 3.0 |
| M | 90 | 16 | 6.0 | 1.7 |
| S | 90 | 0.17 | 6.0 | 0.016 |

(a) Calculated assuming an acute intake occurred at the beginning of a single monitoring interval.

The normalised 24 h urinary excretion sample is 0.83 µg $d^{-1}$, which is significantly less than the DIL of 16 µg $d^{-1}$ for Type M, natural uranium (Table AII.42). Therefore, the chemical toxicity is not an issue in this example.

It is noteworthy that, following a review of the literature, Leggett et al. [Leggett 2012] adopted a concentration of 1.0 µg U $g^{-1}$ kidney as the reference primary guidance level for the prevention of chemical toxicity. They stated that this level of concentration of uranium in the kidneys should not be exceeded at any time. This was in agreement with the U.S. National Research Council committee that concluded that transient adverse renal effects of uranium including proteinuria and glucosuria may occur at peak kidney concentrations as low as 1.0 µg U $g^{-1}$ kidney [NRC 2008].

# ANNEX III - Monitoring and Internal Dosimetry for First Responders in a Major Accident at a Nuclear Facility

In the event of a major accident at a nuclear facility involving releases of radioactive material into the environment, there is a need to quickly identify and quantify potential internal doses received by the people who could have been contaminated as a result of inhalation of radioactive materials. This includes workers present on the nuclear site during the release of radioactive material, "emergency workers" directly implicated in emergency actions to mitigate the consequences of the accident and, if the atmospheric releases exceeded the limit of the nuclear site, members of the public.

This Annex focuses on measurements and internal dose evaluation for a subgroup of emergency workers, namely the first responders, who may be at significant risk of contamination due to their actions during the first hours following radioactive release.

## Definition of First Responders

IAEA Basic Safety Standards (BSS) [IAEA 2014] define an emergency worker as:

> *a worker who may be exposed in excess of occupational dose limits while performing actions to mitigate the consequences of an emergency for human health and safety, quality of life, property and the environment.*

Emergency workers may include workers employed by registrants and undertakings, as well as personnel of response organisations, such as police officers, fire fighters, medical personnel, and drivers and crews of evacuation vehicles. An emergency worker may or may not be designated as such in advance of an emergency.

In the 2013 Directive [EC 2014] the definition of "emergency worker" is even larger as it includes:

> *any person having a defined role in an emergency and who might be exposed to radiation while taking action in response to the emergency.*

This means that, after a major accident at a nuclear facility, the number of persons considered as "emergency workers" could possibly be very large as it may include non-radiation workers or volunteers as well as radiation workers employed at the nuclear facility.

Among emergency workers, the first members of an emergency service to respond at the scene of an emergency are called "first responders" [IAEA 2014]. These workers would respond during the first few hours to a radiological emergency [IAEA 2006].

## Reference Levels for Emergency Occupational Exposures

The IAEA BSS consider that in an emergency exposure situation, the relevant requirements for occupational exposure in planned exposure situations must be applied for emergency workers, following a graded approach. Response organisations and employers must ensure that no emergency worker is subject to an exposure, in an emergency, in excess of 50 mSv other than:

- For the purposes of saving life or preventing serious injury;
- When undertaking actions to prevent severe deterministic effects and actions to prevent the development of catastrophic conditions that could significantly affect people and the environment; or
- When undertaking actions to avert a large collective dose.

The 2013 Directive [EC 2014] defines "emergency occupational exposure" as the exposure received in an emergency exposure situation by an emergency worker. According to the 2013 Directive, this exposure must remain, whenever possible, below the limit on the effective dose for occupational exposure (20 mSv in a single year). For

situations where the above condition is not feasible, the following conditions must apply:

- Reference levels for emergency occupational exposure must be set, in general, below an effective dose of 100 mSv;
- In exceptional situations, in order to save life, prevent severe radiation-induced health effects, or prevent the development of catastrophic conditions, a reference level for an effective dose from external radiation of emergency workers may be set above 100 mSv, but not exceeding 500 mSv.

## Internal Contamination Monitoring for First Responders

The 2013 Directive [EC 2014] states that:

> *In the event of an emergency occupational exposure, Member States shall require radiological monitoring of emergency workers. Individual monitoring or assessment of the individual doses shall be carried out as appropriate to the circumstances.*

The IAEA BSS requires that governments must establish a programme for managing, controlling and recording the doses received in an emergency by emergency workers (requirement 45). This programme must be implemented by response organisations and employers.

The requirements for occupational exposure in planned exposure situations state that employers:

> *shall ensure that workers who could be subject to exposure due to contamination are identified*

and

> *shall arrange for appropriate monitoring to the extent necessary to demonstrate the effectiveness of the measures for protection and safety and to assess intakes of radionuclides and the committed effective doses.*

In the chapter concerning emergency preparedness, the IAEA BSS requires that:

> *If the safety assessment indicates that there is a reasonable likelihood of an emergency affecting either workers or members of the public, the registrant or licensee shall prepare an emergency plan for the protection of people and the environment* (and that this plan shall include) *provision for individual monitoring.*

In accordance with these requirements, all emergency services personnel who could have been contaminated must be monitored, and decontaminated if necessary, at the end of their period of duty [Rojas-Palma 2009]. In case of doubt of significant internal contamination, a treatment (such as with stable iodine, DTPA or Prussian Blue) may also be given, taking into account individual medical information and conditions. In this case, the treatment should be given as soon as possible.

Depending on the capacity for individual measurements and on the number of people to be measured, prioritisation may be needed to determine which persons are to be measured first and which persons are to be measured later [NEA 2014]. Indeed, in a major accident at a nuclear facility, the number of persons to be measured may be very large, and may include members of the public and emergency or non-emergency workers. Processes should be in place for the organisation and the prioritisation of the individual measurements as specified by international reports [NEA 2014] and national documentation, depending, of course, on the capacity of individual measurement devices.

### Individual Internal Contamination Measurements

According to the IAEA BSS requirements, first responders exposed to a contaminated environment during a major accident at a nuclear site should be monitored for internal

contamination in order to assess their exposure. As for radiation workers in a planned exposure situation, this assessment should be performed [IAEA 2014]:

> *on the basis of individual monitoring* (by means of arrangements with) *authorised or approved dosimetry service providers that operate under a quality management system.*

This monitoring may be performed either by *in vivo* or by *in vitro* measurements, depending on the radionuclides involved and the available measurement techniques. *In vivo* monitoring is considered to be more appropriate in the event of an accident [NEA 2014] since the result of the measurement would be rapidly available to the personnel in charge of the workers and to the authorities. This is particularly true if the radionuclide releases include significant activities of radioiodine and/or other short-lived radionuclides which can only be measured (by whole body or thyroid counters or in particular cases by *in vitro* measurements) during the first days after a potential intake. Prompt monitoring is important because many radionuclides which may be present in the releases after a nuclear accident are short-lived ($^{132}$Te, $^{132}$I, $^{133}$I, $^{136}$Cs). In the event that early monitoring is not available for dose assessment, the isotopic composition of the contaminant should be modeled from the known releases or obtained by means of environmental measurements. These alternatives increase the uncertainty on the dose compared with a dose estimated from early individual monitoring data.

In the following cases, *in vitro* measurement should be performed:

- If the releases consist of pure alpha- or beta-emitters with photon emissions of very low energy or intensity;
- If the accident scenario involves uranium or actinide releases not measurable by *in vivo* monitoring, due to, for example, the available *in vivo* measurement system having a detection limit well above the internal contamination levels expected from the released activities;
- To confirm internal contamination in case of persistent external contamination;
- To more precisely assess the internal dose where it is significant [EURADOS 2013].

## *In vivo* Measurements

Individual measurement devices used to identify and quantify the potential internal contamination of the first responders may include:

- Stationary dedicated *in vivo* measurement devices such as whole body, thyroid or lung monitors present on the nuclear site or in a nearby off-site building specially-installed in case of an accident on the site, or on another regional/national nuclear site or in a radiation protection organisation;
- Mobile dedicated *in vivo* measurement devices.

Stationary equipment may be used preferentially when the number of emergency workers is limited as long as the equipment is not affected by the environmental contamination. If software is used to produce estimates of body content based on a built-in library of calibration spectra, the validity of the calibration should be assessed in relation to the particular conditions of measurement [Rojas-Palma 2009]. Monitoring procedures may not be significantly different to those for radiation workers after an abnormal exposure event, that is, a special monitoring programme could be implemented, depending on the radionuclides involved.

The deployment of mobile *in vivo* measurement units, if available, should be considered. This will be particularly important if a large number of first responders are to be monitored, if the on-site equipment is not available and/or travelling to an equipped *in vivo* measurement laboratory is not possible. For example the environmental contamination and/or the background radiation may be too high on-site, the first responders may be needed on the site and travelling to an equipped *in vivo* measurement laboratory located far away may be impractical. Different types of

mobile whole body counters have been developed and can be used to monitor first responders [Dantas 2010; Franck 2014; Youngman 2002; 2008]. These units may also be deployed to detect and quantify internal contamination among members of the public who may have been exposed to the radioactive releases.

As an alternative to dedicated whole body or thyroid counters, rapid monitoring may be performed with portal monitors, dose rate monitors, or hand-held probes [Rojas-Palma 2009]. Another instrument that could be used for rapid monitoring in emergency is the gamma camera, which is available in nuclear medicine departments. This equipment should be efficiency-calibrated in advance, taking into account the radionuclides that could be released, in particular radioiodine.

