Draft Euratom Basic Safety Standards Directive

Version 24 February 2010 (final)

Directives included in the recast:

- Council Directive 96/29/ Euratom of 13 May 1996, laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation (Official Journal L-159 of 29.06.1996, page 1),
- Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure, and repealing Directive 84/466/Euratom (Official Journal L-180 of 09.07.1997, page 22),
- Council Directive 89/618/Euratom of 27 November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency (Official Journal L-357 of 07.12.1989, page 31),
- Council Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionising radiation during their activities in controlled areas (Official Journal L-349 of 13.12.1990, page 21),
- Council Directive 2003/122/Euratom of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources (Official Journal L346 of 31.12.2003, page 57)

Outline of the new European Basic Safety Standards as adopted by the Group of Experts:

- *Preamble (not yet available)*
- Title I: Subject Matter and Scope
- Title II: Definitions
- Title III: System of Protection
- Title IV: Responsibilities for Regulatory Control
- Title V: Requirements for Radiation Protection Education, Training and Information
- Title VI: Justification and Regulatory Control of Planned Exposure Situations
- Title VII: Protection of Workers, Apprentices and Students
- Title VIII: Protection of Patients and other Individuals Submitted to Medical Exposure
- Title IX: Protection of Members of the Public
- Title X: Protection of the Environment
- *Title XI: Final provisions (not yet available)*

- Annexes
    - Annex 1 Bands of reference levels for public exposure expressed in residual effective dose and corresponding societal criteria for existing and emergency exposure situations
    - Annex 2 Activity values defining high activity sealed sources
    - Annex 3 Standard record sheet for high activity sealed sources
    - Annex 4 Access to the high activity sealed sources data
    - Annex 5 Requirements for undertakings
    - Annex 6 Identification and marking of high activity sealed sources
    - Annex 7 Placing on the market of apparatus or products
    - Annex 8 List of industrial sectors involving naturally occurring radioactive material
    - Annex 9 Exemption and clearance criteria
    - Annex 10 Centralised national networks and individual radiological monitoring documents

- Annex 11A Elements to be included in an emergency management system
- Annex 11B Elements to be included in an emergency response plan
- Annex 12A Prior information to the population likely to be affected by an emergency
- Annex 12B Information to be provided to the affected population in case of an emergency
- Annex 13 Indicative list of items to be covered in the national action plans for radon in dwellings, buildings with public access and workplaces
- Annex 14 Indicative list of types of building materials considered for control measures with regard to their emitted gamma radiation
- Annex 15 Definition and use of the activity concentration index for the gamma radiation emitted by building materials
- Annex 16 Practices involving non-medical imaging exposure
- Annex 17 Values and relationships for the estimation of effective and equivalent doses

BASIC SAFETY STANDARDS
Recast Directive

TITLE I

SUBJECT MATTER AND SCOPE

Article 1

1. The subject matter and general purpose of this Directive is the health protection of the public, patients and workers against the dangers of ionising radiation; this Directive also applies to the protection of the environment as a pathway from environmental sources to the exposure of man, complemented where appropriate with specific consideration of the exposure of biota in the environment as a whole; in addition to the general purpose of health and environmental protection this Directive also aims at ensuring adequate control of the safety and security of sources and the provision of appropriate information in an emergency exposure situation, as outlined in Article 2.

2. This Directive shall apply to any planned, existing or emergency exposure situation which involves a risk from exposure to ionising radiation which cannot be disregarded from the radiation protection point of view with regard to the health protection of workers, members of the public, or patients and other individuals subject to medical exposure or with regard to the protection of the environment.

3. This Directive shall apply to all planned exposure situations involving radiation sources, namely:

(a) the production, processing, handling, use, storage, holding, transport, shipment, import to, and export from the Community and the disposal of radioactive material;

(b) the operation of electrical equipment emitting ionising radiation;

(c) exposure situations which involve the presence of natural radiation sources that lead to a significant increase in the exposure of workers or members of the public, in particular:

(i) the operation of aircraft and spacecraft

(ii) exposure to radon in workplaces

(iii) the activities in industries processing materials with naturally occurring radionuclides, or activities related to such processing

(d) any other activity specified by the Member State.

4. This Directive applies to existing exposure situations other than those involving exposures excluded under Article 3; it applies in particular to the exposure of the public to indoor radon and to external exposure from building materials; cases of lasting exposure resulting from the after-effects of an emergency or a past activity shall be dealt with as an existing exposure situation.

5. This Directive applies to the management of emergency exposure situations to the extent that these are deemed to warrant intervention to protect the health of the public or workers or to protect the environment; potential exposures as well as emergency preparedness and planning are part of the requirements for planned exposure situations.

Article 2

1. In addition to the general purpose of this Directive, it aims at the prevention of exposure of workers and members of the public to ionising radiation arising from orphan sources and

from inadequate control of high-activity sealed radioactive sources and at the harmonisation of controls in place in the Member States by defining specific requirements ensuring that each such source is kept under control.

2. This Directive is also intended to define, at Community level, common objectives with regard to measures and procedures for informing the public for the purpose of improving the operational health protection provided in the event of an emergency.

Article 3

This Directive shall not apply to radionuclides naturally contained in the human body, to cosmic radiation prevailing at ground level, to aboveground exposure to radionuclides present in the undisturbed earth's crust or to the operation of any electrical equipment operating at a potential difference of less than 5 kV.

TITLE II

DEFINITIONS

Article 4

For the purpose of this Directive, the following terms have the meaning hereby assigned to them:

Absorbed dose (*D*): the energy absorbed per unit mass

$$D = \frac{\mathrm{d}\bar{\varepsilon}}{\mathrm{d}m}$$

where

– $\mathrm{d}\bar{\varepsilon}$ is the mean energy imparted by ionising radiation to the matter in a volume element,

– $\mathrm{d}m$ is the mass of the matter in this volume element.

In this Directive absorbed dose denotes the dose averaged over a tissue or an organ. The unit for absorbed dose is the gray.

Accelerator: apparatus or installation, in which particles are accelerated, emitting ionising radiation with an energy higher than 1 mega-electron volt (MeV).

Accidental exposure: an exposure of individuals, other than emergency workers, received as a result of an accident.

Activation: process through which a stable nuclide is transformed into a radionuclide by irradiating with particles or high-energy photons the material in which it is contained.

Activity (*A*): the activity, A, of an amount of a radionuclide in a particular energy state at a given time is the quotient of $\mathrm{d}N$ by $\mathrm{d}t$, where $\mathrm{d}N$ is the expectation value of the number of spontaneous nuclear transitions from that energy state in the time interval $\mathrm{d}t$:

$$A = \frac{\mathrm{d}N}{\mathrm{d}t}$$

The unit of activity is the becquerel.

Apprentice: a person receiving training or instruction within the premises of an undertaking with a view to exercising a specific skill.

Authorisation: the granting by a competent authority of written permission for an undertaking to perform specified activities subject to regulatory control in the form of registration or a licence.

Becquerel (Bq): the special name of the unit of activity. One becquerel is equivalent to one nuclear transition per second: 1 Bq = 1 s^{-1}

Building material: a construction product which is produced for incorporation in a permanent manner in a building.

Carers and comforters: individuals knowingly and willingly incurring an exposure to ionising radiation by helping, other than as part of their occupation, in the support and comfort of individuals undergoing or having undergone medical exposure.

Clearance levels: values, established by the competent authority or in national legislation, and expressed in terms of activity concentrations, at or below which materials arising from any practice subject to the requirement of notification or authorisation may be released from the requirements of this Directive.

Clinical audit: a systematic examination or review of medical radiological procedures which seeks to improve the quality and the outcome of patient care through structured review whereby medical radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices where indicated and the application of new standards if necessary.

Clinical responsibility: responsibility regarding individual medical exposures attributed to a practitioner, notably: justification; optimisation; clinical evaluation of the outcome; cooperation with other specialists and the staff, as appropriate, regarding practical aspects; obtaining information, if appropriate, of previous examinations; providing existing medical radiological information and/or records to other practitioners and/or referrer, as required; giving information on the risk of ionising radiation to patients and other individuals involved, as appropriate.

Committed effective dose ($E(\tau)$): the sum of the committed organ or tissue equivalent doses $H(\tau)$ resulting from an intake, each multiplied by the appropriate tissue weighting factor w_T. It is defined by:

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

In specifying $E(\tau)$,τ is given in the number of years over which the integration is made. For the purpose of complying with dose limits specified in this Directive τ shall be a period of 50 years following intake for adults and up to age 70 for children. The unit for committed effective dose is the sievert.

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. It is given by:

$$H_T(\tau) = \int_{t_0}^{t_0+\tau} \dot{H}_T(t)\,\mathrm{d}t$$

for an intake at time t_0 where

$\dot{H}_T(\tau)$ is the relevant equivalent dose rate in organ or tissue T at time t,

τ is the time over which the integration is performed.

In specifying, $H_T(\tau)$ τ is given in years. When τ is not given, a period of 50 years is assumed for adults and up to an age 70 for children. The unit for committed equivalent dose is the sievert.

Competent authority: any authority or authorities designated by a Member State to carry out tasks in accordance with this Directive.

Controlled area: an area subject to special rules for the purpose of protection against ionising radiation or of preventing the spread of radioactive contamination and to which access is controlled.

Diagnostic reference levels: dose levels in medical radiodiagnostic or interventional radiology practices or, in the case of radio-pharmaceuticals, levels of activity, for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment.

Disposal: the emplacement of radioactive waste in an appropriate facility without the intention of retrieval.

Disused sealed source: a sealed source which is no longer used or intended to be used for the practice for which authorisation was granted.

Dose constraint: a constraint set as a prospective upper bound of individual dose used to define the range of options considered in the process of optimisation related to a given radiation source.

Dose limit: the value of the effective dose or the equivalent dose in a specified period that shall not be exceeded for an individual. The dose limit applies to the sum of exposures from all authorised practices.

Dosimetry service: a body or an individual having the competence for calibration, reading or interpretation of individual monitoring devices, or for measurement of radioactivity in the human body or in biological samples, or for assessment of doses, whose capacity to act in this respect is recognized by the competent authorities.

Dwelling: a building intended for housing people.

Effective dose (*E*): the sum of the weighted equivalent doses in all the tissues and organs of the body specified in Annex II from internal and external irradiation. It is defined by the expression:

$$E = \sum_T w_T \, H_T = \sum_T w_T \sum_R w_R \, D_{T,R}$$

where

$D_{T,R}$ is the absorbed dose averaged over tissue or organ T, due to radiation R,

w_R is the radiation weighting factor and

w_T is the tissue weighting factor for tissue or organ T.

The appropriate w_T and w_R values are specified in Annex 17 *[to be added]*. The unit for effective dose is the sievert.

Emergency: a non-routine situation or event that necessitates prompt action primarily to mitigate a hazard or adverse consequences for human health and safety, quality of life, property or the environment. This includes nuclear and radiological emergencies.

Emergency exposure situation: a situation of exposure that is a consequence of any sudden event which requires urgent decisions to be taken in order to control this situation; the event may result from an accident (whether or not envisaged as a potential exposure) or from a malicious act.

Emergency management system: legal or administrative framework establishing responsibilities for emergency preparedness and response, and arrangements for decision making in the event of an emergency exposure situation.

Emergency occupational exposure: exposure received in an emergency exposure situation as occupational exposure to individuals undertaking actions to mitigate the consequences of the emergency.

Emergency response plan: arrangements to plan for adequate response in the event of an emergency exposure situation related to a specific facility or activity on the basis of postulated events and related scenarios.

Emergency worker: any person having a defined role as a worker in an emergency and who might be exposed while taking actions in response to the emergency.

Equivalent dose (H_T): the absorbed dose, in tissue or organ *T* weighted for the type and quality of radiation *R*. It is given by:

$$H_{T,R} = w_R \, D_{T,R}$$

where

– $D_{T,R}$ is the absorbed dose averaged over tissue or organ *T*, due to radiation *R*,

– w_R is the radiation weighting factor.

When the radiation field is composed of types and energies with different values of w_R, the total equivalent dose, H_T, is given by:

$$H_T = \sum_R w_R \, D_{T,R}$$

The appropriate w_R values are specified in Annex 17 *[to be added]*. The unit for equivalent dose is the sievert.

Existing exposure situation: an exposure situation that already exists when a decision on its control has to be taken and which does not call or no longer calls for urgent measures to be taken.

Exposed worker: person, either self-employed or working under an employer, who is subject to exposure at work carried out within a practice regulated by this Directive and who is liable to receive doses exceeding one or other of the dose levels equal to the dose limits for members of the public.

Exposure: the act of exposing or condition of being exposed to ionising radiation [emitted outside the body (external exposure) or within the body (internal exposure)].

Exposure situation: general term to designate a situation giving rise to the exposure, including the radiation sources and the activities or actions which may affect the exposure from these radiation sources.

Gray (Gy): the special name of the unit of absorbed dose. One gray is equal to one joule per kilogram: 1Gy = 1 J kg^{-1}.

Health detriment: an estimate of the risk of reduction in length and quality of life occurring in a population following exposure. This includes (loss arising from) tissue effects, cancer and severe genetic disorder.

Health screening: a procedure using medical radiological installations for early diagnosis in population groups at risk.

High activity sealed source: a sealed source in which the amount of radioactive material exceeds the values laid down in Annex 2.

Individual detriment: clinically observable deleterious effects that are expressed in individuals or their descendants, the appearance of which is either immediate or delayed and, in the latter case, implies a probability rather than a certainty of appearance.

Inspection: an investigation by any competent authority to verify compliance with national provisions.

Intake: the activities of radionuclides entering the body from the external environment.

Interventional radiology: the use of X ray imaging techniques, in addition to those involving ultrasound or magnetic resonance imaging, to introduce and guide devices in the body for diagnostic or treatment purposes.

Ionising radiation: the transfer of energy in the form of particles or electromagnetic waves of a wavelength of 100 nanometer or less (a frequency of 3 10^{15} Hertz or more) capable of producing ions directly or indirectly.

Licence: a permission granted by the competent authority, on application, to carry out a practice subject to conditions laid down in a specific licence document.

Medical physics expert: an individual having the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to medical exposure, whose competence to act is recognized by the competent authorities.

Medical exposure: exposure incurred by patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment, intended to benefit the health or the well-being of the exposed individual. Exposure incurred by carers and comforters and by volunteers in biomedical research.

Medical radiological: pertaining to radiodiagnostic and radiotherapeutic procedures, and interventional radiology or other planning and guiding radiology.

Medical radiological installation: a facility containing medical radiological equipment.

Medical radiological procedure: any procedure giving rise to medical exposure.

Members of the public: individuals subject to public exposure.

Natural radiation source: sources of ionising radiation from natural terrestrial or cosmic origin.

Non-medical imaging exposure: any deliberate exposure of humans for imaging purposes where the primary motivation for making the exposure is not related to the health or the well-being of the individual being exposed.

Normal exposure: exposure that is expected to occur under the normal operating conditions of a facility or activity (including maintenance, inspection, decommissioning), including possible minor mishaps that can be kept under control, i.e. during normal operation and anticipated operational occurrences.

Notification: submission of a document to the competent authority to notify the intention to carry out a practice within the scope of this Directive.

Occupational exposure: exposure of workers incurred in the course of their work.

Occupational health service: a health professional or body having the competence for medical surveillance of exposed workers, whose capacity to act in that respect is recognized by the competent authorities.

Orphan source: a sealed source which is neither exempted nor under regulatory control, e.g. because it has never been under regulatory control or because it has been abandoned, lost, misplaced, stolen or otherwise transferred without proper authorisation.

Outside worker: any exposed worker of category A, who is not employed by the undertaking responsible for the supervised and controlled area, but performs activities in these areas, including trainees, apprentices and students.

Planned exposure situation: a planned situation of exposure involving the deliberate introduction of a radiation source or of activities which alter exposure pathways so as to cause the exposure or potential exposure of people. Planned exposure situations may include both normal exposures and potential exposures.

Potential exposure: exposure that is not expected to be delivered with certainty but that may result from an event or sequence of events of a probabilistic nature, including equipment failures and operating errors.

Practical aspects (of medical exposure procedures): the physical conduct of a medical exposure and any supporting aspects including handling and use of medical radiological equipment, and the assessment of technical and physical parameters including radiation doses, calibration and maintenance of equipment, preparation and administration of radio-pharmaceuticals and image processing as carried out amongst others by radiographers, and technicians in nuclear medicine and radiotherapy.

Practice: any type of activity that introduces additional radiation sources or alters exposure pathways and which is managed as a planned exposure situation.

Practitioner: a medical doctor, dentist or other health professional, who is entitled to take clinical responsibility for an individual medical exposure in accordance with national requirements.

Projected dose: the dose that would be expected to be incurred if no protective measures were to be taken.

Protective measures: measures, other than remedial action, for the purpose of avoiding or reducing doses that might otherwise be received in an emergency exposure situation or an existing exposure situation.

Public exposure: exposure to individuals, excluding any occupational or medical exposure.

Quality assurance: all those planned and systematic actions necessary to provide adequate confidence that a structure, system, component or procedure will perform satisfactorily complying with agreed standards.

Quality control: the set of operations (programming, coordinating, implementing) intended to maintain or to improve quality. It covers monitoring, evaluation and maintenance at required levels of all characteristics of performance of equipment that can be defined, measured, and controlled. Quality control is a part of quality assurance.

Radiation generator: a device capable of generating ionising radiation, such as X rays, neutrons, electrons or other charged particles, which may be used for scientific, industrial or medical purposes.

Radiation protection expert: an individual having the knowledge, training and experience needed to give radiation protection advice in order to ensure effective protection of individuals, whose capacity to act is recognized by the competent authorities.

Radiation protection officer: an individual technically competent in radiation protection matters relevant for a given type of practice who is designated by the undertaking to oversee the implementation of the radiation protection arrangements of the undertaking.

Radiation source: an entity that may cause radiation exposure – such as by emitting ionising radiation or by releasing radioactive material – and can be treated as a single entity for protection and safety purposes.

Radioactive material: material incorporating radioactive substances;

Radioactive substance: any substance that contains one or more radionuclides the activity concentration of which cannot be disregarded as far as radiation protection is concerned.

Radioactive source: a radiation source incorporating radioactive material for the purposes of utilizing its radioactivity.

Radioactive waste: radioactive material for which no further use is foreseen.

Radiodiagnostic: pertaining to *in-vivo* diagnostic nuclear medicine, medical diagnostic radiology, and dental radiology.

Radiotherapeutic: pertaining to radiotherapy including nuclear medicine for therapeutic purposes.

Radon: the isotope Rn-222 and its progeny, where appropriate (exposure to radon means exposure to radon progeny).

Radon-prone area: a geographic area or administrative region defined on the basis of surveys indicating that the percentage of dwellings expected to exceed the national reference level is significantly higher than in other parts of the country.

Reference level: in an emergency exposure situation or in an existing exposure situation, the level of dose or risk, above which it is judged to be inappropriate to plan to allow exposures to occur, and below which optimisation of protection should continue to be implemented.

Referrer: a medical doctor, dentist or other health professional, who is entitled to refer individuals for medical exposure to a practitioner, in accordance with national requirements.

Registration: a permission granted in a document by the competent authority, or granted by national legislation, to carry out an activity in accordance with conditions laid down in national legislation.

Representative person: An individual receiving a dose that is representative of the more highly exposed individuals in the population.

Residual dose: the dose expected to be incurred from all exposure pathways after protective measures have been fully implemented, or in case a decision has been taken not to implement any protective measures.

Response strategy: set of different preventive and protective actions to respond to postulated or actual events so as to manage an emergency exposure situation in accordance with the stated objectives; within an emergency response plan, response strategies will be established for each postulated event and scenario.

Risk constraint: a constraint set as a restriction on the individual risk from a radiation source (risk in the sense of probability of health detriment due to a potential exposure, which is a function of the probability of an unintended event causing a dose, and the probability of detriment due to that dose).

Sealed source: a radioactive source in which the radioactive material is (a) permanently sealed in a capsule or (b) closely bonded in a solid form.

Sievert (Sv): the special name of the unit of equivalent or effective dose. One sievert is equivalent to one joule per kilogram: 1 Sv = 1 J kg^{-1}.

Source container: the containment of a sealed source not being an integral part of the source, but meant for shielding the source during its use, transport, handling, etc.

Storage: the holding of radioactive sources or radioactive waste in a facility that provides adequate containment, with the intention of retrieval.

Supplier: any natural or legal person who supplies or makes available a sealed source.

Supervised area: an area subject to appropriate supervision for the purpose of protection against ionising radiation.

Thoron: the isotope Rn-220.

Transfer: a transfer of a sealed source from one undertaking to another one.

Undertaking: a natural or legal person who has legal responsibility for carrying out a practice or who has legal responsibility for a radiation source (including cases where the owner or holder of a radiation source does not conduct related activities).

Unintended exposure: medical exposure that is significantly different to the one intended for a given purpose.

TITLE III

System of Radiation Protection

Article 5

Member States shall establish legal requirements and an appropriate regime of regulatory control which for all exposure situations within the scope of this Directive reflects a system of radiation protection based on the principles of justification, optimisation and dose limitation:

(a) Decisions introducing or altering a radiation source, an exposure pathway or actual exposures shall be justified: the decision shall be taken with the intent to ensure that the individual or societal benefit resulting from that decision shall offset the detriment that it may cause.

(b) In all exposure situations radiation protection shall be optimised with the intent that the magnitude and likelihood of exposures and the number of individuals exposed are kept as low as reasonably achievable, economic and societal factors being taken into account, while the optimisation of protection of individuals undergoing medical exposures shall be commensurate with the medical purpose of the exposure as described in Article 81.

(c) In planned occupational and public exposures, the sum of doses to an individual from all regulated radiation sources shall not exceed the dose limits laid down for occupational exposure and public exposure. Dose limits do not apply to medical exposures.

Dose related tools for optimisation

Article 6

Dose constraints for occupational and public exposure

In the optimisation of protection in planned exposure situations related to a given radiation source, dose constraints shall be established, as appropriate, for workers and members of the public.

(a) For occupational exposures, the dose constraint shall be an upper bound on the individual dose to define the range of protection options considered in the process of optimisation, to be established as an operational tool in cooperation between the employer and the undertaking under supervision of the competent authorities.

(b) For public exposure, the dose constraint shall be an upper bound on the individual dose that members of the public receive from the planned operation of a specified radiation source; competent authorities shall set constraints in such a way as to also ensure compliance with the dose limit for the sum of doses to the same individual from all authorised practices;

(c) With regard to potential exposures optimisation shall include adequate management of the safety and security of sources and facilities, and where appropriate risk constraints may be established.

(d) In general, dose constraints shall be established in terms of individual effective dose over a year or any other appropriate shorter time period; where appropriate dose constraints may apply to organ doses (in terms of equivalent doses), as a precautionary measure to allow for uncertainties on health detriment below the threshold for deterministic effects.

(e) Where dose constraints are introduced to restrict any protracted accumulated exposure, these shall be established in terms of annual effective dose or equivalent dose to an organ.

Article 7

Dose constraints for medical exposure

For medical exposure of patients, dose constraints do not apply. For comforters and carers and for volunteers participating in medical and biomedical research (for whom no direct medical benefit is expected from the exposure), dose constraints shall be established as a value of individual dose that is unlikely to be exceeded for the period of respective examination or treatment or research project.

Article 8

Reference levels for emergency and existing exposure situations

Reference levels shall be established as a level of effective or organ dose above which it is judged to be inappropriate to envisage exposures to occur in emergency or existing exposure situations. Optimised protective strategies shall be planned and implemented with the objective of reducing individual doses below the reference levels. The chosen values for reference levels shall depend upon the type of exposure situation under consideration. Optimisation of protection shall give priority to exposures above the reference level. The choice of a reference level should take into consideration both radiological protection requirements as well as societal criteria. The choice of reference levels of effective dose should take into account the three bands of reference levels described in Annex 1.

Dose limitation

Article 9

Age limit for exposed workers

Subject to Article 12 paragraph 2, persons under 18 years of age may not be assigned to any work which would result in their being exposed workers.

Article 10

Dose limits for occupational exposure

The limit on effective dose for occupational exposure shall be 20 millisievert (‘mSv’) in any single year. However, in special circumstances or for certain planned exposure situations specified in national legislation, a higher effective dose may be authorised in a single year, subject to a maximum effective dose of 50 mSv in any single year, provided that the average dose over any five consecutive years does not exceed 20 mSv per year, or for emergency workers subject to specific conditions laid down in Title VII.

Without prejudice to this dose limit:

(a) the limit on equivalent dose for the lens of the eye shall be X mSv[1] in a year;

(b) the limit on equivalent dose for the skin shall be 500 mSv in a year. This limit shall apply to the dose averaged over any area of 1 cm², regardless of the area exposed;

(c) the limit on equivalent dose for the hands, forearms, feet and ankles shall be 500 mSv in a year.

Article 11

1. As soon as a pregnant woman informs the undertaking of her condition, in accordance with national legislation or national practice, the protection of the child to be born shall be comparable with that provided for members of the public. The conditions for the pregnant woman in the context of her employment shall therefore be such that the equivalent dose to the child to be born will be as low as reasonably achievable and that it will be unlikely that this dose will exceed 1 mSv during at least the remainder of the pregnancy.

2. As soon as a breastfeeding woman informs the undertaking of her condition she shall not be employed in work involving a significant risk of incorporation of radionuclides.

Article 12

1. The dose limits for apprentices aged 18 years or over and students aged 18 years or over who, in the course of their studies, are obliged to work with radiation sources shall be the same as the dose limits for occupational exposure laid down in Article 10.

2. The limit for effective dose for apprentices aged between 16 and 18 years and for students aged between 16 and 18 years who, in the course of their studies, are obliged to work with radiation sources shall be 6 mSv per year. Without prejudice to this dose limit:

(a) the limit on equivalent dose for the lens of the eye shall be Y mSv[2] in a year;

(b) the limit on equivalent dose for the skin shall be 150 mSv in a year. This limit shall apply to the dose averaged over any area of 1 cm², regardless of the area exposed;

(c) the limit on equivalent dose for the hands, forearms, feet and ankles shall be 150 mSv in a year.

3. The dose limits for apprentices and students who are not subject to the provisions of paragraphs 1 and 2 shall be the same as the dose limits for members of the public specified in Article 13.

Article 13

Dose limits for public exposure

Without prejudice to the requirements for optimisation of protection, the limit on effective dose for public exposure shall be 1 mSv in a year.

Without prejudice to this dose limit:

(a) the limit on equivalent dose for the lens of the eye shall be Z mSv[3] in a year;

(b) the limit on equivalent dose for the skin shall be 50 mSv in a year averaged over any 1 cm² area of skin, regardless of the area exposed.

[1] The present dose limit for the lens of the eye of 150 mSv/y is currently under review by an ICRP task group.
[2] The present dose limit for the lens of the eye of 50 mSv/y is currently under review by an ICRP task group.
[3] The present dose limit for the lens of the eye of 15 mSv/y is currently under review by an ICRP task group.

Article 14

Estimation of effective and equivalent dose

For the estimation of effective and equivalent doses the following values and relationships shall be used:

(a) For external radiation, the values and relationships given in Annex 17 *[to be added later]* shall be used to estimate the relevant effective and equivalent doses;

(b) For internal exposure from a radionuclide or from a mixture of radionuclides, the values and relationships given in Annex 17 *[to be added later]* and ingestion and inhalation dose coefficients in the international basic safety standards published by IAEA shall be used to estimate the effective doses.

The competent authorities may allow the use of equivalent methods.

TITLE IV

RESPONSIBILITIES FOR REGULATORY CONTROL

Section 1

Institutional infrastructure

Article 15

Competent authority

1. Member States shall designate the competent authority or authorities to carry out tasks in accordance with this Directive.

2. Member States shall forward to the Commission the name and the address of the competent authority or authorities and their respective areas of competence for rapidly communicating with such authorities.

3. Where Member States have more than one competent authority for the control of high-activity sealed sources and orphan sources, they shall designate one point of contact to act as an interface with correspondents in other Member States.

4. Member States shall forward to the Commission any changes to the data referred to in paragraphs 2 and 3.

5. The Commission shall communicate the information referred to in paragraphs 2, 3 and 4 to all competent authorities in the Community and shall publish it periodically in the Official Journal of the European Union, at intervals of no more than two years.

Article 16

Recognition of services and experts

1. Member States shall make the necessary arrangements for the recognition of:

- occupational health services,
- dosimetry services,
- radiation protection experts,
- medical physics experts,

Member States shall ensure that the necessary arrangements are in place to ensure the continuity of expertise of these services and experts.

2. Member States shall specify the recognition requirements and communicate these to the Commission together with the name and address of the competent authorities, entrusted with the recognition. Member States shall communicate any changes to the data referred to in this paragraph.