The advantages and disadvantages of the different monitoring techniques are listed in Table AIII.1

**Table AIII.1** Advantages/disadvantage of the monitoring techniques

| Monitoring techniques | Advantages | Disadvantages |
|---|---|---|
| Fixed whole body monitor | Low detection limit<br>Already used routinely | May be far from the nuclear site |
| Mobile whole body monitor | Mobile, on-site measurement | Requires event-specific setting up and dedicated staff |
| Hand-held monitor | Monitoring of a large number of persons | High detection limits |
| Urine bioassay | Low detection limits<br>Able to confirm an intake (less prone to external contamination) | Management of excreta samples<br>Delayed result if chemistry is required (alpha emitters) |
| Faecal bioassay | Low detection limits<br>Appropriate for radionuclides excreted via faeces (e.g. for intakes of insoluble compounds) | Management of excreta samples<br>Delayed result if chemistry is required (alpha emitters) |

In any case, prior to internal contamination measurement, external contamination must be monitored and, if needed, decontamination should be performed. External contamination can be detected using portal monitors or hand-held survey meter probes. In general, the sequence is: external contamination monitoring; decontamination (if needed); and initial internal contamination monitoring.

The objectives of external contamination monitoring are:

- To identify the need for external decontamination in order to avoid radiation skin lesions and to prevent further internal contamination via ingestion and/or direct skin transfer of the radionuclide;
- To allocate high priority for internal contamination measurement to workers presenting external contamination; particularly if the contamination is detected around the nose as this is an indicator of a risk of inhalation;
- To allow discrimination between external and internal contamination during *in vivo* measurement and so reduce errors in assessment of the internal contamination.

## Assessment of the Emergency Worker Doses

The IAEA BSS requires that:

> *response organizations and employers shall take all reasonable steps to assess and record the doses received in an emergency by emergency workers. Information on the doses received and information concerning the associated health risks shall be communicated to the workers involved.*

Arrangements to assess any radiation dose for emergency workers is also emphasised in ICRP Publication 109 [ICRP 2009a], as is the need for appropriate training and provision of personal protective equipment. Moreover, as stated above, the 2013 Directive [EC 2014] requires that in the event of an emergency occupational exposure:

> *Individual monitoring or assessment of the individual doses shall be carried out as appropriate to the circumstances.*

### Initial Dose Assessment

Depending on the number of emergency workers to be monitored, the complexity of the dose assessment and the availability of monitoring equipment for repeated measurements, initial dose assessment may be performed in order to:

- Evaluate the need for medical assessment (for example, administration of Prussian Blue to enhance caesium elimination or administration of DTPA to enhance elimination of actinides);
- Communicate on health risks with the worker in the event of a positive result;
- Inform decisions on the need for additional and/or more accurate monitoring and more accurate dose assessments.

Initial dose assessment should be based on:

- The characteristics of the atmospheric releases, pre-established for different scenarios of accident, depending on the nuclear site;
- Conservative hypotheses for the date(s) and periods of contamination, for example by assuming an acute intake at the time of the beginning of the radioactive release.

Simple tools for dose assessment that have been developed to simplify the decision making process, to allow the public to be reassured, and possibly to provide information to allow initial decisions on treatment to be made [Ménétrier 2007], may be used initially.

### Internal Dose Assessment

More accurate dose assessment should be based on the results of individual measurements, available data on the characteristics of the contaminant and the exposure conditions specific to the worker. Working times and location should be recorded, if possible, to enable dose reconstruction based on occupancy times of the worker and the activities performed. The dose assessment is dependent on the accuracy of the date and/or time period of possible contamination and this issue is a major source of uncertainty in the dose evaluation process.

The ISO 27048:2011 approach for internal dose assessment, as described in **Chapter E**, may be used to assess doses [ISO 2011]. If the reference level for emergency occupational exposure is potentially exceeded, it is recommended to use the IDEAS Guidelines [EURADOS 2013].

Concerning the characteristics of the contaminant, when no other information is available, an AMAD of 5 µm should be considered for the emergency workers contaminated on the site and an AMAD of 1 µm should be considere for those contaminated outside the nuclear facility.

## Emergency Worker Dose Records

The IAEA BSS require that:

> *the government shall establish a programme for managing, controlling and **recording the doses** received in an emergency by emergency workers, which shall be implemented by response organisations and employers.*

Records must include:

*any assessments made of doses, exposures and intakes due to actions taken in an emergency or due to accidents or other incidents, which shall be distinguished from assessments of doses, exposures and intakes due to normal conditions of work and which shall include references to reports of any relevant investigations.*

The result of the individual measurement and, in the event of internal contamination, the dose assessed, should be communicated to each person and recorded in their dose record file, medical file or equivalent, consistent with the requirements of the country.

The requirements specified in the 2013 Directive [EC 2014] on recording, reporting and access to the results of individual monitoring explicitly refer to and therefore apply to emergency occupational exposure.

For workers who are not routinely exposed to radiation as a result of their normal employment, specific databases could be developed at the national level as one aspect of preparedness for a radiological/nuclear accident.

# ANNEX IV – Internal Dosimetry for Assessment of Risk to Health

Earlier chapter and annexes of this report present internal dose assessment in the context of occupational radiation protection. In this case, the purpose of a dose evaluation is essentially to verify that workers have not received a significant fraction of the relevant dose limit either routinely, or in the event of an incident. Dose evaluation for assessment of health risks requires different considerations of issues. The objective of this Annex is to present the specific aspects of internal dose assessment performed for the evaluation of health risk rather than assessments performed for radiation protection purposes.

## Health risk resulting from internal contamination

Whatever the mode of exposure to ionising radiation, by external irradiation or by internal contamination, health effects depend, among other factors, on the dose received.

Two types of effect may be distinguished, for which it is either the severity or the probability of occurrence that varies with the radiation dose:

- "deterministic" effects, resulting from tissue reactions, and characterised by a threshold dose above which lesions appear, such as depletion of hematopoietic lineages, sterility, skin effects, etc., and for which the severity increases with the dose;
- "stochastic" effects, primarily cancer and genetic effects but also non-cancer effects such as cataracts or cardio-vascular diseases, for which the probability of occurrence increases with the dose, but for which severity is independent of the dose.

In general, internal contamination results only in a risk of stochastic effects, mainly cancer. However, in rare cases of severe contamination, it may also lead to a risk of deterministic effects. Moreover, recent studies have suggested potential (non-carcinogenic and non-deterministic) health effects from low dose internal chronic exposure (e.g. $^{137}$Cs, $^{90}$Sr).

### Carcinogenic Effects due to Internal Contamination

A report published in 2012 by the International Agency for Research on Cancer (IARC) evaluates the carcinogenic nature of radiation [IARC 2012]. It reviews data on exposure conditions (medical, environmental, animal experiments, etc.) and on the health effects revealed in the studies available at the time of writing. The report concludes that incorporated radionuclides that emit alpha-particles or beta-particles are carcinogenic to humans (group 1).

### Deterministic Effects due to Internal Contamination

Another IARC report includes a literature review on deterministic effects revealed after external and internal contamination in man and animals [IARC 2001]. Effects were observed in various organs and tissues including bone, teeth, eye, skin, liver, bone marrow, gonads, lungs and thyroid.

## Purpose of Internal Dosimetry for the Assessment of Risk to Health versus Radiation Protection Purposes

Experts in internal dosimetry may be asked to provide dose assessments for the purpose of assessment of health risks in three main different circumstances:

- when a worker has been internally contaminated at a level which may result in adverse effects on health;
- In the event of a claim for compensation when a worker develops a disease which may have been caused by occupational exposure to radiation;

- for quantitative estimation of the exposure in epidemiology studies.

### Internal Dosimetry following an Accidental Intake

Dose assessment is the first step in the evaluation of health risks once a significant accidental intake has occurred. In this case, the main purposes of the dose and health risk assessment are:

- to provide data to support judgements on the need for a therapeutic action. Even if, in some situations, treatment should be given before any dose assessment is performed (for example, stable iodine tablets if a significant contamination by radioiodine is suspected, or DTPA in the event of a wound contaminated by plutonium and/or americium), rapid initial dose assessment is needed in order to justify the continuation of treatment and to adapt it;
- to decide and implement the most suitable post-exposure medical monitoring;
- to communicate on the risk with the worker.

In practice, special monitoring programmes will be set up if an accidental intake is suspected, in order to quantify the exposure. Recommendations on dose assessment after special monitoring are presented in **Chapter E, Section E3**, and in **Section E4** for wound cases. In the event of decorporation therapy, dose assessment is described in **Section E5**.

### Internal Dosimetry for Compensation Cases

Another circumstance where dose assessment may be required is when a worker has developed a disease (such as cancer) which could be considered to result from occupational exposure to ionising radiation. The compensation regimes for occupational diseases are specific to each country. Compensation is straightforward in cases where the cancer is included in lists of occupational diseases and exposure meets the criteria prescribed in the relevant country. Where no such list-based approaches are followed, the occupational origin of a given cancer should be established on an individual basis. In this case, dose assessment is required in order to calculate a probability of causation (PC), which is then used to determine the relationship between an observed level of exposure and the development of the disease.

### Internal Dosimetry for Epidemiological Studies

Dose assessment will also be required for epidemiological studies that evaluate the effect of internal contamination on health. These studies may be concerned with professional exposure (mainly due to alpha emitting radionuclides), medical exposure (by example after nuclear medicine treatment), exposure to radon at home, or accidental/post-accidental exposure to a contaminated environment (for instance, in the areas around Chernobyl or Fukushima). Reliable internal dose assessment is mandatory to correctly estimate a dose-response relationship in these studies.