3. Member States shall specify other services or experts requiring particular radiation protection qualifications and where appropriate the process for the recognition of such qualifications.

4. The Commission shall make the information received under paragraph 2 available to the Member States.

Article 17

Occupational Health Services

The occupational health services shall perform medical surveillance of workers with regard to their exposure to ionising radiation and their fitness for the tasks assigned to them.

Article 18

Dosimetry Services

Dosimetry services shall determine the internal and external dose to exposed workers subject to individual monitoring in order to establish the recorded dose in cooperation with the undertaking and the occupational health service. This includes the calibration, reading and interpretation of individual monitoring devices, and the measurement of radioactivity in the human body and in biological samples.

Article 19

Radiation Protection Expert

The Radiation Protection Expert shall, on the basis of professional judgement, measurements and assessments give competent advice to the undertaking on matters related to occupational exposure and public exposure. The advice shall include, but not be limited to, the following:

- plans for new installations and the acceptance into service of new or modified radiation sources in relation to any engineering controls, design features, safety features and warning devices relevant to radiation protection;
- the categorization of controlled and supervised areas;
- the classification of workers;
- the content of workplace and individual monitoring programmes;
- the appropriate radiation monitoring instrumentation to be used;
- the appropriate methods of personal dosimetry;
- the optimisation and the establishment of appropriate dose constraints,
- quality assurance, including quality control;
- the environmental monitoring programme;

- radioactive waste disposal requirements.
- the arrangements for prevention of accidents and incidents, preparedness and response in emergency exposure situations;
- training and retraining programs for exposed workers;

Where appropriate, the task of the Radiation Protection Expert can be carried out by a group of specialists together having the necessary expertise.

Article 20

Medical Physics Expert

1. Within the healthcare environment, the Medical Physics Expert shall, as appropriate, act or give specialist advice on matters relating to radiation physics applied to medical exposure.

2. Depending on the medical radiological practice, the Medical Physics Expert shall take responsibility for dosimetry, including physical measurements related to the evaluation of the dose delivered to the patient and contribute in particular to the following:

- the optimisation of radiation protection of patients and other individuals submitted to medical exposure, including the establishment and the use of diagnostic reference levels;
- the definition and performance of quality assurance tests of the medical radiological equipment;
- the preparation of technical specifications for medical radiological equipment and installation design;
- the surveillance of the medical radiological installations with regard to radiation protection;
- the selection of equipment required to perform radiation protection measurements and give advice on medical radiological equipment;
- the training of practitioners and other staff in relevant aspects of radiation protection.

Where appropriate, the task of the Medical Physics Expert can be carried out by a Medical Physics Service.

Article 21

Radiation Protection Officer

1. Member States shall require, where appropriate, the establishment of a radiation protection officer to perform radiation protection tasks within undertakings. Member States shall require that the undertaking provides to the radiation protection officers the means necessary for them to carry out their duties. The radiation protection officer shall report directly to the undertaking.

2. Depending on the nature of the practice, the tasks of the radiation protection officer may include the following:

- ensuring that work with radiation is carried out in accordance with the requirements of any specified procedures or local rules;
- oversee the implementation of the programme of workplace monitoring;
- maintain adequate records of radioactive sources held by the practice;

- carry out periodic assessments of the condition of the relevant safety and warning systems;
- oversee the implementation of the personal monitoring programme;
- oversee the implementation of the health surveillance programme;
- give new employees an introduction in local rules and procedures;
- give advice and comments on work plans;
- authorise work plans;
- provide reports to the local management.
- participate in the arrangements for prevention, preparedness and response for emergency exposure situations;
- liaison with the radiation protection expert;

Where appropriate, the task of the Radiation Protection Officer can be carried out by a radiation protection unit established within an undertaking.

Section 2

Control of sealed sources

Article 22

1. Member States shall make arrangements for keeping adequate control of sealed sources with regard to their location, use and disuse.

2. Member States shall require the undertaking to keep records of all such sources under its responsibility, their location and their transfer.

3. Member States shall set up a system to enable them to be adequately informed of individual transfers of sealed sources where necessary, but in any case of transfers of high activity sources.

4. Member States shall require each undertaking holding a sealed source promptly to notify the competent authority of any loss, theft or unauthorized use of a sealed source.

Article 23

Member States shall ensure that, before issuing authorisation for practices involving a high activity sealed source:

(a) adequate arrangements, including those arising from this Directive, have been made for the safe management and security of sources, including when they become disused sources. These latter arrangements may provide for the transfer of these sources to the supplier or their placement in a disposal or storage facility or an obligation for the manufacturer or the supplier to receive these sources;

(b) adequate provision, by way of a financial security or any other equivalent means appropriate to the source in question, have been made for the safe management of sources when they become disused sources, including the case where the undertaking becomes insolvent or goes out of business.

Article 24

In addition to the general licensing requirements in Title VI, Member States shall ensure that the licence for the manufacture, use or taking possession of a high activity sealed source covers:

a) minimum performance criteria for source, source container and additional equipment;

b) work procedures to be followed;

c) adequate management of disused sources, including agreements regarding the transfer, if appropriate, of disused sources to a manufacturer, a supplier, another authorised undertaking or a waste disposal or storage facility.

Article 25

Member States shall require that the records for high activity sealed sources shall include the information set out in Annex 3 and the undertaking shall provide the competent authorities with a copy of all or part of these records whenever so requested and at least in the situations set out in Annex 4. The undertaking's records shall be available for inspection by the competent authority.

Article 26

The competent authorities shall keep records of authorised undertakings and of the high activity sealed sources they hold. These records shall include the radionuclide involved, the activity at the time of manufacture, or if this activity is not known, the activity at the time of the first placing on the market or at the time the undertaking acquired the source, and the type of source. The competent authorities shall keep the records up to date, taking transfers into account, among other factors.

Article 27

1. The undertakings, except those operating facilities for the long-term storage and disposal of high activity sealed sources, shall check and maintain the integrity of the high activity sealed source and its location and shall ensure adequate control of the transfer of the source as specified in Annex 5.

2. The manufacturer, the supplier, and each undertaking shall ensure that the high activity sealed sources and containers comply with the requirements for identification and marking specified in Annex 6.

Section 3

Orphan sources

Article 28

1. Member States shall require any person encountering an orphan source to promptly notify the emergency organisation or the competent authority and to refrain from any further action on the source until these authorities have given appropriate instructions.

2. Member States shall make arrangements for the establishment of systems aimed at detecting orphan sources in places such as large metal scrap yards and major metal scrap recycling installations where orphan sources may generally be encountered, or at significant nodal transit points, wherever appropriate, such as customs posts.

3. Member States shall ensure that specialised technical advice and assistance is promptly made available to the persons, working in such places not normally involved in operations

subject to radiation protection requirements. The primary aim of advice and assistance shall be the protection of workers and members of the public from radiation and the safety of the source.

Article 29

Metal contamination

Member States shall require that a metal scrap recycling installation promptly notifies to the competent authority any melting of an orphan source and require that the contaminated metal not be further processed without authorisation by the competent authority.

Article 30

1. Member States shall ensure that the competent authorities are prepared, or have made provision, including assignment of responsibilities, to recover orphan sources and to deal with emergencies due to orphan sources and have drawn up appropriate response plans and measures.

2. Member States shall ensure that campaigns are organised, as appropriate, to recover orphan sources left behind from past practices.

The campaigns may include the financial participation of Member States in the costs of recovering, managing and disposing of the sources and may also include surveys of historical records of authorities, such as customs, and of undertakings, such as research institutes, material testing institutes or hospitals.

Article 31

Member States shall ensure that, on the basis of arrangements to be decided by Member States, a system of financial security is established or any other equivalent means to cover intervention costs relating to the recovery of orphan sources and which may result from implementation of the requirements set out in Article 30.

Section 4

Emergency exposure situations

Article 32

Emergency management system

1. Member States shall ensure that account is taken of the fact that emergencies may occur on its territory and that it may be affected by emergencies occurring outside its territory. Member States shall establish an emergency management system and ensure adequate administrative provisions to maintain such a system.

2. The emergency management system shall be designed to be commensurate with the results of a threat assessment and to be able to respond effectively to emergency exposure situations in connection with practices as well as with other unforeseen events including malevolent acts and the discovery of orphan sources.

3. The emergency management system shall arrange for the establishment of emergency response plans with the objective of avoiding deterministic effects in any individual in the affected population and at reducing the risk of stochastic effects, taking account of the general principles of radiation protection and the reference levels referred to in Title III. The emergency management system shall include the elements listed in Annex 11A.

Article 33

Emergency preparedness

1. Member States shall ensure that emergency response plans are established in advance for the various types of emergencies identified by the threat assessment.

2. Member States shall ensure that emergency response plans are tested, reviewed and revised to an appropriate extent at regular intervals.

3. The emergency response plans shall, where appropriate, incorporate relevant elements of the emergency management system referred to in Article 32.

4. The emergency response plans shall include the elements defined in Annex 11B

Article 34

International cooperation

1. Member States shall cooperate with other Member States or non-Member States in relation to possible emergencies on its own territory which may affect other Member States or non-Member States, in order to facilitate the organisation of radiological protection in these States.

2. Member States shall, in the event of an emergency occurring on its territory or being likely to have radiological consequences on its territory, establish relations to obtain cooperation with any other Member State or non-Member State which may be involved.

3. Member States shall promptly exchange information and cooperate with other relevant Member States or third countries and with relevant international organisations as regards loss, removal, theft or discovery of high activity sealed sources, other radioactive sources and radioactive material of concern and as regards related follow-up or investigations, without prejudice to relevant confidentiality requirements and relevant national regulations.

Section 5

Existing exposure situations

Article 35

1. Member States shall ensure that programmes are established to identify and evaluate existing exposure situations and to determine which occupational and public exposures are of concern from a radiation protection point of view.

2. The requirements for existing exposure situations shall apply to:

(a) Exposure due to contamination of areas by residual radioactive material from:

(i) Past activities that were never subject to regulatory control or were not regulated according to present requirements;

(ii) An emergency, after the emergency exposure situation has been declared ended, as provided for in the emergency management system;

(iii) Residues from past activities for which the undertaking is no longer legally accountable;

(b) Exposure to natural radiation sources, including:

(i) Indoor exposure to radon and thoron, in workplaces, dwellings and other buildings;

(ii) Indoor external exposure from building materials;

(c) Exposure to commodities incorporating

(i) radionuclides coming from contaminated areas specified in (a) or

(ii) naturally occurring radionuclides, in particular in foodstuffs, drinking water as well as in building materials;

(d) Other existing exposure situations which cannot be disregarded from a radiation protection point of view.

3. Member States may decide, allowing for the general principle of justification, that an existing exposure situation warrants no consideration of protective measures.

4. Existing exposure situations which are the legal responsibility of an undertaking and which are found to be of concern from a radiation protection point of view shall be subject to the relevant requirements for planned exposure situations.

Article 36

Establishment of strategies

1. Member States shall arrange for the establishment of strategies to ensure that existing exposure situations are managed appropriately and that the resources made available for their management are commensurate with the risks and with the effectiveness of protective measures.

2. The competent authority assigned to establish a strategy for managing an existing exposure situation shall ensure that the strategy contains:

(a) The objectives pursued by the strategy;

(b) Appropriate reference levels, taking into account the criteria laid down in Annex 1.

Article 37

Implementation

1. Member States shall assign responsibilities to a competent authority for the establishment and implementation of strategies for the management of existing exposures, and, as appropriate, to registrants, licensees and other parties involved in the implementation of remedial and protective measures, and provide as appropriate for the involvement of stakeholders in decisions regarding the development and implementation of strategies for managing exposures.

2. For all protective measures considered for the implementation of the strategy, their form, scale and duration shall be optimised.

3. The distribution of residual doses that has resulted from the implementation of the strategy shall be assessed; further efforts shall be considered aiming at reducing any exposures that are still above the reference level.

4. Throughout the implementation of the strategy, the competent authority shall on a regular basis:

(a) perform evaluations of the available remedial and protective measures for the achievement of the objectives and of the efficiency of planned and implemented measures;

(b) provide information to exposed individuals on the potential health risks and on the available means for reducing their own exposure;

(c) provide guidance for the management of exposures at the individual or local level;

(d) with regard to practices involving naturally occurring radioactive material that are not managed as a planned exposure situation, provide information to undertakings on appropriate means for monitoring concentrations and exposures and for taking corrective measures in the framework of overall health and safety requirements.

Article 38

Radon action plan

1. Member States shall establish an action plan to manage long term risks from radon exposures in dwellings, buildings with public access and workplaces for any source of radon ingress, whether from soil, building materials or water. The action plan shall take into account the issues specified in Annex 13.

2. Member States shall forward the action plan and information on any identified radon prone areas to the Commission. The action plan and information on radon prone areas shall be updated on a regular basis.

Section 6

System of enforcement

Article 39

Inspections

1. Member States shall establish a system or systems of inspection to enforce the provisions introduced in compliance with this Directive and to initiate surveillance and corrective action wherever necessary.

2. The competent authority shall establish a systematic inspection programme taking into account the potential magnitude and nature of the hazard associated with practices, general assessment of radiation protection issues within the practices and state of compliance with the provisions adopted pursuant to this Directive.

3. Member States shall ensure that the findings from each inspection are recorded and the reports communicated to the undertaking concerned.

4. The inspection programme and the main findings from its implementation shall be made available to the public.

5. The competent authority shall ensure that mechanisms are in place for the timely dissemination of information to relevant parties, including manufacturers and suppliers of sources and, where appropriate, international organisations, of protection and safety information concerning lessons learned from inspections and from reported incidents and accidents and related findings.

Article 40

Enforcement

1. Member States shall ensure that the competent authority has the authority to require the undertaking to take action to remedy deficiencies and prevent their recurrence or to withdraw, where appropriate, authorisation when the results of a regulatory inspection or another regulatory assessment indicate that the undertaking is not in compliance with the requirements adopted pursuant to this Directive.

2. Member States shall determine the penalties applicable to breaches of the national provisions adopted pursuant to this Directive.

3. The enforcement measures referred to in this article shall be effective and proportionate.

Title V

REQUIREMENTS FOR RADIATION PROTECTION EDUCATION, TRAINING AND INFORMATION

Article 41

Member States shall ensure that an adequate legislative and administrative framework is established for providing appropriate radiation protection education, training and information to all individuals whose tasks require specific competences in radiation protection. In particular, appropriate education, training and retraining shall be in place to allow the recognition of radiation protection experts, medical physics experts, occupational health services, and dosimetry services. Training, retraining and information of relevant individuals shall be repeated at appropriate intervals and documented.