## Evaluation of the Risk of Stochastic Effects after an Accidental Exposure

### Use of Effective Dose for the initial Estimation of Risk to Health

ICRP has defined the radiation protection quantities equivalent dose to organs and effective dose. The concept of effective dose was developed in order to manage all exposures of an individual, regardless of the type of radiation and irradiated body region (exposure of all or part of the body to various types of external radiations and to incorporated radionuclides). Based on biological and epidemiological data, ICRP established conversion coefficients relating effective dose to a nominal health detriment, and defined dose limits such that when the effective dose remains below the relevant limit, it ensures that the risk of stochastic health effects is maintained at an acceptable level and that tissular reactions are avoided.

The health detriment per unit effective dose calculated by ICRP for radiation protection purposes corresponds to a nominal value for the exposure of a reference individual, calculated as a weighted average of different effects over a population under a range of possible modes of exposure. As such it does not provide an accurate assessment of the risk for a specific individual under a specific exposure. However, even though effective dose was developed for radiation protection purposes, ICRP Publication 103 [ICRP 2007] states that:

> *In retrospective assessments of doses to specified individuals that may substantially exceed dose limits, effective dose can provide a first approximate measure of the overall detriment.*

In other words, although the effective dose is not sufficient to evaluate health risk precisely, in particular the risk of cancer occurrence, it can be used to provide an initial estimate of the order of magnitude of this risk.

ICRP Publication 60 estimates the lifetime risk of cancer mortality to be 4% per sievert for adult workers subjected to low or moderate radiation exposure and/or a low dose rate (in the case of chronic exposure) [ICRP 1994b]. UNSCEAR's 2006 report estimates the whole-life risk of death by solid cancer to be 4.3-7.2% per sievert and that of death by leukaemia to be 0.6-1% per sievert [UNSCEAR 2008]. The BEIR VII report estimates the excess number of deaths by solid cancer after exposure to 0.1 Gy to be 4.1 in 1,000 for men and 6.3 in 1,000 for women, and the excess number of death by leukaemia to be 0.7 in 1,000 for men and 0.5 in 1,000 for women [NRC 2006].

On the basis of these data, as a first approximation, an excess of deaths by cancer of 5% per sievert after accidental exposure may be used to evaluate the global carcinogenic risk when the dose substantially exceed dose limits. However caution should be exercised when deciding to communicate the result of the initial assessment to the worker as a more accurate assessment may be substantially different.

## Use of Absorbed Doses and/or Equivalent Doses for the final Estimation of Stochastic Risk to Health

A more precise estimation of individual radiation-induced cancer risk must be based on committed doses in tissue and/or organs, as stated by ICRP Publication 103:

> *If radiation dose and risk need to be assessed in a more accurate way, further specific estimates of organ or tissue doses are necessary, especially if organ-specific risks for the specified individuals are needed.*

To assess the stochastic risk in different organs more finely, the absorbed doses and/or the equivalent doses received by organs and tissue must then be evaluated. This must be done specifically for the worker concerned by adapting the biokinetic and dosimetric hypotheses, as suggested by ICRP Publication 103:

> *For the assessment and judgment of individual cases absorbed doses to organs or tissues should be used together with the most appropriate biokinetic parameters, data on biological effectiveness of the ionising radiation and risk coefficients.*

The individual stochastic risk will be assessed by experts, applying risk coefficients (for estimation of risk per unit dose) based on experimental and human experience. These risk coefficients should, if possible, be adapted to the gender and age of the individual. Ideally, and if available, risk coefficients from epidemiological study reports based on the same type of contamination (and due to the same radionuclide) and on a similar population should be used, for example in the event of contamination by radioiodine. If not available, risk coefficients based on studies with the most similar exposure conditions (for instance, radionuclides with comparable biokinetic behaviour and type of emitted radiation) should be used. In many cases, however, risk coefficients from studies of external exposure will have to be used.

Risk coefficients are derived from epidemiological studies or the reports of various institutions, notably the United Nations Scientific Committee on the Effects of Atomic

Radiation [UNSCEAR 2006], the Committee on the Biological Effects of Ionizing Radiation [NRC 2006] at the National Academy of Sciences, and the International Commission on Radiological Protection (ICRP), which have all made estimates of the cancer risk associated with radiation exposure. The estimates made by these bodies are mainly derived from studies of the survivors of the nuclear bombs dropped on Hiroshima and Nagasaki, and on groups of people who have received irradiation doses for therapeutic or diagnostic purposes, or who were exposed in their work (e.g. uranium miners, clock face painters using radium).

The choice of the internal dose to an organ to be assessed (absorbed dose or equivalent dose) depends on the dose quantity used in the "risk per unit dose" coefficient used to estimate the risk to health. The risk coefficients derived from epidemiological studies are appropriate for a specific mode of exposure and a specific effect. They are generally expressed relative to the absorbed dose in a given organ. The dose coefficients provided by organisations such as UNSCEAR, BEIR and ICRP may be expressed relative to absorbed doses or relative to equivalent or effective doses.

While for radiation protection purposes, estimation of the uncertainties is not mandatory during the assessment of the absorbed and/or equivalent doses, ICRP Publication 103 states that for the assessment of risk to health:

> *uncertainties [for the assessment and judgment of individual cases absorbed doses to organs or tissues] should be taken into consideration.*

Moreover, depending on the case, other factors may need to be considered, in particular health and medical history and co-exposures (other exposures to environmental and professional carcinogenic agents).

## Evaluation of the Risk of Deterministic Effects after an Accidental Exposure

### Doses for the Estimation of Deterministic Risk to Health

ICRP Publication 103 states that the effective dose is not suitable for evaluating tissue reactions, in other words for the evaluation of deterministic effects.

In cases of exposure to a high dose that might lead to deterministic effects (in addition to stochastic effects), the risk assessment of these deterministic effects is based on the absorbed doses, each weighted by the appropriate Relative Biological Effectiveness (RBE) as defined by ICRP Publication 103:

> *For such purposes, doses should be evaluated in terms of absorbed dose (in gray, Gy), and where high-LET radiations (e.g., neutrons or alpha particles) are involved, an absorbed dose, weighted with an appropriate RBE, should be used.*

Experts must evaluate the risk of deterministic effects on the basis of the absorbed dose in the organ/tissue, taking into account the spread over time of the doses received after internal contamination considering that:

> *In general, fractionated doses or protracted doses at low dose rate are less damaging than are acute doses.*

As is the case for stochastic effects, absorbed doses must be estimated specifically for the worker concerned by adapting the biokinetic and dosimetric hypotheses, and it may be opportune to take into consideration the uncertainties during dose assessment.

The individual evaluation of the risk of deterministic effects should be based on published studies of exposure to the radionuclides responsible for the contamination. References are available in the report produced by UNSCEAR [UNSCEAR 2006] and, more specifically for internal exposure, in the report of the International Agency for Research on Cancer published in 2001 [IARC 2001].

### RBE-weighted Absorbed Organ Dose for Deterministic Effects

During a radiological emergency, the RBE-weighted absorbed doses for severe deterministic effects may be calculated using values given in an IAEA EPR-Medical publication [IAEA 2005] which assumes, for example, a RBE of 0.2 for $^{131}I$ irradiating internally the thyroid gland and a RBE of 2 for alpha particles irradiating internally the red bone marrow. However, significant uncertainties may be associated with these values.

Organs for which absorbed doses can be calculated include lungs, red bone marrow colon and thyroid for radioactive isotopes of tellurium, iodine, technetium, and rhenium [IAEA 2005].

The RBE-weighted absorbed dose is obtained by multiplying the absorbed dose by the RBE factor. The SI unit used to express the RBE-weighted absorbed dose is J $kg^{-1}$ and is given the name gray-equivalent (Gy-Eq).

RBE-weighted absorbed dose, calculated using a 30-day integration period for absorbed dose, may be compared to the generic reference levels for medical actions given in IAEA EPR-Medical [IAEA 2005].

## Probability of Causation for Compensation Cases

Dose assessment is the first step to provide input to a determination of the probability of causation (PC) when a worker has developed a disease which may have arisen from exposure to radiation at work.

Increased cancer risks associated with radiation exposure have been ascertained on the basis of epidemiological observations in exposed groups. However, in no case can it be proved that a particular cancer was due to an earlier exposure, as a radiation induced cancer is indistinguishable from one induced by other agents. The concept of the probability of causation *(PC)* has been developed to answer the question: if a person has been exposed to ionising radiation and subsequently contracts cancer, what is the probability that the cancer was due to the earlier exposure? [IAEA 1996b]

The PC value depends on the dose received by the worker, and is defined as the fraction of the risk at the age of occurrence for the given cancer that is attributable to the exposure, i.e.:

$$PC = \frac{\Delta r(D,t,e,s)}{r_0(a,s) + \Delta r(D,t,e,s)}$$

where $r_0(a, s)$ is the cancer rate for age $a$ and sex $s$ for the particular cancer type under consideration and $\Delta r\ (D, t, e, s)$ is the excess cancer rate due to exposure to a dose of radiation $D$ at age $e$ and time since exposure $t$ (= $a$ - $e$). The rate for a given cancer is the probability per unit time for a person of sex $s$ and age $a$ to develop the cancer.

So the excess cancer rate due to exposure for a given worker and a given disease is a function of the dose $D$ received by the worker. As the other parameters for the calculation of the excess cancer rate include the age at exposure and the time since exposure, the distribution of total dose received over time also needs to be taken into account.