Article 42

Information and training of exposed workers, apprentices and students

1. Member States shall require the undertaking to inform exposed workers, apprentices and students who are subject to occupational exposure on:

(a) the health risks involved in their work:

- the general radiation protection procedures and precautions to be taken and, in particular, those involved with operational and working conditions in respect of both the practice in general and each type of work station or job to which they may be assigned,
- the emergency response plans and procedures,
- the importance of complying with the technical, medical and administrative requirements;

(b) in the case of women, the importance of early declaration of pregnancy in view of the risks of exposure for the child to be born and the risk of contaminating a nursing infant after incorporation of radionuclides.

2. Member States shall require that the undertaking provides appropriate radiation protection training and information programmes for their personnel.

3. In addition to the information and training in the field of radiation protection specified in this article, the undertaking responsible for high activity sealed sources shall ensure that such training includes specific requirements for the safe management and security of high-activity sealed sources with a view to preparing the relevant workers adequately for any events, affecting their own safety or the radiation protection of other individuals. The information and training shall place particular emphasis on the necessary safety requirements and shall contain specific information on possible consequences of the loss of adequate control of high-activity sealed sources.

Article 43

Information and training of workers potentially exposed to orphan sources

Member States shall make arrangements to ensure that the management and workers in installations where orphan sources are most likely to be found or processed (e.g. large metal scrap yards and major metal scrap recycling plants), and the management and workers in significant nodal transit points (e.g. customs posts), are

(a) informed of the possibility that they may be confronted with a source;

(b) advised and trained in the visual detection of sources and of their containers;

(c) informed of basic facts about ionising radiation and its effects;

(d) informed about detection systems;

(e) informed of and trained in the action to be taken on site in the event of the detection or suspected detection of a source.

Article 44

Information and training to emergency workers

1. Member States shall ensure that emergency workers and any other person, who might be involved in the organisation of emergency assistance in the event of an emergency are given adequate and regularly updated information on the health risks their intervention might involve and on the precautionary measures to be taken in such an event; this information shall take into account the range of potential emergencies.

2. As soon as an emergency occurs, this information shall be supplemented appropriately, having regard to the specific circumstances.

3. Member States shall ensure that emergency workers receive regular training as foreseen in the emergency management system referred to in Article 32; this training shall include where appropriate suitable practical exercises.

4. Members States shall ensure that, complementary to the emergency response training in paragraph 3, the organisation responsible for the protection of emergency workers, as referred to in Article 56, paragraph 1(b) provides these workers with appropriate radiation protection training and information.

Article 45

Education, information and training in the field of medical exposure

1. Member States shall ensure that practitioners and those individuals involved in the practical aspects of medical exposure procedures have adequate education, information, theoretical and practical training for the purpose of medical radiological practices, as well as relevant competence in radiation protection.

For this purpose Member States shall ensure that appropriate curricula are established and shall recognize the corresponding diplomas, certificates or formal qualifications.

2. Individuals undergoing relevant training programmes may participate in practical aspects for the procedures mentioned in Article 82 paragraph 4.

3. Member States shall ensure that continuing education and training after qualification is provided and, in the special case of the clinical use of new techniques, the organisation of training related to these techniques and to the relevant radiation protection requirements.

4. Member States shall ensure that mechanisms are in place for the timely dissemination of appropriate information relevant to radiation protection in medical exposure on lessons learned from significant events.

5. Member States shall ensure the introduction of a course on radiation protection in the basic curriculum of medical and dental schools.

TITLE VI

JUSTIFICATION AND REGULATORY CONTROL OF PLANNED EXPOSURE SITUATIONS

Article 46

Justification

1. Member States shall ensure that new classes of practices resulting in exposure to ionising radiation are justified in advance of being first adopted or first approved.

2. Existing classes of practices shall be reviewed as to justification whenever new and important evidence about their efficacy or potential consequences is acquired.

Article 47

New types of apparatus or products

1. With regard to new types of apparatus or products:

(a) Member States shall require any undertaking intending to place on the market a new type of apparatus or product to provide the competent authorities with relevant information such as listed in Annex 7a to enable the authorities, on the basis of national requirements such as listed in Annex 7b, to decide whether the intended use is justified, to grant the manufacturer or importer with a type approval for the apparatus or product, and where appropriate permit its use as a consumer product outside regulated practices.

(b) The competent authorities may review the existing authorisations and type approvals on a regular basis, and if necessary withdraw the authorisation when there is new and important evidence on the efficacy or potential consequences of the use of the apparatus or product.

(c) The competent authorities shall inform the competent authorities of other Member States of the type approvals that have been granted and of the underlying documentation and assessment; competent authorities shall allow for such received information, as well as applicable European and international standards, in making their own decisions with regard to authorising or exempting the use of such types of apparatus or product[4].

Article 48

Member States shall prohibit the deliberate addition of radioactive substances in the production of foodstuffs, toys, personal ornaments and cosmetics, and the import or export of such goods shall be prohibited. Without prejudice to the EC legislation on food irradiation (Directive 1999/2/EC), practices involving activation of material resulting in an increase in the activity in the associated goods are deemed not to be justified.

Article 49

[4] Check relation with requirements from other EC Directives. Check the role of the Commission in the proposed information exchange.

Practices involving the deliberate exposure of humans for non-medical purposes

1. Member States shall ensure the identification, by means of surveys or by any other appropriate means, of practices involving non-medical imaging exposure, taking into account the list of such practices, as defined in Annex 16.

2. Member States shall ensure that special attention is given to the justification of practices involving non-medical imaging exposure, in particular

a) All types of practices involving non-medical imaging exposure, as indicated in Annex 16, shall be justified in advance before being generally accepted.

b) Each particular application of a generally accepted type of practice shall be justified in advance.

c) All individual non-medical imaging exposure procedures implemented by medical staff using medical radiological equipment (type A in Annex 16) shall be justified in advance taking into account the specific objectives of the procedure and the characteristics of the individual involved.

d) The general and the particular justification of practices involving non-medical imaging exposure, as specified in (a) and (b), shall be subject to periodic review by the competent authority.

3. Where a Member State has determined that a particular practice of deliberate non-medical exposure of humans is justified it shall ensure that:

(a) the practice is subject to authorisation

(b) requirements for the practice, including criteria for individual implementation, are established by the competent authority, in cooperation with other relevant agencies and professional bodies as appropriate.

(c) dose constraints are established for each practice. Such dose constraints shall be well below the dose limit for members of the public, including, whenever practicable, for procedures implemented by medical staff using medical equipment (Type A in Annex 16); for other practices (type B) the dose constraint shall satisfy the requirements of Article 6 (b).

(d) Relevant requirements of Title VIII, including those for equipment, optimisation, responsibilities and special protection during pregnancy, are met for procedures implemented by medical staff using medical radiological equipment.

(e) Informed consent of the individual to be exposed is sought, allowing for cases where the law enforcement bodies may proceed without consent according to national legislation.

(f) Alternative techniques which do not involve exposure to ionising radiation are available where the exposure is routinely carried out for security purposes.

Article 50

Identification of practices involving naturally occurring radioactive material

Member States shall ensure the identification, by means of surveys or by any other appropriate means, of practices involving naturally occurring radioactive material and leading to exposure of workers or of members of the public which cannot be disregarded from the radiation protection point of view, taking the list of industrial sectors in Annex 8 into account.

Article 51

Notification

1. Member States shall require all practices, including those practices identified according to Article 50, to be notified, except for justified practices involving the following:

(a) materials containing radioactive substances where the quantities of the activity involved do not exceed in total the exemption values set out in Annex 9 or higher values, for specific applications, authorised by the competent authorities that nevertheless satisfy the general criteria set out in Annex 9; or

(b) materials containing radioactive substances provided that the concentrations of activity per unit mass do not exceed the exemption values set out in column 3 of Table A or Table C of Annex 9 or higher values, for specific applications, authorised by the competent authorities that nevertheless satisfy the general criteria set out in Annex 9; or

(c) any cathode ray tube intended for the display of visual images, or other electrical apparatus operating at a potential difference not exceeding 30 kV, or any other apparatus or product which is of a type approved by the competent authorities of the Member State, provided that:

(i). it does not cause, in normal operating conditions, a dose rate exceeding 1 $\mu Sv \cdot h^{-1}$ at a distance of 0.1 m from any accessible surface of the apparatus; and

(ii). if it contains radioactive substances, that these substances are embedded in a capsule or fixed to a solid holder; and

(iii). conditions for disposal have been specified by the competent authorities.

2. Member States may exempt further types of practices from the requirement of notification subject to compliance with the general exemption criteria established in Annex 9, or in such cases where an assessment of the optimisation of protection shows that exemption is the best option.

3. Practices involving naturally occurring radioactive material, identified according to Article 50, producing or processing residues which are known to be recycled into identified building materials, are subject to notification if the activity concentration index as defined in Annex 15 in the resulting building materials is liable to exceed 1. The undertaking shall also in this case inform the user of the residue about the activity concentration of the residue.

4. In situations identified by Member States where there is concern that a practice identified according to Article 50 may lead to the presence of naturally occurring radionuclides in water liable to affect the quality of drinking water supplies, or affect any other exposure pathways, so as to be of concern from a radiation protection point of view, the competent authority may require that such practice shall be subject to notification irrespective of the provisions of paragraph 1(b).

5. For practices subject to notification, Member States shall specify the information to be provided by the undertaking so as to allow the competent authority to establish appropriate means of regulatory control,

Article 52

1. Member States shall require any notified practice to be subject to regulatory control commensurate with the magnitude and likelihood of exposures resulting from the practice, and commensurate with the extent by which regulatory control may have an impact on reducing such exposures or improving the safety of the installations.

2. Notified practices may be exempted from authorisation as specified in national law or as decided by the competent authority.

3. In case of moderate amounts of material as specified by Member States, the activity concentration values laid down in Annex 9 Table D (old exemption values) may be used for this purpose.

4. Notified practices which are not exempted shall be subject to authorisation through registration or licensing.

Article 53

Authorisation

1. In cases where a limited risk of exposure does not necessitate the examination of individual cases and the practice is undertaken in accordance with conditions laid down in national legislation, competent authorities may limit regulatory control to registration of the practice and an appropriate frequency of inspections.

2. Member States shall require licensing for the following practices:

(a) operation and decommissioning of any facility of the nuclear fuel cycle and exploitation and closure of uranium mining;

(b) the deliberate addition of radioactive substances in the production and manufacture of consumer goods and the import or export of such goods;

(c) the deliberate addition of radioactive substances in the production and manufacture of products, including medicinal products, and the import or export of such goods;

(d) the manufacture, use or taking possession of a high-activity sealed source;

(e) operation, decommissioning and closure of any facility for the processing, storage or disposal of radioactive waste;

(f) practices in which workers are liable to exceed an annual effective dose of 6 mSv in normal operations and under normal working conditions;

(g) practices discharging significant amounts of airborne or liquid effluent to the environment.

3. Member States shall require either registration or licensing of the following practices:

(a) the deliberate administration of radioactive substances to persons and, in so far as radiation protection of human beings is concerned, animals for the purpose of medical or veterinary diagnosis, treatment or research;

(b) the use of radiation generators or radioactive sources for industrial radiography or processing of products or research and the use of accelerators except electron microscopes.

(c) the use of radiation generators or radioactive sources for medical exposures;

(d) the manufacture and operation of electrical equipment emitting ionising radiation and operating at a potential difference of more than 30 kV, as well as the import or export of such equipment;

(e) practices in which workers are liable to exceed an annual effective dose of 1 mSv in normal operation and under normal working conditions.

(f) industries involving naturally occurring radioactive material identified by Member States as required in Article 50, and liable to lead to an effective dose to a member of the public equal to or exceeding 0.3 mSv per year.

4. Registration or licensing may be required for practices other than those listed in Article 53 paragraph 2 and paragraph 3.

Article 54

1. Member States shall require the provision of information commensurate with the nature of the practice and the risks involved. Upon acceptance of the information provided as part of a licence application, the Member State's competent authority may as appropriate grant a licence associated with conditions for the protection of workers, of patients, or of members of the public, or register the practice subject to compliance with legal requirements ;

(a) The licence application shall cover at least the following information:

- Responsibilities and organisational arrangements for protection and safety
- Staff competences, including information and training
- Design features of the installation and radiation sources
- Anticipated occupational and public exposures in normal operation
- Safety assessment of the activities and the installation in order to:
  - Identify the ways in which potential exposures or accidental and unintended medical exposures could be incurred
  - Estimate, to the extent practicable, the probabilities and magnitude of potential exposures
  - Assess the quality and extent of protection and safety provisions, including engineering features as well as administrative procedures.
  - Define the operational limits and conditions of operation
- Emergency procedures and communication links
- Maintenance, testing, inspection and servicing so as to ensure that the radiation source and the installation continue to meet the design requirements, operational limits and conditions of operation throughout their lifetime
- Management of radioactive waste and arrangements for the disposal of such waste in accordance with applicable regulatory requirements
- Management of disused sealed sources
- Quality assurance

(b) The licence shall include specific conditions so as to ensure that the relevant elements of the licence application are legally enforceable or to impose appropriate restrictions to the operational limits or conditions of operation, as well as the conduct of a formal documented implementation of the principle of optimisation.

(c) Where applicable, the licence shall include a discharge authorisation established according to the requirements laid down in Title IX for the authorisation of the release of liquid or airborne radioactive effluent to the environment.

2. Member states shall require the undertaking to promptly notify the occurrence of any significant event resulting or liable to result in the exposure of an individual beyond the operational limits or conditions of operation specified in licensing requirements with regard to occupational or public exposure or as defined by the authorities for medical exposure.

Article 55

Release from regulatory control

1. The disposal, recycling or reuse of radioactive materials arising from any authorised practice is subject to authorisation.

2. The materials for disposal, recycling or reuse may be released from the requirements of this Directive provided that the concentrations of activity per unit mass

(a) do not exceed the values set out in column 3 of Table A; or

(b) comply with specific clearance levels and associated requirements for specific materials or for materials originating from specific types of practices; these specific clearance levels, in addition to the general clearance levels referred to in (a), shall be established by the national competent authority following the general exemption criteria defined in Annex 9 and taking into account technical guidance provided by the Community.