Examples of PC calculations are given in a document published by IAEA, ILO and WHO [ILO 2010]. The value of the calculated probability of causation may be compared to a predetermined threshold below which workers are not compensated and/or may be used to determine the compensation amount.

The US Department of Energy Employees Occupational Illness Compensation Program [ILO 2010] states that:

> *to provide appropriate input to the probability of causation calculation, the annual internal and external dose to the organ or tissue that developed cancer is reconstructed from the date of the covered employee's first employment to*

*the date of diagnosis. For internal exposures, doses delivered in each tissue in each year of exposure are calculated. The dose reconstruction methods are also designed to incorporate the full range of scientific uncertainty.*

In the UK Compensation Scheme for Radiation Linked Diseases, the employer is required to provide information on the year by year internal and external dose. Calculation of the equivalent dose in each calendar year to the organ of interest due to internally deposited radionuclides is estimated from bioassay measurements. When the dose to the organ of interest cannot be calculated (for example if the organ is not included in a software package, e.g. prostate) a surrogate organ is chosen. The surrogate organ/tissue must be likely to have a similar amount of uptake to the organ of interest and to experience a similar magnitude and temporal pattern of dose delivery from target organs.

## Epidemiological Studies of Radiation Workers

Epidemiological studies on the health effects of radiation make use of cohorts derived from different populations:

- Patients treated by radiotherapy, brachytherapy or radionuclide therapy, or exposed to diagnostic X-rays;
- Workers (in nuclear power plants, in uranium nuclear fuel cycle plants, in research, in medical or industrial installations, etc.);
- The general public (Japanese atomic bomb survivors, populations living in an environment with a high level of radiation due to natural background or accidental release of radionuclides).

Among these studies, those based on workers are particularly interesting, since they may provide direct estimates of risk to health after protracted low doses of radiation. An accurate and precise assessment of the doses received by the workers is mandatory to correctly estimate dose-response relationship. Occupational exposure is mainly due to external exposures but for some workers (for example those involved in the uranium nuclear cycle), radionuclide intake results in an important component of the dose received. In these cases, an internal dosimetry protocol needs to be defined [Thierry-Chef 2008], based on:

- data available for the dose assessment (individual *in vivo* and/or *in vitro* measurements, environmental activities, etc.);
- reconstruction of the exposure conditions of the workers (period of work, information on the incident, physico-chemical and isotopic characterisation of the potential contaminant, etc.);
- health effects studied (including cancers and leukaemia but also non-cancer effects such as cardiovascular or cerebrovascular diseases).

The use of effective dose is not appropriate for the assessment of exposure in epidemiological studies. In this case, annual absorbed doses to the organs/tissues of interest are calculated for each individual worker. Uncertainties associated with the annual internal doses assessed are also provided. The doses are calculated from the date of first exposure to the date of the cancer diagnosis, if available, or alternatively to the date of death or date last known to be alive [Bouville 2015]. Estimation of absorbed doses allows the study of:

- effects of exposure to different types of radiation; in this case, annual absorbed doses arising from low linear-energy transfer (LET) radiation should be calculated separately from absorbed doses arising from high-LET radiation (e.g. from exposure to uranium or plutonium);
- non-cancerous effects, providing the possibility of deriving specific values for Relative Biological Effectiveness (RBE).

The doses arising from different radionuclides may be calculated separately and as a total, and the external gamma dose may be included in the calculation of the total

absorbed dose to specific organs for individual workers. Organs/tissues of interest are selected on the basis of the epidemiological endpoint. They may include lung (alveolar-interstitial, bronchial, and bronchiolar regions), upper airways (mouth and nose), red bone marrow, liver, kidney, stomach, small intestine, colon, endosteum (bone surfaces), heart, lymph nodes, brain, skin and/or gonads.

# Annex V – Compilation of Recommendations

G = Grade: M = Mandatory, I = International, A = Advisory (see Table A.2)

## CHAPTER A – Section A2 - Implementation by Internal Dosimetry Services: Duties, Partners and Approval

| R# | G | Text of the recommendation |
|---|---|---|
| | | ***Q1**: What are the roles and duties of an Internal Dosimetry Service and which competencies are required?* |
| A01 | M | Competent authorities in the Member States must implement a system for approval/recognition of internal dosimetry services that perform monitoring for internal contamination by measurements of activity directly in the body and/or in excreta sample (urine/faeces), and the subsequent dose assessments [EC 2014]. |
| A02 | A | Internal dosimetry services may also be approved to perform monitoring by measurement of activity-in-air samples, and to perform the subsequent dose assessments. |
| A03 | A | Competent authorities in the Member States should aim to harmonise these systems for approval of dosimetry services to enable mutual recognition of the services throughout Europe. |
| | | ***Q2**: Who are the main partners of internal dosimetry services?* |
| A04 | A | Internal dosimetry services should establish communication with the radiation protection units of the customer (i.e. the undertaking, and in the case of outside workers also the employer), the Occupational Health Services, the data system for individual radiological monitoring (e.g. a National Dose Register) and other internal dosimetry services. |
| | | ***Q3**: What types of criteria should be set for approval of an internal dosimetry service?* |
| A05 | I | The criteria defined by the competent authority for approval of internal dosimetry services should address:<br>• Definitions or references to established methods for bioassay measurements that should be applied by internal dosimetry services.<br>• Minimum performance criteria for the measurement procedures and ways to monitor compliance with the criteria.<br>• Specification by the IDS of reference procedures for evaluating (routine) monitoring data and the subsequent dose assessment.<br>Minimum requirements on the reporting and documentation of measurements and dose assessments should be specified by the competent authority.<br>Several ISO standards on these topics are available [ISO 2006; 2010b; 2011; 2015c; ISO/IEC 2005] |

## CHAPTER C – Monitoring Programmes

| R# | G | Text of the recommendation |
|---|---|---|
| | | ***Q1**: What is the overall purpose of an individual monitoring programme in the context of occupational intakes of radionuclides, and how does it relate to general radiation protection programmes?* |
| C01 | I | An individual monitoring programme for workers occupationally exposed to a risk of internal contamination should be designed to verify and document that the worker is adequately protected against the risk and that the protection complies with legal requirements [ISO 2006]. It is an essential component of the general radiation protection programme of the undertaking. |
| | | ***Q2**: What types of information are required in order to make decisions on the* |

| R# | G | Text of the recommendation |
|---|---|---|
| | | *need for, and design of, an individual monitoring programme?* |
| C02 | I | The types of information required include [ISO 2006]:<br>• the radionuclide(s) to which workers may be exposed and the radiations emitted by their decay;<br>• the decay rate(s) of the radionuclide(s);<br>• the retention of the radionuclide(s) in the body or excretion from the body as a function of time after an acute intake. |
| C03 | A | Information of the following types should also be collected:<br>• working practices and sources of exposure;<br>• likely route(s) of intake;<br>• potential time patterns of intake;<br>• physical form of the materials involved;<br>• chemical form of these materials. |
| | | ***Q3**: How should workers be identified for whom individual monitoring may be required?* |
| C04 | M | Systematic monitoring is mandatory for workers liable to receive effective doses greater than 6 mSv per year (category A). For other workers (category B), monitoring should be sufficient to demonstrate that the classification is correct [EC 2014]. |
| C05 | I | In general, the assignment of a monitoring programme to an individual should be based on the likelihood that the individual could receive an intake of radioactive material exceeding a predetermined level, as a result of normal operations or in the event of an accident [ICRP 2015b]. |
| C06 | A | The evaluation of the likelihood of intakes for groups of workers should be based on past experience and past and current monitoring data if available. |
| | | ***Q4**: How should the need for an individual monitoring programme be determined and what type of monitoring programme should be selected?* |
| C07 | I | The need for an individual monitoring programme should be determined from a consideration of the following factors [ISO 2006]:<br>• The magnitude of the likely exposures;<br>• The need to recognise and evaluate events resulting in intakes (should they occur);<br>• The need to assess the effectiveness of protective equipment.<br>Evaluation of these factors should take into account all radionuclides and the different scenarios in which a worker could be exposed during routine operations. |
| C08 | A | The basis of the evaluation should be available data from earlier monitoring programmes (individual or workplace monitoring) and/or results of dedicated measurements currently performed at the workplace to characterise radiological conditions. If no such data are available, the decision factor approach [IAEA 1999a] should be employed. |
| C09 | I | The type of monitoring programme should be selected based on comparison of the estimated likely annual dose with predefined reference levels. The recording level as defined by ISO [ISO 2006] should be used as the reference level that indicates the need for a routine monitoring programme. If the need for routine monitoring is not indicated, confirmatory monitoring may be employed to demonstrate that this is the case. |
| C10 | I | Individual monitoring techniques should be applied if the worker is liable to receive doses exceeding the investigation levels defined by ISO [ISO 2006]. |
| C11 | A | Monitoring programmes using individual monitoring techniques are also recommended in situations where the estimated likely annual dose falls between the recording and investigation level. |
| | | ***Q5**: What requirements should be considered when designing a routine monitoring programme?* |
| C12 | I | In routine monitoring, bioassay measurements should be performed on a regular schedule. The monitoring interval and the technique should be chosen in such a way that:<br>• the programme reliably detects intakes resulting in doses at the recording |