3. For the clearance of materials containing naturally occurring radionuclides the values for the concentrations of activity per unit mass shall in general be those laid down in Table C of Annex 9; however:

(a) for practices subject to licensing as specified in Article 53 paragraph 3 (f) the dose criteria for clearance of naturally occurring radionuclides shall be complied with,

(b) for other licensed practices, in particular those belonging to the nuclear fuel cycle, the clearance levels shall comply with the dose criterion for clearance of materials containing artificial radionuclides,

(c) for authorised practices subject to notification as specified under Article 51 paragraph 3, the corresponding requirements for the placing on the market of building materials shall be complied with.

4. The deliberate dilution of radioactive residues, other than the mixing of materials that takes place in normal operations when radioactivity is not a consideration, shall not be permitted. The competent authority may however authorise in specific situations the mixing of radioactive residues containing naturally occurring radioactive material with other materials to promote the reuse and recycling of these materials and to reduce public exposure.

TITLE VII

PROTECTION OF WORKERS, APPRENTICES AND STUDENTS

Article 56

Responsibilities

1. The requirements for occupational exposure in this Title VII and in Title III Articles 10, 11, 12 (Dose limits for occupational exposure) shall apply to the protection of workers in any exposure situation in which their exposure at work or as the result of work is the legal responsibility of an undertaking or another legal person, including for instance:

(a) the employer of outside workers,

(b) the organisation responsible for the protection of emergency workers,

(c) the organisation responsible for the remediation of contaminated land, buildings and other constructions.

2. The responsibility of an undertaking for occupational exposure shall extend to apprentices and students who in the course of their studies are obliged to work with radiation sources and to individuals who are self-employed or work on a voluntary basis or for a charity organisation.

Article 57

Operational protection of workers

Operational protection of exposed workers shall be based on:

(a) prior evaluation to identify the nature and magnitude of the radiological risk to exposed workers

(b) implementation of the optimisation of radiation protection in all working conditions;

(c) classification of workers into different categories;

(d) implementation of control measures and monitoring relating to the different areas and working conditions, including, where necessary, individual monitoring;

(e) medical surveillance.

Article 58

1. The undertaking shall be responsible for assessing and implementing arrangements for the radiation protection of exposed workers.

2. Member States shall require the undertaking to consult a radiation protection expert on the examination and testing of protective devices and measuring instruments comprising in particular:

(a) prior critical examination of plans for installations from the point of view of radiation protection;

(b) the acceptance into service of new or modified radiation sources from the point of view of radiation protection;

(c) regular checking of the effectiveness of protective devices and techniques;

(d) regular calibration of measuring instruments and regular checking that they are serviceable and correctly used.

Article 59

Arrangements in workplaces

1. For the purposes of radiation protection, arrangements shall be made as regards all workplaces where there is a possibility of exposure to ionising radiation in excess of 1 mSv per year effective dose or an equivalent dose of one tenth of the dose limits for the lens of the eyes, skin and extremities laid down in Article 10 in Title III. Such arrangements must be appropriate to the nature of the installations and sources and to the magnitude and nature of the risks.

2. For practices involving naturally occurring radioactive material where the effective dose to workers is liable to exceed 6 mSv per year all requirements in Title VII shall apply. Where the effective dose to workers is less than or equal to 6 mSv per year the competent authorities shall at least require undertakings to keep exposures under review, taking into account the potential for protection to be improved or the potential for doses to increase over time or as a result of changes in the process or work instructions.

3. For undertakings operating aircraft where the effective dose of the crew to cosmic radiation is liable to exceed 6 mSv per year relevant requirements in Title VII shall apply. Where the effective dose to the crew is less than or equal to 6 mSv per year and liable to be above 1 mSv per year, the competent authorities shall at least require undertakings to keep exposures under review, taking into account the potential for doses to change over time or as a result of changes in the work arrangement. The undertakings shall take appropriate measures, in particular:

– to assess the exposure of the crew concerned,

– to take into account the assessed exposure when organizing working schedules with a view to reducing the doses of highly exposed crew,

– to inform the workers concerned of the health risks their work involves and their individual dose.

4. Arrangements in workplaces shall include a classification of workplaces into different areas, where appropriate, by reference to an assessment of the expected annual doses and the probability and magnitude of potential exposures.

5. A distinction shall be made between controlled areas and supervised areas. The competent authorities shall establish guidance on the classification of controlled and supervised areas which is relevant to particular circumstances.

6. The undertaking shall keep under review the working conditions in controlled and supervised areas.

Article 60

Requirements for controlled areas

1. The minimum requirements for a controlled area are as follows:

(a) the controlled area shall be delineated and access to it shall be restricted to individuals who have received appropriate instructions and shall be controlled in accordance with written procedures provided by the undertaking. Wherever there is a significant risk of the spread of radioactive contamination, specific arrangements shall be made, including access and exit of individuals and goods, and the monitoring of the contamination within the controlled area and in the adjacent area;

(b) taking into account the nature and extent of radiological risks in the controlled area, radiological surveillance of the working environment shall be organized in accordance with the provisions of Article 63;

(c) signs indicating type of area, nature of the sources and their inherent risks shall be displayed;

(d) working instructions appropriate to the radiological risk associated with the sources and the operations involved shall be laid down.

2. The implementation of these duties shall be carried out under the responsibility of the undertaking following consultations with the radiation protection expert.

Article 61

Requirements for supervised areas

1. The requirements for a supervised area are as follows:

(a) as a minimum, taking into account the nature and extent of radiological risks in the supervised area, radiological surveillance of the working environment shall be organized in accordance with the provisions of Article 63;

(b) if appropriate, signs indicating type of area, nature of the sources and their inherent risks shall be displayed;

(c) if appropriate, working instructions appropriate to the radiological risk associated with the sources and the operations involved shall be laid down.

2. The implementation of these duties shall be carried out under the responsibility of the undertaking following consultations with the radiation protection expert.

Article 62

Categorisation of exposed workers

1. For the purposes of monitoring and surveillance, a distinction shall be made between two categories of exposed workers:

(a) Category A: those exposed workers who are liable to receive an effective dose greater than 6 mSv per year or an equivalent dose greater than 3/10 of the dose limits for the lens of the eye, skin and extremities laid down in Article 10;

(b) Category B: those exposed workers who are not classified as exposed category A workers and who are liable to receive an effective dose greater than 1 mSv per year or an equivalent dose greater than the dose limits for the lens of the eye and the skin laid down in Article 13.

2. This distinction shall be made prior to employment for work that will be cause of exposure and be subject to regular review on the basis of working conditions and medical surveillance.

3. For emergency workers the distinction, where appropriate, shall have no effect on requirements for monitoring (Articles 63 – 68) as long as the workers are not involved in an actual emergency exposure situation.

Article 63

Monitoring of workplaces

1. The radiological surveillance of the working environment referred to in Articles 60 paragraph1 (b) and 61 paragraph 1 (a) shall comprise, where appropriate:

(a) the measurement of external dose rates, indicating the nature and quality of the radiation in question;

(b) the measurement of air activity concentration and surface density of contaminating radionuclides, indicating their nature and their physical and chemical states;

(c) the measurement of radon concentrations in the workplace.

2. The results of these measurements shall be recorded and shall be used, if necessary, for estimating individual doses, as provided for in Article 64 and in Article 66.

Article 64

Individual monitoring

1. Category A workers shall be systematically monitored based on individual measurements which are established by a dosimetry service. In cases where category A workers are liable to receive significant internal contamination or significant exposure of the lens of the eye or extremities an adequate system for monitoring should be set up; the competent authority may provide general guidance for identifying such workers.

2. Monitoring for category B workers shall be at least sufficient to demonstrate that such workers are correctly classified in category B. Member States may require individual monitoring and if necessary individual measurements, established by a dosimetry service, for category B workers.

3. In cases where individual measurements are impossible or inadequate, the individual monitoring shall be based on an estimate arrived at either from individual measurements

made on other exposed workers or from the results of the surveillance of the workplace provided for in Article 63.

Article 65

Monitoring in the case of accidental exposure

In the case of accidental exposure the relevant doses and their distribution in the body shall be assessed.

Article 66

Recording and reporting of results

1. A record containing the results of the individual monitoring shall be made for each exposed worker for whom such monitoring is performed.

2. For the purposes of paragraph 1 the following shall be retained during the working life involving exposure to ionising radiation of exposed workers, and afterwards until the individual has or would have attained the age of 75 years, but in any case not less than 30 years from the termination of the work involving exposure:

(a) a record of the exposures measured or estimated, as the case may be, of individual doses pursuant to Articles 76, 64, 65 and 77;

(b) in the case of exposures referred to in Articles 65 and 77, the reports relating to the circumstances and the action taken;

(c) the results of workplace monitoring used to assess individual doses where necessary.

3. Exposure referred to in Articles 76, 65 and 77 shall be recorded separately in the dose record referred to in paragraph 1.

4. Where the results of monitoring are used for the management of planned exposure situations, appropriate arrangements shall be made in the records for not including exposures attributed to an existing exposure situation (e.g. background external radiation or radon ingress from soil in case of industries processing naturally occurring radioactive material).

Article 67

1. The Member States shall require that the results of the individual monitoring required by Articles 64, 65 and 77 be:

(a) made available to the competent authorities, to the undertaking, and to the employer of outside workers;

(b) made available to the worker concerned in accordance with Article 68 paragraph 1;

(c) submitted to the occupational health services in order to interpret their implications for human health, as provided for in Article 69;

(d) submitted to a centralised national network (national dose register) established by the Member State;

(e) noted in an individual radiological monitoring document issued for every outside worker.

2. Member States shall determine the arrangements under which the results of individual monitoring are conveyed. [Placeholder for an ongoing development to propose a European Radiation Passport]

3. In the case of an accidental or emergency exposure, the results of individual monitoring shall be submitted without delay.

Article 68

1. Member States shall require that workers have access at their request to the results of their individual monitoring, including the results of measurements which may have been used in estimating them, or of the assessment of their doses made as a result of workplace measurements.

2. Member States shall facilitate the exchange amongst competent authorities, or occupational health services, or radiation protection experts, or dosimetry services within the European Community of all relevant information on the doses previously received by a worker in order to perform the medical examination prior to employment or classification as a category A worker pursuant to Article 70 and to control the further exposure of workers.

Article 69

Medical surveillance of exposed workers

1. The medical surveillance of exposed workers shall be based on the principles that govern occupational medicine generally.

2. Notwithstanding the overall responsibility of the undertaking and, in the case of outside workers of the employer, the medical surveillance of category A workers shall be the responsibility of occupational health services.

This medical surveillance must allow for ascertaining the state of health of workers under surveillance as regards their fitness for the tasks assigned to them. To this end the occupational health services must have access to any relevant information they require including the environmental conditions existing in the working premises.

3. Medical surveillance shall include:

(a) a medical examination prior to employment or classification as category A worker.

The purpose of this thorough examination shall be to determine the worker's fitness for a post as category A worker for which the worker is being considered;

(b) Periodic reviews of health.

The state of health of each category A worker shall be reviewed at least once a year, in order to determine whether they remain fit to perform their duties. The nature of these reviews, which can be performed as many times as the occupational health services considers necessary, shall depend on the type of work and on the individual worker's state of health.

4. The occupational health services may indicate the need for medical surveillance to continue after cessation of work for as long as they consider it necessary to safeguard the health of the person concerned.

Article 70

Medical classification

The following medical classification shall be adopted with respect to fitness for work as a category A worker:

(a) fit;

(b) fit, subject to certain conditions;

(c) unfit.

Article 71

No worker may be employed or classified for any period in a specific post as a category A worker if the medical findings deem the worker unfit for that specific post.

Article 72

Medical records

1. A medical record shall be opened for each category A worker and kept up to date so long as the worker remains a worker of that category. Thereafter it shall be retained until the individual has or would have attained the age of 75 years, but in any case not less than 30 years from the termination of the work involving exposure to ionising radiation.

2. The medical record shall include information regarding the nature of the employment, the results of the medical examinations prior to employment or classification as category A worker, the periodic reviews of health and the record of doses required by Article 66.

Article 73

Special surveillance

1. Special medical surveillance shall be provided in each case where 50 mSv annual effective dose or any of the organ dose limits laid down in Article 10 has been exceeded.

2. Subsequent conditions of exposure shall be subject to the agreement of the occupational health services.

Article 74

In addition to the medical surveillance of exposed workers provided for in Article 69, provision shall be made for any further action in relation to the health protection of the exposed individual considered necessary by the occupational health services such as further examinations, decontamination measures or urgent remedial treatment.

Article 75

Appeals

Member States shall lay down the procedure for appeal against the findings and decisions made in pursuance of Articles 70, 71 and 73.

Article 76

Protection of Outside workers

1. Member States shall ensure that the radiological monitoring system affords outside workers equivalent protection to that for workers employed on a permanent basis by the undertaking.

2. The undertaking shall be responsible either directly or through contractual agreements with the employer of outside workers, for the operational aspects of the radiation protection of outside workers.

3. In particular, the undertaking must

(a) check that the outside worker concerned has been passed as medically fit for the activities to be assigned to the worker;

(b) ensure that, in addition to the basic training in radiation protection referred to in Article 42, the outside worker has received specific training in connection with the characteristics of both the controlled area and the activities;

(c) ensure that the outside worker has been issued with the necessary personal protective equipment;

(d) also ensure that the outside worker receives individual exposure monitoring appropriate to the nature of the activities, and any operational dosimetric monitoring that may be necessary;

(e) ensure compliance with the system of protection as defined in Title III;

(f) ensure or take all appropriate steps to ensure that after every activity the radiological data of individual exposure monitoring of each outside worker within the meaning of Annex 10, Part A, paragraph 5, are recorded.

4. Employers of outside workers shall, either directly or through contractual agreements with the undertaking, ensure the radiation protection of their workers is in accordance with the relevant provisions of this Directive, and in particular:

(a) ensure compliance with the system of protection as defined in Title III;

(b) provide the information and training in the field of radiation protection referred to in Article 42;

(c) guarantee that their workers are subject to assessment of exposure and medical surveillance under the conditions laid down in Articles 63 to 74;

(d) ensure that the radiological data of the individual exposure monitoring of each of their workers within the meaning of Annex 10, part A, paragraph 4 to this Directive are kept up to date in the networks and individual documents referred to in Article 67.

5. Every outside worker shall be obliged to make his or her own contribution as far as practicable towards the protection that the radiological monitoring system referred to in Article 76 paragraph 1 is intended to afford him or her.

Article 77

Specially authorised exposures

1. In exceptional circumstances, excluding emergencies and evaluated case by case, the competent authorities may, where some specific operation so requires, authorize individual occupational exposures of some identified volunteer workers exceeding the dose limits set out in Article 10, provided that such exposures are limited in time, confined to certain working areas and within maximum exposure levels defined for the particular case by the competent authorities. The following conditions shall be taken into account:

(a) only category A workers as defined in Article 62 may be subject to specially authorized exposures;

(b) apprentices, students, pregnant women, and breastfeeding women if there is a risk of incorporation of radionuclides, shall be excluded from such exposures;

(c) the undertaking shall carefully justify these exposures in advance and thoroughly discuss them with the voluntary workers, their representatives, the occupational health services or the radiation protection expert;

(d) information about the risks involved and the precautions to be taken during the operation shall be provided to the relevant workers in advance;

(e) all doses relating to such exposures shall be separately recorded in the medical record referred to in Article 73 and the individual record referred to in Article 67.

2. The exceeding of dose limits as a result of specially authorized exposures shall not necessarily constitute a reason by the employer for excluding the worker from his or her usual occupation or relocating the worker, without the agreement of the worker.

3. The exposure of space crew above the dose limits shall be managed as a specially authorised exposure.

Article 78

Emergency occupational exposure

1. Emergency response organisations shall ensure that no emergency worker shall undertake actions resulting in doses in excess of 50 mSv, except in specific cases identified in the national emergency plan. In such cases appropriate reference levels above 50 mSv shall be defined. In exceptional situations, in order to save life, prevent severe radiation-induced health effects, or prevent the development of catastrophic conditions, a reference level above 100 mSv may be set.

2. Emergency response organisations shall ensure that emergency workers who are liable to undertake actions whereby 50 mSv may be exceeded are volunteers who have been clearly and comprehensively informed in advance of the associated health risk as well as on the available protection measures.

3. In the event of an actual emergency exposure, Member States shall require radiological monitoring and medical surveillance of emergency workers. Individual monitoring or assessment of the individual doses shall be carried out as appropriate to the circumstances.

Article 79

Radon in workplaces

1. Within the framework of the action plan, referred to in Article 38, Member States shall establish national reference levels for indoor radon concentrations, which shall not exceed an annual average of 1 000 Bq m^{-3} for workplaces.

2. Within the framework of the national action plan Member States shall ensure that radon measurements are carried out in workplaces located at ground floor or at basement level within radon prone areas and in specific types of workplaces as identified in the action plan.

3. Member States shall require undertakings in which the national reference level for existing workplaces is exceeded to take appropriate action in order to reduce radon concentrations or exposures, in accordance with the principle of optimisation laid down in Title III.

4. Where workplaces or specific rooms within a building continue to exceed the reference level despite the actions carried out as required in paragraph 3, the Member States shall apply the dose limits laid down in Article 10 and, where appropriate, the requirements set up for occupational exposure in planned exposure situations as laid down in Title VII.

TITLE VIII

PROTECTION OF PATIENTS AND OTHER INDIVIDUALS SUBMITTED TO MEDICAL EXPOSURE

Article 80

Justification

1. Medical exposure shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct benefits to health or well-being of an individual and the benefits to society, against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionising radiation.

Account shall also be taken of the radiation detriment from the exposure of the medical radiological staff and of other individuals.

In particular:

a) - all new types of practices involving medical exposure shall be justified in advance before being generally adopted,

- existing types of practices involving medical exposure shall be reviewed whenever new, important evidence about their efficacy or consequences is acquired.

(b) all individual medical exposures shall be justified in advance taking into account the specific objectives of the exposure and the characteristics of the individual involved.

If a type of practice involving a medical exposure is not justified in general, a specific individual exposure of this type could be justified in special circumstances, to be evaluated on a case-by-case basis and documented.

The referrer and the practitioner as specified by Member States, shall seek, where practicable, to obtain previous diagnostic information or medical records relevant to the planned exposure and consider these data to avoid unnecessary exposure.

(c) medical exposure for biomedical and medical research shall be examined by an ethics committee, set up in accordance with national procedures and/or by the competent authorities.

(d) Specific justification for medical radiological procedures to be performed as part of a health screening programme shall be carried out by the health authority in conjunction with appropriate professional bodies

2. Exposure of carers and comforters shall show a sufficient net benefit, taking into account also the direct health benefits to a patient, the benefits to the carer / comforter and the detriment that the exposure might cause.

3. Any medical radiological procedure on an asymptomatic individual, intended to be performed for early detection of disease shall be part of a health screening programme, or shall require specific documented justification for that individual by the practitioner, in consultation with the referrer, following guidelines from relevant professional bodies and competent authorities. Special attention shall be given to the provision of information to the patients, as required by Article 82 paragraph 3.

4. If an exposure can not be justified, it shall be prohibited.

Article 81

Optimisation

1. All doses due to medical exposure for radiodiagnostic and interventional radiology purposes shall be kept as low as reasonably achievable consistent with obtaining the required imaging information, taking into account economic and social factors.

For all medical exposure of individuals for radiotherapeutic purposes, exposures of target volumes shall be individually planned; taking into account that doses of non-target volumes and tissues shall be as low as reasonably achievable and consistent with the intended radiotherapeutic purpose of the exposure.

2. Member States shall:

(a) promote the establishment, the regular review and the use of diagnostic reference levels for radiodiagnostic examinations, and when appropriate, for interventional radiology procedures, and the availability of guidance for this purpose having regard to European diagnostic reference levels where available;

(b) ensure that for each biomedical and medical research project:

- the individuals concerned shall participate voluntarily,

- these individuals shall be informed about the risks of this exposure,

- a dose constraint is established for individuals for whom no direct medical benefit is expected from this exposure,

- in the case of patients who voluntarily accept to undergo an experimental diagnostic or therapeutic practice and who are expected to receive a diagnostic or therapeutic benefit from this practice, the involved levels of doses shall be considered on an individual basis by the practitioner and/or referrer.

3. The optimisation process shall include the selection of equipment, the consistent production of adequate diagnostic information or therapeutic outcome as well as the practical aspects, quality assurance including quality control and the assessment and evaluation of patient and staff doses or administered activities, taking into account economic and social factors.

4. Member States shall ensure that:

(a) dose constraints are established for exposure of carers and comforters;

(b) appropriate guidance is established for exposure of carers and comforters;

(c) in the case of a patient undergoing a treatment or diagnosis with radionuclides, where appropriate the practitioner or the undertaking provides the patient or legal guardian with written instructions, with a view to the restriction of doses to persons in contact with the patient as far as reasonably achievable and to provide information on the risks of ionising radiation.

These instructions shall be handed out before leaving the hospital or clinic or a similar institution.

Article 82

Responsibilities

1. The referrer as well as the practitioner shall be involved as specified by Member States in the justification process at the appropriate level.

2. Member States shall ensure that any medical exposure is effected under the clinical responsibility of a practitioner.

3. The practitioner shall ensure that the patient or legal guardian is provided with adequate information relating to the benefits and risks associated with the radiation dose from the

medical exposure to enable informed consent. Similar information as well as relevant guidance as provided under Article 81 paragraph 4(b) shall be given to carers and comforters.

4. The practical aspects of the medical exposure procedure or part of it may be delegated by the undertaking or the practitioner, as appropriate, to one or more individuals entitled to act in this respect in a recognized field of specialization.

Article 83

Procedures

1. Written protocols for every type of standard medical radiological procedure shall be established for each equipment.

2. Member States shall ensure that recommendations concerning referral criteria for medical exposure of patients, including radiation doses, are available to the referrers to medical exposure.

3. In medical radiological practices, a medical physics expert shall be appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice. In particular:

(a) In radiotherapeutic practices, other than standardized therapeutic nuclear medicine practices, a medical physics expert shall be closely involved.

(b) In standardized therapeutical nuclear medicine and diagnostic practices, in radiodiagnostic and interventional radiology practices, a medical physics expert shall be involved.

(c) For other simple radiodiagnostic procedures, a medical physics expert shall be involved, as appropriate, for consultation and advice on matters relating to radiation protection concerning medical exposure.

4. Clinical audits shall be carried out in accordance with national procedures.

5. Member States shall ensure that appropriate local reviews are undertaken whenever diagnostic reference levels are consistently exceeded and that corrective actions are taken where appropriate.

Article 84

Training

Member States shall ensure that training and recognition requirements, as defined in Articles 16, 41 and 45, are met for the practitioner, the medical physics expert and those individuals referred to in Article 82 paragraph 4.

Article 85

Equipment

1. Member States shall take such steps as they may consider necessary with a view to avoiding unnecessary proliferation of medical radiological equipment.

2. Member States shall ensure that:

- all medical radiological equipment in use is kept under strict surveillance regarding radiation protection,

- an up-to-date inventory of medical radiological equipment for each medical radiological installation is available to the competent authorities,

- appropriate quality assurance programmes including quality control measures and dose or administered activity assessments are implemented by the undertaking, and

- acceptance testing, involving the medical physics expert, is carried out before the first use of the equipment for clinical purposes, and thereafter performance testing on a regular basis, and after any major maintenance procedure.

3. Competent authorities shall take steps to ensure that necessary measures are taken by the undertaking to improve inadequate or defective features of the equipment. They shall also adopt specific criteria of acceptability for equipment in order to indicate when appropriate remedial action is necessary, including, if appropriate, taking the equipment out of service.

4. The use of fluoroscopy equipment without a device to control the dose rate, or without an image intensifier or equivalent device, is not justified and shall therefore be prohibited.

5. Any system used for interventional radiology and computed tomography shall have a device informing the practitioner of the quantity of radiation produced by the equipment during the medical radiological procedure. Any other medical radiodiagnostic equipment brought into use after this Directive has been brought into force shall have such a device or equivalent means of determining the quantity of radiation produced. In this case the radiation dose shall form part of the report on the examination.

Article 86

Special practices

1. Member States shall ensure that appropriate medical radiological equipment, practical techniques and ancillary equipment are used for the medical exposure

- of children,

- as part of a health screening programme,

- involving high doses to the patient, such as interventional radiology, computed tomography or radiotherapy.

Special attention shall be given to the quality assurance programmes, including quality control measures and the assessment of dose or administered activity, as mentioned in Article 85 paragraph 2, for these practices.

2. Member States shall ensure that practitioners and those individuals referred to in Article 82 paragraph 4 performing the exposure referred to in paragraph 1 obtain appropriate training on these medical radiological practices as required by Article 45.

Article 87

Special protection during pregnancy and breast feeding

1. In the case of a woman of childbearing age, the referrer and the practitioner shall inquire as specified by Member States whether she is pregnant, or breastfeeding, if relevant; and

If pregnancy cannot be excluded, depending on the type of medical exposure, in particular if abdominal and pelvic regions are involved, special attention shall be given to the justification, particularly the urgency, and to the optimisation of the medical exposure taking into account the exposure both of the expectant mother and the unborn child.

2. In the case of breastfeeding women, in nuclear medicine depending on the type of medical examination or treatment, special attention shall be given to the justification, particularly the urgency, and to the optimisation of the medical exposure, taking into account the exposure both for the mother and the child.

3. Without prejudice to paragraph 1 and 2, Member States shall take measures contributing to increasing the awareness of women subject to this Article, such as public notices in appropriate places.

Article 88

Accidental and unintended exposures

Member States shall ensure that

(a) all reasonable steps to minimize the probability and the magnitude of accidental or unintended exposures of patients from all medical radiological procedures are taken, economic and social factors being taken into account.

(b) for radiotherapeutic practices the quality assurance programme includes a study of risk of accidental or unintended exposures.

(c) for all medical exposures the undertaking implements a registration and analysis system of events involving or potentially involving accidental or unintended exposures.

(d) the undertaking declares as soon as possible to the competent authorities the occurrence of significant events as defined by the authorities, including the results of the investigation and the corrective measures to avoid such events.

(e) arrangements are made to inform the referrer, the practitioner and the patient about an unintended or accidental exposure.

Article 89

Estimates of population doses

Member States shall ensure that the distribution of individual dose estimates from medical exposure is determined and shall take into account the age distribution and the gender of the exposed population.

TITLE IX

PROTECTION OF THE MEMBERS OF THE PUBLIC

Article 90

Member States shall create the conditions necessary to ensure the best possible protection of members of the public under the prevailing circumstances based on the principles set out in Title III System of protection and to apply the requirements laid down in this title.

Article 91

1. Operational protection of the members of the public in normal circumstances from practices subject to licensing means all arrangements and surveys for detecting and eliminating the factors which, in the course of any operation involving exposure to ionising

radiation, are liable to create a risk of exposure for the population which cannot be disregarded from the radiation protection point of view. Such protection shall include the following tasks:

(a) examination and approval of plans for installations involving an exposure risk, and of the proposed siting of such installations within the territory concerned, from the point of view of radiation protection;

(b) acceptance into service of such new installations subject to adequate protection being provided against any exposure or radioactive contamination liable to extend beyond the perimeter, taking into account, if relevant, demographic, meteorological, geological, hydrological and ecological conditions;

(c) examination and approval of plans for the discharge of radioactive effluents.

These tasks shall be carried out in accordance with rules laid down by the competent authorities on the basis of the extent of the exposure risk involved.

2. The competent authority shall establish authorised limits for discharging radioactive effluents: these discharge authorisations shall

(a) take into account the results of the optimisation of public exposure

(b) reflect good practice in the operation of similar facilities

(c) allow margin for operational flexibility of a facility.

Article 92

Member States shall, on the basis of the extent of the exposure risk involved, establish a system for the estimation of doses to members of the public from planned exposure situations.

The competent authorities shall identify practices where a realistic assessment of doses to members of the public shall be done. For other practices a screening assessment with generic data may be sufficient.

For the realistic assessments of doses the competent authority shall:

(a) ensure that dose estimates from practices referred to in Article 91 are made as realistic as possible for representative persons;

(b) decide on the frequency of assessments and take all necessary steps to identify the representative person, taking into account the effective pathways of transmission of the radioactive substances;

(c) ensure, taking into account the radiological risks, that the estimates of doses to members of the public include:

– assessment of the doses due to external radiation, indicating, where appropriate, the quality of the radiation in question,

– assessment of the intake of radionuclides, indicating the nature of the radionuclides and, where necessary, their physical and chemical states, and determination of the activity and concentrations of these radionuclides,

– assessment of the doses that the representative person is liable to receive and specification of the characteristics of the representative person.

(d) require records to be kept and be made available to all stakeholders relating to measurements of external exposure, estimates of intakes of radionuclides and radioactive contamination as well as the results of the assessment of the doses received by the representative person.

Article 93

1. Member States shall require the undertaking responsible for practices where a discharge authorisation is granted to monitor appropriately the radioactive airborne or liquid discharges into the environment and to report the results of this monitoring to the competent authority.