| R# | G | Text of the recommendation |
|---|---|---|
| | | levels, and<br>• the maximum underestimate in the resulting dose due to unknown time of intake is less than a factor of three.<br>For the commonly- encountered radionuclides, the methods and intervals provided by ISO [ISO 2006] or ICRP [ICRP 1997] should be used. |
| C13 | I | If there are no positive measurements during a routine monitoring interval, the fact that the measurement has been performed should be documented [ISO 2011]. |
| C14 | I | Dose assessments should be performed using defined reference assumptions. Documentation and record keeping of measurements and dose assessments should follow formal procedures and should enable later reproduction of the conditions of the measurement and a recalculation of the doses [ISO 2011]. |
| | | ***Q6**: What requirements should be considered when designing other types of monitoring programme?* |
| C15 | I | Non-routine (special, task-related and confirmatory) monitoring programmes should be specified in such a way that sufficient information for the subsequent dose assessment is provided. A combination of several monitoring methods may be specified. The methods and number of measurements required for special monitoring provided by ISO [ISO 2006] or EURADOS [EURADOS 2013] should be used. |
| C16 | I | Information about the specific events triggering non-routine monitoring should be used in the dose assessment procedure [ISO 2011]. |
| | | ***Q7**: How should potential exposures to short-lived radionuclides (e.g. such as are used for medical applications) be taken into account when designing a monitoring programme?* |
| C17 | I | In cases where short-lived radionuclides are encountered, triage monitoring programmes may be employed. They may be performed directly at the facility using available monitors.<br>Triage threshold levels (specified in terms of the quantities measured using the available equipment) should be defined. These levels may be used to trigger special monitoring for confirmation and assessment of the intake. Further information is provided by ISO [ISO 2016b]. |
| | | ***Q8**: How should a monitoring programme and its implementation be documented?* |
| C18 | I | The strategy and the objectives of the monitoring programme as well as the methods, techniques, models and assumptions should be documented [ISO 2006]. |
| C19 | A | A quality assurance (QA) system should be implemented that not only monitors measurement aspects, but also the dose assessment aspects and the quality of the overall programme. The QA system should be based on the general laboratory standard ISO/IEC 17025:2005 [ISO/IEC 2005] and the ISO standards on monitoring and dose assessment [ISO 2006; 2010b; 2011]. |

## CHAPTER D – Methods of Individual and Workplace Monitoring

| R# | G | Text of the recommendation |
|---|---|---|
| | | ***Q1**: What are the methods that should be used for individual monitoring and workplace monitoring?* |
| D01 | I | The requirements presented in ISO 20553:2006 [ISO 2006] for individual monitoring methods and workplace monitoring methods should be adopted, taking into account the advantages and limitations (including sensitivity and availability) of the different measurement methods. |
| | | ***Q2**: How should in vivo bioassay of the activity of radionuclides retained in the body that emit penetrating radiation be performed?* |
| D02 | I | In vivo measurement of radionuclides in the body should be employed for radionuclides |

| R# | G | Text of the recommendation |
|---|---|---|
| | | emitting penetrating radiation that can be detected outside of the body (mainly high energy X-ray and gamma emitting radionuclides) wherever feasible [ICRU 2003; IAEA 1996]. Methods should satisfy the performance criteria for radiobioassay set by ISO 28218:2010 [ISO 2010b]. |
| D03 | I | For radionuclides that are X/gamma emitters (>100 keV) and are rapidly absorbed from the respiratory tract into the body (e.g. $^{137}$Cs, $^{60}$Co), whole body monitoring using NaI(Tl) scintillation detectors and/or HPGe semiconductor detectors should be performed [ICRU 2003; IAEA 1996] |
| D04 | I | Monitoring of specific organs using NaI(Tl) scintillation detectors and/or HPGe semiconductor detectors should be performed for X/gamma emitting radionuclides that concentrate in particular organs or tissues (e.g. $^{131}$I in the thyroid) [ICRU 2003; IAEA 1996] |
| D05 | I | Whole body counters<br>HPGe detectors should be used for *in vivo* measurements of low energy X-ray and gamma emitters (< 100 keV). The design should allow easy and reproducible placement of detectors close to the organ of interest.<br>Where available, HPGe detectors should be used for *in vivo* measurements of complex mixtures of radionuclides, for uranium, for measurements of transuranic radionuclides and for $^{131}$I/$^{125}$I.<br>Partial body counters<br>If the radionuclide deposits preferentially in a single organ such as the thyroid (e.g. $^{125}$I, $^{131}$I), then partial body monitoring of the relevant organ should be chosen. [ICRU 2003; IAEA 1996]<br>If the intake is chronic, or where intakes occurred in the past, measurements of X/gamma emitting radionuclides in specific organs should be performed. For bone seeking radionuclides, measurements on the knee or skull are recommended. Calibrations should be performed using phantoms that simulate the organ of interest. |
| D06 | I | In the case of radiological or nuclear (RN) emergencies, NaI(Tl) scintillation detectors may be used in the early days after the accident especially for triage based on the level of contamination. To achieve better capabilities (in terms of both qualitative and quantitative information) it is recommended that whole body and organ monitoring based on HPGe detectors or a combination of both types are used. [ICRU 2003; IAEA 1996] |
| D07 | I | *In vivo* measurement laboratories should estimate their own uncertainties. The IDEAS Guidelines, ISO 27048:2011 and NCRP Report No. 164 (Appendix D) provide general information about how to calculate the uncertainties in different *in vivo* monitoring geometries. |
| D08 | I | To calibrate in vivo monitoring systems for measurements of radionuclides distributed in all or part of the body, laboratories should use active physical phantoms simulating internal contamination of organs or total body [ICRU 2003; IAEA 1996]. |
| D09 | I | It is recommended to document the sources of nuclear data used in the laboratory. It is recommended to use only a reference library (e.g. the DDEP data) throughout all procedures. This aids the accreditation process by guaranteeing traceability of results. |
| D10 | I | Calibrations should be performed using phantoms that simulate the organ of interest. The size of the calibration phantom and the distribution of the radionuclides should match that expected in the human subject [ICRU 2003; IAEA 1996]. |
| D11 | I | When calibrating detection systems for the measurements of low energy photon emitters in the lungs (radioisotopes of americium, uranium, plutonium and others) more realistic anthropomorphic phantoms (e.g. the Lawrence Livermore phantom) should be used [ICRU 1992; IAEA 1996]. |
| D12 | A | Numerical calibration techniques may be used as an alternative tool for *in vivo* measurement calibrations. It is recommended that national competent authorities consider adapting approval protocols of *in vivo* monitoring laboratories to allow the use of numerical calibration techniques, subject to the implementation of an appropriate quality assurance programme that includes appropriate validation procedures. |
| D13 | A | *In vivo* measurements of $^{232}$Th and $^{238}$U can be carried out with much better detection limits when its progeny are measured. However, the extrapolation to parent radionuclide activities may have significant associated uncertainties. In this case, *in* |

| R# | G | Text of the recommendation |
|---|---|---|
| | | *vitro* measurements of the parent radionuclide are recommended in order to avoid large uncertainties and inconsistencies in the results. |
| D14 | A | The measurement of exhaled radon/thoron may be used for the assessment of the uranium/thorium content of the human body. |
| | | ***Q3**: How should the excretion rate (Bq $d^{-1}$) of incorporated radionuclides in biological samples be measured?* |
| D15 | I | The worker should be made responsible for collecting bioassay samples according to clearly written instructions using sample containment provided by the bioassay laboratory.<br>Hand washing before provision of samples should be required as it is important to reduce possibility of additional cross contamination of samples. [ISO 2012a] |
| D16 | I | Sample collection should be made in non-contaminated areas to avoid accidental contamination of the sample. [ISO 2012a] |
| D17 | I | A 24-hour urine sample is preferred, as no correction for sample duration is then needed. [ISO 2011] |
| D18 | I | When 24-hour collection cannot be achieved, it is recommended that either creatinine normalisation or volume normalisation should be used to estimate 24-hour excretion [ISO 2011]. It may be assumed that creatinine is excreted at an average rate of 1.7 g $d^{-1}$ for men and 1.0 g $d^{-1}$ for women. Regarding volume correction, an excretion rate of 1.6 l $d^{-1}$ may be assumed for male adults and 1.2 l $d^{-1}$ for woman excretion [ICRP 2002]. |
| D19 | I | Faeces bioassay should be used to assess inhalation intakes of insoluble radionuclides where urine bioassay does not provide adequate sensitivity; the representativeness of reference values for daily faecal mass excretion is an important source of uncertainty. Collection of 3-day total voids should be made to reduce such uncertainty, especially just after the time of the intake. [ISO 2015d] |
| D20 | I | Each radionuclide-specific procedure should specify its own requirements for sample preparation depending on the radionuclide, the requirements of the detection system, the characteristics of the sample matrix and the level of sensitivity that is required. [ISO 2012a] |
| D21 | I | Sample collection, sample preparation, analyte concentration, and measurement should be specified in every analysis to be performed, regardless of the sample or analyte. [ISO 2012a] |
| D22 | I | When urine samples are not promptly analysed or must be stored, they should be refrigerated, acidified to minimise precipitation and/or add a preservative to prevent bacterial growth. It is usual to stabilise samples with concentrated nitric acid. [ISO 2012a] |
| D23 | I | Faeces samples should be analysed promptly, ashed or preserved by deep freezing because of their biodegradation. [ISO 2012a] |
| D24 | I | The method used for monitoring should have adequate sensitivity to detect the activity levels of interest. [ISO 2010b] |
| D25 | I | Analysis of excreta samples should be used to assess intakes of radionuclides that do not emit energetic photons (e.g. $^{3}H$), as it is the only available bioassay method. [ISO 2010b] |
| D26 | I | The selection of a specific in vitro method depends on the level of activity in the samples and the availability of instrumentation and technical expertise in the laboratory. Methods should satisfy the performance criteria for radiobioassay set by ISO 28218:2010 [ISO 2010b]. |
| D27 | I | In vitro measurement laboratories should characterise the sensitivity of their techniques by calculating the DL (detection limit) and the DT (decision threshold) according to ISO 28218:2010 [ISO 2010b], by measuring blank samples under routine conditions. |
| D28 | I | In vitro measurement laboratories should estimate their own sources of uncertainty. The IDEAS Guidelines, ISO 27048:2011, and NCRP report No. 164 (Appendix F) provide general information about how to calculate the uncertainties. |