2. Member states shall require any undertaking responsible for a nuclear power reactor or reprocessing plant to monitor discharges in normal operation in agreement with the standardised information selected for monitoring and reporting to the European Commission as laid down in Commission Recommendation 2004/2/Euratom[5].

Article 94

1. Member States shall require the undertaking to carry out the following tasks:

(a) achieving and maintaining an optimal level of protection;

(b) checking the effectiveness and maintenance of technical devices;

(c) acceptance into service, from the point of view of surveillance of radiation protection, of equipment and procedures for measuring and assessing, as appropriate, exposure of members of the public and radioactive contamination of the environment;

(d) regular calibration of measuring instruments and regular checking that they are serviceable and correctly used.

2. Radiation protection experts and, as appropriate, radiation protection officers shall be involved in the discharge of these duties.

Article 95

Member States shall ensure that an appropriate environmental monitoring programme is in place for the purpose of estimating the exposure of members of the public.

Emergency exposure situations

Article 96

Emergency response

1. Member States shall make provision for the immediate notification to its competent authorities by the undertaking responsible for a practice of any emergency occurring in its facility or related to its activities and shall require the undertaking to take all appropriate action to reduce the consequences.

2. Member States shall ensure that in the event of an emergency on its own territory, the undertaking makes an initial provisional assessment of the circumstances and consequences of the emergency and assists with protective measures.

3. Member States shall ensure that provision is made for protective measures related to:

– the radiation source, to reduce or stop the direct radiation and emission of radionuclides, or to prevent exposure or contamination resulting from orphan sources,

– the environment, to reduce the transfer of radioactive substances to individuals,

– individuals, to reduce exposure.

[5] OJ L 2/36 of 6.1.2004

4. In the event of an emergency on or outside its territory, the Member State or the emergency response organisation shall require:

(a) the organisation of appropriate protective measures, taking account of the real characteristics of the emergency and in accordance with the optimised protection strategy as part of the emergency response plan [refer to Annex 11 B];

(b) the assessment and recording of the consequences of the emergency and of the effectiveness of the protective measures.

5. The Member State or the emergency response organisation shall, if the situation so requires, ensure that provision is made to organise the medical treatment of victims.

Article 97

1. Member States shall ensure that the population likely to be affected in the event of an emergency is given information about the health protection measures applicable to it and about the action it should take in the event of such an emergency.

2. The information supplied shall at least include the elements set out in Annex 12A.

3. This information shall be communicated to the population referred to in paragraph 1 without any request being made.

4. Member States shall update the information and circulate it at regular intervals and whenever significant changes in the arrangements that it describes take place. This information shall be permanently available to the public.

Article 98

1. Member States shall ensure that, when an emergency occurs, the population actually affected is informed without delay of the facts of the emergency, of the steps to be taken and, as appropriate to the case in point, of the health protection measures applicable to it.

2. The information provided shall cover the points contained in Annex 12B which are relevant to the type of emergency.

Existing exposure situations

Article 99

Contaminated areas

1. Strategies for managing contaminated areas shall include, where applicable, the following:

(a) delineation of the affected regions and identification of the affected population;

(b) consideration of the need for and extent of protective measures applied to the affected regions and populations;

(c) consideration of the need to prevent or control access to, or to impose restrictions on living conditions in the affected regions;

(d) assessment of the exposure of different groups in the population and of the means available to individuals for controlling their own exposure;

(e) objectives and long-term goals pursued by the strategy and corresponding reference level.

2. For areas with long-lasting residual contamination in which the Member State has decided to allow habitation and the resumption of social and economic activities, Member States shall ensure, in consultation with stakeholders that arrangements are in place, as necessary, for the ongoing control of exposure with the aim of establishing living conditions that can be considered as normal, including:

(a) Establishment of reference levels consistent with day-to-day life;

(b) Establishment of an infrastructure to support continuing self-help protective measures in the affected areas, such as information provision, advice and monitoring.

Article 100

Radon in dwellings and buildings with public access

1. Within the framework of the action, referred to in Article 38, plan Member States shall establish national reference levels for indoor radon concentrations, which shall not exceed (as an annual average):

200 Bq m^{-3} for new dwellings and new buildings with public access

300 Bq m^{-3} for existing dwellings

300 Bq m^{-3} for existing buildings with public access, allowing for the occupancy time with a maximum of 1 000 Bq m^{-3}.

2. Within the framework of the national action plan Member States shall

(a) Take action to identify existing dwellings exceeding the reference level and to encourage radon reducing measures in existing dwellings where the reference levels are exceeded

(b) Ensure that radon measurements are carried out in buildings with public access within radon prone areas.

3. Member States shall establish specific building codes to prevent radon ingress from the soil and, as specified in the national action plan, from building materials, and require compliance with such building codes, in particular in radon prone areas, so as to avoid radon concentrations exceeding the reference level for new buildings.

4. Member States shall provide local and national information on prevailing radon concentrations, on the associated health risks and on the available technical means for reducing existing radon concentrations.

Article 101

Building materials

1. The requirements in Article 101 paragraphs 2 - 7 shall apply to the following:

- building materials which are identified and listed by the relevant competent authority as being of concern from the radiation protection point of view, taking into account the indicative list of materials set out in Annex 14 with regard to their emitted gamma radiation, or,

- building materials which the authority has assessed to be of concern in the national action plan for radon, as specified in Article 38.

2. For identified types of building materials the industries placing such materials on the market

(a) shall determine the concentrations of the radionuclides specified in Annex 15;

(b) shall provide information to the competent authority on the results of measurements and of the corresponding activity concentration index, as defined in Annex 15.

3. The competent authority shall make arrangements for the classification of identified types of building materials, as laid down in Annex 15, on the basis of their intended use and activity concentration index.

4. Identified types of building materials which are not liable to give doses exceeding the reference level of 1 mSv per year for indoor external exposure from building materials, in excess of prevailing outdoor external exposure, are exempted from requirements at national level, without prejudice to Article 38, except for appropriate further monitoring of activity concentrations if so required.

5. Building materials which are of category A as specified in Annex 15 shall be exempted from any restrictions with regard to their placing on the market in the European Union.

6. For identified types of building materials which are liable to give doses exceeding the reference level of 1 mSv per year for indoor external exposure from building materials, in excess of the prevailing outdoor external exposure, the competent authority shall decide on appropriate measures ranging from registration and general application of relevant building codes, to specific restrictions on the envisaged use of such materials.

7. Information on identified types of building materials, relevant to the implementation of building codes, including their radionuclide concentrations, activity concentration index and corresponding classification, shall be made available prior to their placing on the market.

TITLE X

PROTECTION OF THE ENVIRONMENT

Article 102

Member States shall include, in the legal framework for radiation protection, provision for the radiation protection of non-human species in the environment; this legal framework shall introduce environmental criteria aiming at the protection of populations of vulnerable or representative non-human species with regard to their significance as part of the ecosystem. Where appropriate, practices shall be identified for which regulatory control is warranted in order to implement the requirements in this legal framework and take account of appropriate environmental assessment criteria.

Article 103

Member States' competent authorities, when establishing authorised limits on discharges of radioactive effluents, in accordance with Article 91 paragraph 2, shall also ensure adequate protection of non-human species; for this purpose a generic screening assessment may be conducted to provide reliance that the environmental criteria are met.

Article 104

Member States shall require undertakings to take appropriate technical measures with the aim to avoid that in the event of an accidental release there will be significant environmental damage, or to mitigate the extent of such consequences.

Article 105

While establishing environmental monitoring programmes, or requiring such programmes to be carried out, Member States' competent authorities shall include representative non-human species, if necessary, in addition to such environmental media which constitute a pathway of exposure to members of the public.

Annex 1

Bands of reference levels for public exposure expressed in residual effective dose and corresponding societal criteria for existing and emergency exposure situations

Without prejudice to reference levels set for organ doses, reference levels expressed in effective dose shall be set in the range of 1 to 20 mSv per year for existing exposure situations and 20 to 100 mSv for emergency exposure situations.

In specific situations a reference level below these ranges shall be considered, in particular:

- in an emergency exposure situation where appropriate protection can be provided without causing a disproportionate detriment from the corresponding countermeasures or an excessive cost, a reference level below 20 mSv;
- a reference level below 1 mSv per year may be set, where appropriate, for specific source-related exposures or pathways of exposure, within an existing exposure situation.

For the transition of an emergency exposure situation to an existing exposure situation appropriate reference levels shall be set, in particular for the termination of long-term countermeasures such as relocation.

Reference levels shall be established allowing for the features of the prevailing situations as well as for societal criteria, which may include the following:

- for exposures below 1 mSv or 1 mSv per year, general information on the level of exposure, without specific consideration of individual exposures;
- in the range up to 20 mSv or 20 mSv per year, specific information to enable individuals to manage their own exposure, if possible;
- in the range up to 100 mSv or 100 mSv per year, assessment of individual doses and specific information on radiation risks and on available actions to reduce exposures.

Annex 2

Activity values defining high activity sealed sources

For radionuclides not listed in the table below, but referred to in Annex 9, Table D, the relevant activity level is one hundredth of the corresponding A1 value given in the IAEA Regulations for the safe transport of radioactive materials (1).

Radionuclide	***Activity level (TBq)***
Am-241	1E-01[(b)]
Cf-252	5E-04
Co-60	4E-03
Cs-137	2E-02[(a)]
Gd-153	1E-01
I-125	2E-01
Ir-192	1E-02
Kr-85	1E-01
Pm-147	4E-01
Pu-238	1E-01[(a)]
Ra-226	2E-03[(b)]
Se-75	3E-02
Sr-90 (Y-90)	3E-03[(a)]
Tm-170	3E-02
Fe-55	4E-01
Pd-103	4E-01[(a)]
Tl-204	1E-01

(a) The activity level includes contributions from progeny with half-lives less than 10 days.

(b) Includes neutron sources with beryllium.

Annex 3

Standard record sheet for high activity sealed sources

[see separate file]

Annex 4

Access to the high activity sealed sources data

The undertaking shall provide the competent authority with an electronic or written copy of the records referred to in Article 25 and Annex 3 as follows:

- without undue delay, at the time of the establishment of such records, which should be as soon as possible after the source is acquired,
- at intervals, to be determined by Member States/competent authorities, of not more than 12 months thereafter,
- if the situation indicated on the information sheet has changed,
- without undue delay on the closure of the records for a specific source when the undertaking no longer holds this source; in this case the name of the undertaking or waste disposal and storage facility to which the source is transferred shall be included,
- without undue delay on the closure of such records when the undertaking no longer holds any sources.

Annex 5

Requirements for undertakings

Each undertaking, responsible for a high activity sealed source shall:

(a) ensure that suitable tests, such as leak tests based on international standards, are undertaken regularly in order to check and maintain the integrity of each source;

(b) regularly verify, at specific intervals which may be determined by Member States, that each source and, where relevant, the equipment containing the source, is still present and in apparently good condition at its place of use or of storage;

(c) ensure that each fixed and mobile source is subject to adequate documented measures, such as written protocols and procedures, aimed at preventing unauthorised access to or loss or theft of the source or its damage by fire;

(d) promptly notify the competent authority of any loss, theft or unauthorised use of a source, arrange for a check on the integrity of each source after any event, including fire, that may have damaged the source and, if appropriate, inform the competent authority thereof and of the measures taken;

(e) return each disused source to the supplier or place it in a recognised installation or transfer it to another authorised undertaking unless otherwise agreed by the competent authority, without undue delay after termination of the use;

(f) ascertain that, before a transfer is made, the recipient holds appropriate authorisation;

Annex 6

Identification and marking of high activity sealed sources

1. Each high activity sealed source is identified by a unique number. This number shall be engraved or stamped on the source, where practicable.

This number shall also be engraved or stamped on the source container. If this is not feasible or in the case of reusable transport containers, the source container shall at least have information on the nature of the source.

The manufacturer or the supplier shall ensure that the source container and, where practicable, the source are marked and labelled with an appropriate sign to warn people of the radiation hazard.

The manufacturer shall provide a photograph of each manufactured source design type and of the typical source container.

2. The undertaking shall ensure that each high activity sealed source is accompanied by written information indicating that the source is identified and marked in compliance with point 1 and that the markings and labels referred to in point 1 remain legible. The information shall include photographs of the source, source container, transport packaging, device and equipment as appropriate.

Annex 7

Placing on the market of apparatus or products

a) Any undertaking intending to place on the market apparatus or products provides the competent authorities with all relevant information as to the:

- technical characteristics of the apparatus
- in case of apparatus containing radioactive substances, information on the means of fixation of the source in a holder and on shielding
- dose rates at relevant distances for the use of the apparatus or product, including dose rates at a distance of 0.1 m of any accessible surface
- intended use of the apparatus or product, information on the relative performance of the new apparatus or product compared to existing ones
- expected doses to regular users of the apparatus.

b) The competent authorities will make an assessment of the above information and in particular assess:

- whether the performance of the apparatus or product justifies its intended use;
- whether the design is adequate in order to reduce the exposures in normal use and the likelihood and consequences of misuse or accidental exposures;
- in case of consumer products, whether the product is adequately designed and does not necessitate specific precautions for disposal when it is no longer in use;
- in case of apparatus or products for use in practices, whether conditions for disposal are adequate;
- whether the apparatus or product is appropriately labelled and suitable documentation is provided to the customer with instructions for proper use and disposal.

Annex 8
List of industrial sectors involving naturally occurring radioactive material

When applying Article 50 the following list of industrial sectors involving naturally occurring radioactive material, including relevant secondary processes, shall be taken into account:

- Extraction of rare earths from monazite
- Production of thorium compounds and manufacture of thorium-containing products
- Processing of niobium/tantalum ore
- Oil and gas production
- Geothermal energy production
- TiO_2 pigment production
- Thermal phosphorus production
- Zircon and zirconium industry
- Production of phosphate fertilisers
- Cement production, maintenance of clinker ovens
- Coal-fired power plants, maintenance of boilers
- Phosphoric acid production,
- Primary iron production,
- Tin/lead/copper smelting,
- Ground water filtration facilities,
- Mining of ores other than uranium ore.

Annex 9

Exemption and clearance criteria

1. Exemption

Justified practices may be exempted from the requirements of notification and authorisation either directly, on the basis of compliance with numerical exemption criteria (exempt activity values (Bq) or exempt concentration values (Bq/g)) laid down in this Annex (section 2), or through a regulatory decision, on the basis of the information provided in conjunction with the notification of the practice and in line with general exemption criteria (section 3), to exempt the practice from further requirements.