| R# | G | Text of the recommendation |
|---|---|---|
| D29 | A | Fluorometry, KPA, alpha spectrometry and ICP-MS analytical methods may be employed for measurement of natural uranium in urine (ISO 16638-1:20015, Annex C) [ISO 2015d]. However, alpha spectrometry is the established method for the measurement of enriched uranium. |
| D30 | A | The use of ICP-MS or TIMS should be considered for the measurement of long-lived radionuclides. The main advantage is the short time (minutes) needed to perform the measurement and the sample preparation. The methods can be particularly useful in the event of accidental exposures involving uranium. However the methods are not sensitive enough for short-lived radionuclides (e.g. $^{241}$Am). In this case alpha spectrometry is recommended. |
| D31 | A | Alpha spectrometry is nevertheless recommended as the default method for measurements of alpha emitters in bioassay samples, on the basis of cost, versatility, throughput and availability. |
| D32 | A | Beta emitters may be quantified by liquid scintillation counting through direct measurement. Special attention should be given to reduction of the quenching processes. |
| D33 | A | Gamma spectrometry is recommended for the determination of radionuclides that emit gamma rays in biological samples, by direct and non-destructive measurement using scintillation (NaI(Tl)) or semiconductor (HPGe) detectors. Faeces samples require sample preparation before gamma spectrometric analysis. |
| D34 | I | When an occupational exposure to NORM materials has been detected, the mean natural background level in bioassay samples should be determined using the procedure set down in [ISO 2015d]. |
| D35 | A | Due to the relatively high detection limits of direct measurements and the problems with interpretation of monitoring data arising from lack of knowledge of the parent-daughter equilibrium state, *in vitro* bioassay measurements (urine and faeces) of all radionuclides are recommended for individual monitoring of exposed workers to NORM. |
| | | ***Q4**: How is the radionuclide concentration in air monitored in a workplace?* |
| D36 | A | Workplace monitoring (PAS/SAS monitoring) may be used for the assessment of occupational exposures to airborne radionuclides, but it is important to establish realistic assumptions about exposure conditions. |
| D37 | A | Exposure to some alpha, beta or gamma-emitters can be evaluated by PAS/SAS measurements, particularly $^{131}$I and uranium, thorium and plutonium isotopes, although the results are not always used for individual dose evaluation. |
| D38 | A | PAS can be particularly useful for assessing exposures in cases where *in vivo* and *in vitro* measurements do not have sufficient sensitivity to quantify exposures above 6 mSv reliably, as is the case for monitoring of exposures to some airborne actinide radionuclides. |
| D39 | A | PAS may be used to obtain satisfactory estimates of intake for groups of workers. However, for individuals, lack of correlation between assessments using PAS and *in vitro* analysis of bioassay samples can occur. |

## CHAPTER E – Routine and Special Dose Assessment

### E1 - Interpretation of Monitoring Data

| R# | G | Text of the recommendation |
|---|---|---|
| | | ***Q2**: What additional information and data is required in order to interpret individual monitoring data?* |
| E01 | A | To aid the interpretation of individual monitoring data, information should be collected on: the identity of radionuclide(s) to which workers are exposed, exposure locations, working practices, any exposure event, likely route of intake, whether exposure is likely to be continuous or discrete, time pattern of exposure, physical and chemical form of the radionuclide(s), use of PPE, any treatment with blocking or decorporation agents.<br>Judgements should be made on: (a) the extent of the information required and on (b) the effort expended on its examination. Interpretation of special monitoring requires more information and effort than routine monitoring, as do cases where the potential dose for an individual worker could approach or exceed the annual dose limit. This proviso also applies to recommendations E03 and E04. |
| | | ***Q3**: Where can this information be found?* |
| E02 | A | Arrangements should be made to allow collection of such information from sources within the workplace, from workplace monitoring, and on individual monitoring from within the dosimetry service. |
| | | ***Q4**: What information can workplace monitoring provide?* |
| E03 | A | Workplace monitoring data should be examined to provide additional information on the topics addressed in recommendation E01, as well as information on: contamination in the workplace, airborne particle size distribution, and (where appropriate) on potential exposures to parent radionuclides and their progeny, other associated radionuclides, isotopic ratios. |
| | | ***Q5**: How can the results of individual monitoring be used to guide and inform the formal dose assessment procedure?* |
| E04 | A | Individual monitoring data should be examined to provide additional information: nose blow/nasal swab data and personal air sampler data provide information on the likelihood of an inhalation exposure event, *in vivo* and sample bioassay monitoring data can provide information on the biokinetic behaviour of the radionuclide/element. |
| | | ***Q6**: How much emphasis should be placed on information derived from data fitting procedures on exposure conditions and material-specific model parameter values?* |
| E05 | A | Examination of the information addressed by E01, E03 and E04 should be performed in order to provide a better understanding of the exposure, and to aid and direct the formal dose assessment process. |
| | | ***Q7**: What are the issues that might prevent a straightforward interpretation of individual monitoring data?* |
| E06 | A | Dose assessors should be aware of a number of confounding factors that can result in erroneous dose assessments: external contamination of the body, treatment with medical radioisotopes, contamination of bioassay samples, errors in the bioassay sample collection period, background radiation in *in vivo* monitoring, contribution to *in vivo* measured counts from activity in other organs, dietary intakes (for NORM materials), independent biokinetic behaviour of radioactive progeny used to monitor for intake of the parent, independent biokinetic behaviour of mixtures of radionuclides, radionuclides in an unusual physical or chemical form. |

### E2 - Dose Assessment and Interpretation: Routine Monitoring

| R# | G | Text of the recommendation |
|---|---|---|
| | | ***Q8**: How should dose assessments after routine monitoring be performed in* |

| R# | G | Text of the recommendation |
|---|---|---|
| | | *practice?* |
| E07 | I | Newly established dosimetry services and services that have not yet adopted a systematic approach, are recommended to adopt the methodology for dose assessment after routine monitoring described in Section E2 [ISO 2011; EURADOS 2013]. The use of the IDEAS Guidelines by dosimetry services that have already adopted them as a reference methodology, irrespective of the assessed dose, is not excluded by these recommendations for cases where it can be concluded that the annual dose limit would not be exceeded. |
| | | ***Q9**: How does the recommended approach for routine monitoring compare with the ISO 27048:2011 and the IDEAS Guidelines methodologies?* |
| E08 | I | The recommended approach comprises the ISO 27048:2011 approach (left side of Figure E.1 and Table E.1) [ISO 2011], and, when the analysis indicates that the annual dose limit may potentially be exceeded, the IDEAS Guidelines [EURADOS 2013]. |

## E3 - Dose Assessment and Interpretation: Special Monitoring

| R# | G | Text of the recommendation |
|---|---|---|
| | | ***Q10**: How should dose assessments after special monitoring be performed in practice?* |
| E09 | I | New established dosimetry services and services that have not yet adopted a systematic approach are recommended to adopt the methodology described in Section E3 for dose assessment after special monitoring [ISO 2011; EURADOS 2013]. The use of the IDEAS Guidelines, by dosimetry services that have already adopted them as a reference methodology, is not excluded by these recommendations, for cases where it can be concluded that the annual dose limit would not be exceeded. |
| | | ***Q11**: How does the recommended approach for special monitoring compare with the ISO 27048:2011 and the IDEAS Guidelines methodologies?* |
| E10 | I | The recommended approach comprises the ISO 27048:2011 approach (right side of Figure E.1 and Table E.2) [ISO 2011] and, when the analysis indicates that the annual dose limit may potentially be exceeded, the IDEAS Guidelines [EURADOS 2013]. |
| | | ***Q12**: When selecting dose assessment software, what are the desired capabilities that should be taken into consideration?* |
| E11 | A | In selecting dose assessment software tools, a graded approach following Tables E.3 should be applied: "ESSENTIAL" capabilities, which refer to the application of the ICRP reference models, ISO 27048:2011 and the IDEAS Guidelines, are recommended; consider giving preference to those software tools which implement the capabilities indicated as "ADVISABLE". |
| | | ***Q13**: What issues should be considered when using dedicated software?* |
| E12 | A | The standard type of software tool should allow the evaluation of intakes and doses using default ICRP models and parameter values, taking into account contributions of previous, already assessed intakes. For advanced types of software tool, use of non-default assumptions and material-specific or site-specific model parameter values should be included. |