2. Exemption and clearance values

The exempt total activity values (Bq) for the total activity involved in the practice are laid down in Column 2 of Table A for artificial radionuclides (*total activity values for exemption – unchanged since RP65)* and for some naturally occurring radionuclides used in consumer goods; for other practices involving naturally occurring radionuclides such values are in general not applicable. Potassium salts in quantities less than 1000 kg are exempted.

The exempt activity concentration values (Bq/g) for the materials involved in the practice are laid down in Column 3 of Table A *(will contain the values specified in IAEA Safety Guide RS-G-1.7)* for artificial radionuclides and in Table C for naturally occurring radionuclides. The values in Table A are given for individual radionuclides, where applicable also for short-lived radionuclides in equilibrium with the parent nuclide as indicated in Table B. The values in Table C apply to all radionuclides in the decay chain of U-238 or Th-232, but for segments of the decay chain which are not in equilibrium with the parent radionuclide higher values may be applied.

The concentration values in Table A, column 3, or in Table C, also apply to the clearance of solid materials for re-use, recycling, conventional disposal or incineration. Higher values may be defined for specific materials or specific pathways, taking Community guidance into account, including where appropriate additional requirements in terms of surface activity or monitoring requirements.

For mixtures of artificial radionuclides the sum of nuclide specific activities or concentrations (for various radionuclides contained in the same matrix) divided by the corresponding exemption value shall be determined to be less than unity. Where appropriate this condition can be verified on the basis of best estimates of the composition of the radionuclide vector. The values in Table C apply individually to each parent nuclide.

The values in Table C shall not be used to exempt the incorporation into building materials of residues from industries processing naturally occurring radioactive material. Such recycling of residues from identified industries shall be managed as an authorised practice or be exempted on the basis of the general exemption criteria laid down in Section 3. For this purpose compliance of the sum of radionuclide concentrations with the appropriate value of the radionuclide index I for building materials defined in Annex 15 shall be verified.

Artificial radionuclides

[…Table A … *Column 2 will contain the present values in Column 2 of the 96/29/Euratom Directive – Total quantity (Bq). Column 3 will contain values from IAEA Safety Guide RS-G-1.7 – Concentration (kBq/kg)*.]

For radionuclides not listed in Table A, the competent authority shall assign appropriate values for the quantities and concentrations of activity per unit mass where the need arises. Values thus assigned shall be complementary to those in Table A.

The values laid down in Table A column 2 (*total activity values for exemption – unchanged since RP65)* apply to the total inventory of radioactive substances held by a person or undertaking as part of a specific practice at any point in time.

Nuclides carrying the suffix '+' or 'sec' in Table A represent parent nuclides in equilibrium with their correspondent daughter nuclides as listed in Table B. In this case the values given in Table A refer to the parent nuclide alone, but already take account of the daughter nuclide(s) present; the suffix 'sec' relates to the full decay chain of primordial radionuclides of the U-238, Th-232 [and …] series.

[…Table B …*Is the present Table B of the 96/29/Euratom Directive*]

Naturally occurring radionuclides

Table C*. Values for natural radionuclides in secular equilibrium in solid materials:*

Natural radionuclides from the U-238 series	1 kBq/kg
Natural radionuclides from the Th-232 series	1 kBq/kg
K-40	10 kBq/kg

Some elements in the decay chain, e.g. Po-210 or Pb-210, may warrant the use of values significantly higher, by up to two orders of magnitude, taking Community guidance into account.

3. General exemption and clearance criteria

The general criteria for exemption of notified practices or clearance of materials from authorised practices are as follows:

(a) the radiological risks to individuals caused by the exempted practice are sufficiently low as to be of no regulatory concern; and

(b) the type of practice has been determined to be justified, and

(c) the exempted practice is inherently safe.

Practices involving small amounts of radioactive substances or low activity concentrations, comparable to the exemption values laid down in Table A or C, and in general all practices involving naturally occurring radionuclides are deemed to fulfil criterion (c).

Practices involving amounts of radioactive substances or activity concentrations, below the exemption values laid down in Table A or C, automatically comply with criterion (a) without further consideration, with the exception of the recycling of residues in building materials. For notified practices not complying with these values an assessment shall be made of the resulting exposure of individuals. For compliance with the general criterion (a) it shall be demonstrated that the following dose criteria are met in all feasible circumstances:

For artificial radionuclides:

The effective dose expected to be incurred by an individual due to the exempted practice is of the order of 10 μSv or less in a year.

For naturally occurring radionuclides:

The dose increment, allowing for the prevailing background radiation from natural radiation sources, liable to be incurred by an individual due to the exempted practice is of the order of 300 μSv or less in a year for members of the public and less than 1 mSv for workers.

The assessment of doses to members of the public shall allow not only for pathways of exposure through airborne or liquid radioactive effluents, but also for pathways resulting from the disposal or recycling of solid residues.

[…Table D …*Is the present Table A column 3 of the 96/29/Euratom Directive*]

Annex 10

Centralised national networks and individual radiological monitoring documents

Part A. Provisions common to the centralised national networks and individual monitoring documents.

1. Any radiological monitoring system of the Member States for outside workers must comprise the following three sections:

- particulars concerning the outside workers' identity;
- particulars to be supplied before the start of any activity;
- particulars to be supplied after the end of any activity.

2. The competent authorities of the Member States shall take the measures necessary to prevent any forgery or misuse of, or illegal tampering with, the radiological monitoring system.

3. Data on the outside worker's identity must also include the worker's sex and date of birth.

4. Before the start of any activity, the data to be supplied via the radiological monitoring system to the undertaking or its occupational health service by the employer of the outside worker or an authority empowered to that end must be as follows:

- the name and address of the employer of the outside worker;
- the medical classification of the outside worker in accordance with Article 70;
- the date of the last periodic health review;
- the results of the outside worker's individual exposure monitoring.

5. The data which the undertaking must record or have recorded by the authority empowered to that end in the radiological monitoring system after the end of any activity must be as follows:

- the period covered by the activity;
- an estimate of any effective dose received by the outside worker;
- in the event of non-uniform exposure, an estimate of the dose-equivalent in the different parts of the body;
- in the event of internal contamination, an estimate of the activity taken in or the committed dose.

Part B. Provisions additional to those in Part A concerning the individual radiological monitoring document

1. The individual radiological monitoring document issued by the Member States' competent authorities for outside workers shall be a non-transferable document.

2. Pursuant to Part A (2), individual documents shall be issued by the Member States' competent authorities, which shall give each individual document an identification number.

Annex 11A

Elements to be included in an emergency management system

1. Threat assessment;
2. Clear allocation of the responsibilities of persons and organisations having a role in preparedness and response arrangements, including establishment and coordination of emergency response organisations with overall responsibilities in managing emergency exposure situations and where appropriate creation of special teams for protective measures;
3. Establishment of emergency response plans at national level, local level and within the installations.
4. Reliable communications and efficient and effective arrangements for cooperation and coordination at on-site, local, national and international levels;
5. Health protection of emergency workers;
6. Education and training of emergency workers and all other persons with duties or responsibilities in emergency response including regular exercises.
7. Arrangements for individual monitoring of emergency workers and the recording of doses.
8. Public information arrangements;
9. Involvement of stakeholders;
10. Transition from emergency response to recovery and remediation.

Annex 11B

Elements to be included in an emergency response plan

For emergency preparedness:

1. Reference levels, allowing for the criteria laid down in Annex 1;
2. Optimised protection strategies for members of the public who may be exposed, for different postulated events and related scenarios;
3. Pre-defined generic criteria for particular protective measures expressed in terms of projected and received dose;
4. Default triggers or operational criteria such as observables and indicators of on-scene conditions.
5. Arrangements for prompt coordination with the emergency response organisation in a neighbouring Member State or non- Member State, for facilities in the vicinity of a national border.
6. Arrangements for the emergency response plan to be reviewed and revised to take account of changes or lessons learned from exercises and events.

Arrangements shall be established in advance to revise these elements, as appropriate during an emergency exposure situation, to accommodate the prevailing conditions as these evolve through the response.

For emergency response:

The response to an emergency exposure situation is undertaken through the timely implementation of preparedness arrangements, including but not limited to:

1. Promptly implementing protective measures, if possible, before any exposure occurs;
2. Assessing the effectiveness of strategies and of implemented actions and adjusting them as appropriate to the prevailing situation;
3. Comparing the expected residual doses against the applicable reference level, focusing on those groups whose doses exceed the reference level;
4. Implementing further protection strategies, as necessary, based on prevailing conditions and available information.

Annex 12A

Prior information to the population likely to be affected by an emergency

1. Basic facts about radioactivity and its effects on human beings and on the environment.
2. The various types of emergency covered and their consequences for the public and the environment.
3. Emergency measures envisaged to alert, protect and assist the public in the event of an emergency.
4. Appropriate information on action to be taken by the public in the event of an emergency.

Annex 12B

Information to be provided to the affected population in case of an emergency

1. On the basis of the emergency response plan previously drawn up in the Member States, the population actually affected in the event of an emergency will rapidly and regularly receive:
    a. information on the type of emergency which has occurred and, where possible, its characteristics (e.g. its origin, extent and probable development);
    b. advice on protection which, depending on the type of emergency, might:
        i. cover the following: restrictions on the consumption of certain foodstuffs and water likely to be contaminated, simple rules on hygiene and decontamination, recommendations to stay indoors, distribution and use of protective substances, evacuation arrangements,
        ii. be accompanied, where necessary, by special warnings for certain population groups;
    c. announcements recommending cooperation with instructions or requests by the competent authorities.
2. If the emergency is preceded by a pre-alarm phase, the population likely to be affected in the event of an emergency should already receive information and advice during that phase, such as:
    a. an invitation to the population concerned to tune in to relevant communication channels,
    b. preparatory advice to establishments with particular collective responsibilities,
    c. recommendations to occupational groups particularly affected.
3. This information and advice will be supplemented if time permits by a reminder of the basic facts about radioactivity and its effects on human beings and on the environment.

Annex 13

Indicative list of items to be covered in the national action plan for radon in dwellings, buildings with public access and workplaces

1. Strategy for conducting surveys of indoor radon concentrations, for management of measurement data (national radon database) and for the establishment of other parameters (soil and rock types, soil gas concentration, permeability and radium -226 content of rock or soil)
2. Available data and criteria used for the delineation of radon prone areas or for the identification of radon prone buildings.
3. Identification of types of buildings with public access and workplaces, e.g. schools, underground workplaces or spas, where measurements are needed, based on a risk assessment including occupancy hours.
4. The basis for the establishment of reference levels for existing dwellings, workplaces, buildings with public access and for new buildings
5. Assignment of responsibilities, governmental and non-governmental, coordination mechanisms and available resources for the implementation of the action plan
6. Strategy for reducing radon exposure in dwellings particularly in radon-prone areas
7. Strategy, including methods and tools, for preventing radon ingress in new buildings, including identification of building materials for which radon exhalation is important.
8. Schedules for audits and reviews of the action plan
9. Strategy for communication to increase public awareness and inform local decision makers of the risks of radon in relation to smoking.
10. Member States shall also, where appropriate, make arrangements to provide guidance on methods and tools for measurements and remedial actions. Criteria for the accreditation of measurement and remediation services should also be considered.
11. Where appropriate the national action plan may foresee the provision of financial support for radon surveys and for remedial action, in particular for private dwellings with very high radon concentrations.
12. Long-term goals in terms of reducing lung cancer risk attributable to radon exposure (for smokers and non-smokers)

Annex 14

Indicative list of types of building materials considered for control measures with regard to their emitted gamma radiation

1. Natural materials

- Alum-shale
- Building materials or additives from natural igneous origin, such as:
  - Granite,
  - Gneiss,
  - Porphyries,
  - Syenite,
  - Basalt,
  - Tuff,
  - Pozzolana,
  - Lava.

2. Materials incorporating residues from industries processing naturally occurring radioactive material, such as:

- Fly ash
- Phosphogypsum
- Phosphorus slag
- Tin slag
- Copper slag
- Red mud (residue from Aluminium production)
- Residues from steel production

Annex 15

Definition and use of the activity concentration index for the gamma radiation emitted by building materials

In application of Article 101.2, for identified types of building materials, the activity concentrations of primordial radionuclides Ra-226, Th-232 (or its decay product Ra-228) and K-40 shall be determined.

The activity concentration index I is given in the following formula:

$I = C_{Ra226}/300\ Bq/kg + C_{Th232}/200\ Bq/kg + C_{K40}/3000\ Bq/kg$

where C_{Ra226}, C_{Th232} and C_{K40} are the activity concentrations in Bq/kg of the corresponding radionuclides in the building material.

The index directly relates to the gamma radiation dose, in excess to typical outdoor exposure, in a building constructed from a specified building material. The activity concentration index applies to the building material, not to its constituents. For application of the index to such constituents, in particular residues from industries processing naturally occurring radioactive material recycled into building materials an appropriate partitioning factor needs to be applied. The activity concentration index shall be used as a screening tool for identifying materials that may be exempted or subject to restrictions. For this purpose the activity concentration index I may be used for the classification of the materials into four classes leading to two categories of building materials (A and B):

	Category (corresponding default dose)	
Use	A (≤ 1 mSv)	B (> 1 mSv)
(1) materials used in bulk amounts	A1 I≤1	B1 I>1
(2) superficial and other materials with restricted use.	A2 I≤6	B2 I>6

The distinction of materials into (1) or (2) according to their use will be based on national building codes.

Where appropriate, actual doses for comparison with the reference level will be assessed using more elaborate models which may also allow for the background outdoor external exposure from local prevailing activity concentrations in the undisturbed earth's crust.

Annex 16

Practices involving non-medical imaging exposure

When applying Article 49 the following list of practices involving non-medical imaging exposure shall be taken into account:

A) Procedures implemented by medical staff using medical radiological equipment

- Radiological health assessment for employment purposes
- Radiological health assessment for immigration purposes
- Radiological health assessment for insurance purposes
- Radiological health assessment for other purposes not intended to bring benefit to the health and the well-being of the exposed individual
- Radiological evaluation of physical development of children and adolescents in view of a career in sports, dancing, etc.
- Radiological age assessment
- Use of ionizing radiation for the identification of concealed objects within the human body

B) Procedures implemented by non-medical staff using non-medical equipment

- Use of ionizing radiation for detection of concealed objects on or attached to the human body
- Use of ionizing radiation for detection of concealed humans as part of cargo-screening
- Other practices involving use of ionizing radiation for legal or security purposes

Annex 17

Values and relationships for the estimation of effective and equivalent doses

[to be added later]