## E4 - Monitoring and Dosimetry for Cutaneous and Wound Cases

| R# | G | Text of the recommendation |
|---|---|---|
| | | ***Q14**: Which dose should be estimated in the event of contamination of the intact skin?* |
| E13 | I | In the case of cutaneous contamination of intact skin, local equivalent dose for the skin ($H_{skin}$) should be assessed over any area of 1 cm² at 0.07 mm nominal depth, |

| R# | G | Text of the recommendation |
|---|---|---|
| | | according to ISO 15382:2016. |
| | | ***Q15**: How should the equivalent dose to the skin be assessed after intact skin contamination?* |
| E14 | I | With repeated measurements by skin monitors or local detectors, the equations E.7 and E.8 and the tables of dose coefficients provided by ISO 15382:2016 and NCRP Publication 156 should be used to evaluate $H_{skin}$. |
| E15 | I | A special monitoring programme should be implemented when a pre-defined reference level of cutaneous contamination on intact skin is exceeded. A combination of *in vivo* and *in vitro* measurements should be performed in order to assess the uptake in the body. |
| | | ***Q16**: Which doses should be estimated in case of contaminated wounds?* |
| E16 | M | In the case of wounds, both the equivalent dose to the area of wounded skin and the committed effective dose resulting from uptake from the wound site should be quantified. |
| | | ***Q17**: What relevant exposure indicators may be used to define the initial assessment following exposure via a wound?* |
| E17 | A | Wound cases should be treated on a case-by-case basis. Monitoring of the local activity around the wound site, the sharp object, dressings and compresses and excised tissue should be implemented to evaluate the equivalent dose to the area of wounded skin. |
| | | ***Q18**: How should the special case of a contaminated wound be treated?* |
| E18 | I | A special monitoring programme should be implemented for wound cases by a combination of *in vivo* and *in vitro* measurements in order to estimate the systemic uptake.<br>In order to evaluate the committed effective dose:<br>• to a first order of magnitude, the assessment should be made assuming a direct injection into blood [SFMT 2011; EURADOS 2013];<br>• depending on circumstances, a more precise wound model may be used. The excretion and retention functions of the NCRP Publication 156 wound model and dose coefficients for radionuclides using a wound model combined with systemic models [Ishigure 2003; Toohey 2011] could be used. |

## E5 - Monitoring and Dose Assessment in the Event of Decorporation Therapy

| R# | G | Text of the recommendation |
|---|---|---|
| | | ***Q19**: How and why is decorporation therapy applied?* |
| E19 | A | The application of decorporation therapy must be balanced against the (toxicological) risks imposed by the drugs used. In occupational contexts, decorporation therapy should only be applied in cases where significant doses are expected. |
| | | ***Q20**: What monitoring is required in the event of decorporation therapy?* |
| E20 | I | In the case of decorporation therapy, special monitoring should be performed. The special monitoring programme should be designed individually for the case considered [ISO 2006]. |
| E21 | A | The data provided by the monitoring should be sufficient for an assessment of the dose and if possible an evaluation of the efficacy of the therapy. |
| | | ***Q21**: How is dose assessed in the event of decorporation therapy?* |
| E22 | A | Dose assessments after decorporation therapy require an expert assessment and need to be case-specific. Consultation of experts in internal dosimetry for the discussion and interpretation of the case is considered helpful and recommended. Publication of the case, the data and its interpretation in a scientific journal should be considered. |

| R# | G | Text of the recommendation |
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| E23 | A | In the case of administration of stable iodine, the assessment of dose resulting from exposure to radioactive iodine should be based on direct thyroid measurement rather than urine monitoring. For the dose assessment the data can be extrapolated to the 50 year commitment period, numerically integrated and then multiplied with radiation weighted S-coefficients. |
| E24 | A | In the case of Prussian Blue treatment after cesium exposure, the dose assessment should be based on direct whole body counting measurements. For the dose assessment the data can be extrapolated to the 50 year commitment period, numerically integrated and then multiplied with radiation weighted S-coefficients. Alternatively modified biokinetic models can be applied, if the observed long-term retention period of the individual can be taken into account. |
| E25 | A | In the case of DTPA treatment, the plutonium intake may be estimated from urine measurements obtained more than 20 days after DTPA administration and/or from urine excretion measured on the day following DTPA administration after correction with a DTPA enhancement factor. This factor may be taken to have a nominal value of 50 or adjusted to an individual-specific value determined after a therapeutic window. The application of the enhancement factor is only valid if the DTPA administrations are separated at least by 2 days. |

## E6 - Radiation Protection for Pregnant and Breastfeeding Workers

| R# | G | Text of the recommendation |
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| | | ***Q22**: Is it necessary to change the working conditions if a worker is pregnant or breastfeeding?* |
| E26 | M | As soon as a pregnant worker informs the undertaking or, in the case of an outside worker, the employer, of the pregnancy, in accordance with national legislation the undertaking, and the employer, must ensure that the employment conditions for the pregnant worker are such that the equivalent dose to the unborn child is as low as reasonably achievable and unlikely to exceed 1 mSv during at least the remainder of the pregnancy.<br>As soon as workers inform the undertaking, or in case of outside workers, the employer, that they are breastfeeding an infant, they must not be employed in work involving a significant risk of intake of radionuclides or of bodily contamination. [EC 2014] |
| | | ***Q23**: Which dose limits apply for the unborn child?* |
| E27 | M | Member States must ensure that the protection of the unborn child is comparable with that provided for members of the public [ISO 2006]. The equivalent dose to the unborn child must be as low as reasonably achievable and unlikely to exceed 1 mSv during at least the remainder of the pregnancy. [EC 2014] |
| E28 | A | The effective external dose and the internal committed effective dose received from the time of conception to 3 months after birth should not exceed 1 mSv. |
| | | ***Q24**: Is it necessary to change the monitoring programme if a worker becomes pregnant?* |
| E29 | A | The monitoring programme may need to be modified (to take into account the need for monitoring of other radionuclides more relevant for foetal doses, and that monitoring intervals should not exceed one month during the remaining period of pregnancy). |

# CHAPTER F - Accuracy Requirements and Uncertainty Analysis

| R# | G | Text of the recommendation |
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| | | ***Q1**: Under what circumstances should uncertainties in assessed dose be* |

| R# | G | Text of the recommendation |
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| | | *assessed, and how should information on uncertainties be used?* |
| F01 | I | The uncertainty on assessed dose should be considered in the design of a monitoring programme [ICRP 2015b; ISO 2006], to assess the reliability of a monitoring procedure [ISO 2011] and for the assessment of risks to health [ICRP 2007]. |
| F02 | I | For statistical tests in the dose assessment procedure and to evaluate its contribution to overall uncertainty in assessed dose, the measurement uncertainty should be expressed by a scattering factor (SF). The values of SF from Tables 4.8 and 4.10 of the IDEAS Guidelines [EURADOS 2013] should be adopted. |
| F03 | I | A routine monitoring programme should be sufficiently sensitive to reliably detect any intake leading to an annual effective dose of more than 1 mSv and sufficiently accurate to avoid an underestimation of the dose by more than a factor of 3 due to uncertainty in the time of intake [ISO 2006, ICRP 1997]. |
| F04 | I | In order to evaluate and improve the reliability of doses assessed using the ISO 27048:2011 procedure [ISO 2011], uncertainties associated with particular monitoring procedures should be assessed using sensitivity analyses. If the assessed dose is more than 0.1 mSv, the uncertainty on dose due to measurement uncertainty and to uncertainty on time of intake should be assessed and documented. If the assessed dose is more than 1 mSv, the uncertainty on particle size distribution and absorption characteristics should also be taken into account in the assessment of dose uncertainty. |
| F05 | A | The uncertainty on assessed dose should be expressed as an interval from the minimum to the maximum value of dose assessed for each factor contributing to overall uncertainty. Each factor is to be considered separately as varying within its 95% confidence interval, while other parameters are fixed as best estimates or default assumptions. The results of this sensitivity analysis should be recorded in the format indicated by Table 7 of ISO 27048:2011 [ISO 2011]. |
| F06 | A | For the evaluation of individual health risk, the uncertainty on all measurements, models and parametersshould be taken into account The method to be applied depends on the individual case and the available information. The indications given in NCRP Publication 164 [NCRP 2010a] may be followed. |

## CHAPTER G – Quality Assurance and Criteria for Approval and Accreditation

| R# | G | Text of the recommendation |
|---|---|---|
| | | ***Q1**: How should the quality of internal dose assessments be assured?* |
| G01 | A | An appropriate quality assurance programme should be established to ensure the quality of internal dosimetry services and to guarantee the reliability of monitoring data and internal dose assessments. |
| | | ***Q2**: How should the reliability of monitoring data used in the assessment of internal doses be guaranteed?* |
| G02 | I | It is recommended that monitoring should conform to the performance criteria of the ISO standards on internal dosimetry [ISO 2006; 2010; 2011; 2015d, 2016b] and ISO/IEC 17025:2005 [ISO/IEC 2005].<br>Participation in inter-laboratory measurement intercomparison programmes and appropriate training of the employees are recommended. |
| | | ***Q3**: How should the reliability of assessments of dose due to occupational intakes of radionuclides be guaranteed?* |
| G03 | I | It is recommended that dose assessment procedures should conform to the quality assurance and quality control criteria and recommendations established in ICRP publications [ICRP 2007; 2015b], ISO 27048:2011 [ISO 2011], the IDEAS Guidelines [EURADOS 2013], IAEA publications [e.g. IAEA 2014] and the 2013 Directive [EC 2014].<br>Participation in intercomparison programmes of dose assessments of internal |

| R# | G | Text of the recommendation |
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| | | exposures and appropriate training of the employees are recommended. |
| | | ***Q4**: How is accreditation of internal dosimetry laboratories and services according to ISO/IEC standards obtained?* |
| G04 | I | The process of implementing any quality standards requires the implementation of a management system and appropriate documentation and procedures and requires the commitment of the organisation in terms of facilitating economic and personal support.<br>A test or calibration laboratory seeking recognition of their technical competence by means of accreditation under ISO/IEC 17025 [ISO/IEC 2005] should meet and show evidence of compliance with all of the requirements contained in that standard. |
| G05 | I | A Quality Manual, a quality policy and management and technical procedures should be developed and records kept as evidence of its implementation. Specific software for quality management system administration may be used to allow more efficient handling of the quality system [ISO/IEC 2005; ISO 2012a, 2015c]. |
| G06 | I | Plans for training of personnel, for control of equipment, for validation of methods, and for quality control (including participation in intercomparison exercises) should be established [ISO/IEC 2005; ISO 2012a, 2015c]. |
| G07 | I | Requirements of the Competent Authority should be taken into account. In the case of accreditation for assessments of dose, a quality management system based on international standards and ICRP recommendations should be used to avoid subjectivity.<br>If implementation is adequate and operation of the quality management system found to be successful, the organisation should apply for accreditation to the National Accreditation Body. |
| | | ***Q5**: What are the purpose, scope and requirements for participation of internal dosimetry laboratories/services in national and international intercomparisons on monitoring and dose assessment?* |
| G08 | A | It is recommended to participate in intercomparison programmes of *in vivo* and *in vitro* monitoring and dose assessment whenever possible as the final step of method validation. In many countries, participation is a mandatory requirement for accreditation of both measurements and assessment of doses resulting from occupational intakes of radionuclides. |
| | | ***Q6:** How should internal doses be recorded and reported?* |
| G09 | A | Approval procedures for dosimetry services in relation to dose recording and reporting should state the justifications for the monitoring programme, the monitoring and reporting periods, the dose information to be reported and the internal dose assessment methods (including principles and software used), specifying the recipient(s) of the dose report. |
| G10 | M | Every Member State must define and fix a recording level (RL) for committed effective dose, E(50) [EC 2014]. |
| G11 | I | An RL of 1 mSv $y^{-1}$ is recommended. If the annual accumulated *E(50)*, over a period of twelve consecutive months or during the calendar year (depending on national regulations), is equal to or greater than 1 mSv, it should be recorded. Values of total annual internal dose less than 1 mSv do not need to be recorded, but an entry "below recording level" should be added to the dose record to show that the individual was subject to routine internal monitoring [ISO 20553]. |
| G12 | A | For doses above the RL, traceability information should be recorded, together with all parameter values used in the assessment (exposure conditions, physico-chemical properties of the compound to which the worker is exposed, justification of the assumptions made, the software used, and the results). |
| | | ***Q7:** For how long should dosimetry data records be retained?* |
| G13 | M | Every Member State must create and maintain a data system for individual radiological monitoring, either as a network or as a National Dose Register, that contains internal dose values for each worker for whom assessments of occupational exposure are required. Dosimetry records must be retained during the period of the working life of the worker concerned and afterwards until they have or would have attained the age of 75 years, but in any case not less than 30 years after termination of the work |

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| | | involving exposure [EC 2014]. |
| | | ***Q8**: What results should be communicated?* |
| G14 | A | Every Member State should guarantee the communication of dosimetry data (that is, the internal dose component for workers) by means that takes into account confidentiality aspects of this information. The communication should also consider the psychological impact on the individual. |

## CHAPTER H – Radon Measurement and Dosimetry for Workers

| R# | G | Text of the recommendation |
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| | | ***Q1**: How should workers be protected against radon exposure?* |
| H01 | M | As part of the national radon action plan, radon measurements in workplaces and mixed-use buildings must be carried out in radon prone areas to demonstrate compliance with national reference levels (NRLs) [EC 2014]. Initially, the aim is to ensure the overall protection of the users of the buildings rather than to control doses to specific individuals. An employer has responsibility towards its employees to ensure radon levels are as low as reasonably achievable.<br>If the appropriate measurement result is above the NRL then optimisation must be carried out to reduce exposures. Such actions include physical remediation measures (mitigation) to reduce radon concentrations, management actions to reduce occupancy, and measurements to investigate the activity concentration during working hours, if appropriate.<br>If mitigation is carried out, then repeat measurements should be made to confirm the effectiveness of the mitigation system and records of the measurements should be kept. Remediated premises should be re-measured periodically to ensure that radon levels remain low. Measurements should also be repeated after any significant building work or changes to an operational cycle affecting exposure conditions such as changes to the heating, ventilation and air conditioning operation.<br>If in spite of mitigation actions radon levels (as an annual average) remain above the NRL, the relevant regulator must be notified. A dose assessment is required taking account of actual parameters of the exposure situation such as occupancy patterns and, potentially, associated regular variations in radon levels. If doses are above 6 mSv per year then the workplace mustl be managed as a planned exposure situation whereas if below or equal to 6 mSv per year they must be kept under review. For some workplaces, such as thermal spas, caves, mines and other underground workplaces, competent authorities may consider from the outset that workers' exposure to radon is occupational [ICRP 2014]. |
| H02 | A | A national protocol/methodology should be developed for the determination of the annual average radon activity concentration in indoor workplaces and for the dose assessment of workers to ensure a consistent approach nationwide. |
| | | ***Q2**: What are the strategies for radon risk communication?* |
| H03 | I | As part of the national radon action plan, information about radon measurements, radon risk and remediation should be communicated to employers and employees. Core messages for employers and employees should be developed that are simple, brief and to the point [WHO 2009]. Employers should: find out if their workplace needs to be tested for radon, carry out appropriate tests, act on the results and share information with employees and building users as appropriate. It should be stressed that practical techniques for mitigation are available. |
| H04 | I | The synergistic effect of tobacco smoking and radon should be communicated to employers and employees [ICRP 2014]. |
| H05 | I | An assessment of the level of knowledge and the perceptions of radon risks of the target audience should be carried out both before and after a risk communication campaign [WHO 2009]. |
| | | ***Q3**: How should it be ensured that measurements are reliable?* |
| H06 | I | A quality assurance programme should be established and maintained by all those |

| R# | G | Text of the recommendation |
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| | | providing radon measurement services. It is preferable but not mandatory that radon measurement services, testing and calibration laboratories are accredited in accordance with ISO/IEC 17025:2005. |
| H07 | I | Regular calibrations, duplicate measurements, blind tests, laboratory and field background measurements should be part of the quality assurance programme. Radon services are also recommended to participate in intercomparison exercises or performance tests [WHO 2009; ICRU 2012]. |
| H08 | I | Measurements should be metrologically traceable. The measurement uncertainty should be estimated, taking account of both calibration and field measurement uncertainties, and should be in accordance with [ISO/IEC 2008]. |
| | | ***Q4**: What measurement strategies for workplace monitoring should be adopted to demonstrate compliance with reference levels and dose limits?* |
| H09 | I | The monitoring strategy for indoor workplaces should take account of the exposure conditions and the operation cycle. Typically, for indoor workplace monitoring, area radon gas measurements are recommended to investigate if the annual average radon concentration is below the NRL. Long-term measurements over a period of a year are advisable. However, if for practical reasons this is not feasible, then a measurement period of at least 3 months is recommended. Seasonal correction factors may be applied, if appropriate, to convert 3-month measurements to annual averages but these factors should be derived for a given climate or region. National or regional studies should, therefore, be undertaken to determine if there is an observable and reliable seasonal variation. An alternative approach is to use the heating season measurement without correction for a conservative estimate of the annual average radon concentration [ICRU 2012]. |
| H10 | I | The choice of the detector for radon gas measurements depends upon the purpose of the measurement, the detector's suitability and the cost. Alpha track detectors are recommended for long-term measurements although electret ionisation chambers are a suitable alternative. In situations of suspected high thoron activities, it is recommended to use radon-thoron discriminative detectors [ICRU 2012]. |
| H11 | I | Stationary devices for area measurements of radon gas should be installed at positions that are representative of the worker's exposure, i.e. within the breathing zone (generally 1-2 metres above floor level) of regularly occupied locations. The aim is to measure radon in relevant parts of the workplace that are regularly occupied including: a representative number of ground floor locations and all regularly occupied spaces that are below ground level [WHO 2009; ICRU 2012]. |
| H12 | I | For indoor workplaces, where the radon level (as an annual average) remain above the NRL and where significant cyclic variations in radon concentrations are likely, time-resolved measurements should be considered to explore the activity concentration during working hours. In such cases, devices with a maximum time resolution of one hour are recommended [ICRU 2012]. |
| | | ***Q5**: When should radon progeny measurements be employed?* |
| H13 | I | Radon progeny measurements are recommended at workplaces where the equilibrium factor varies significantly because of variation in the ventilation or fluctuations in aerosol particle concentration [ICRU 2012]. |
| | | ***Q6**: When should individual monitoring be employed?* |
| H14 | I | In workplaces where workers' exposure to radon is considered as occupational or is managed as a planned exposure situation, individual exposure or dose assessments are required to demonstrate compliance with reference levels and dose limits. Depending upon exposure conditions, individual as well as area monitoring may be applied. If the spatial and temporal conditions are very variable or if the individual frequently changes exposure sites with different exposure conditions then individual monitoring is generally recommended, if appropriate. For example, personal monitors are used in many underground workplaces, such as mines, where the exposure conditions are variable [ICRP 2014; ICRU 2012]. |
| | | ***Q7**: Which dose coefficients should be used?* |
| H15 | A | The latest dose conversion factors recommended by ICRP for the inhalation of radon |

| R# | G | Text of the recommendation |
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| | | progeny and thoron progeny should be used for radiation protection purposes, if a dose assessment is required. The Article 31 Group of Experts will continue to review updates of ICRP Publications, and the European Commission will make recommendations on dose coefficients for radon taking account of their opinions. |

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