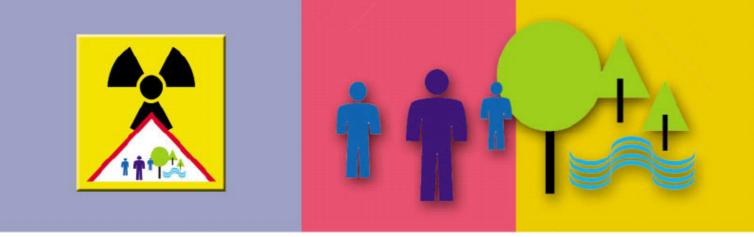
# RADIATION PROTECTION



Evaluation of the application of the concepts of exemption and clearance for practices according to title III of Council Directive 96/29/Euratom of 13 May 1996 in EU Member States

Volume 1: Main Report

Issue N° 134



## **Radiation Protection 134**

Evaluation of the application of the concepts of exemption and clearance for practices according to title III of Council Directive 96/29/Euratom of 13 May 1996 in EU Member States

**Volume 1: Main Report** 

Directorate-General for Energy and Transport
Directorate H – Nuclear Safety and Safeguards
Unit H.4 – Radiation Protection

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## Evaluation of the Application of the Concepts of Exemption and Clearance for Practices According to Title III of Council Directive 96/29/EURATOM of 13 May 1996 in EU Member States

**Volume 1: Main Report** 

by

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#### Foreword

The concepts of Exemption and Clearance for practices are laid down in Title III of Council Directive 96/29/EURATOM of 13 May 1996, establishing basic safety standards (BSS) for the protection of the health of workers and the general public against the dangers arising from ionising radiation. The Commission was interested in having an overview of how it was implemented in order to improve the harmonisation of the measures already adopted in the Member States.

The Commission contracted the present study to a group of consultants lead by National Nuclear Corporation (NNC), together with the Nuclear Research and consultancy Group (NRG) and the National Radiological Protection Board (NRPB). The study aimed to compile information on legal instruments and their practical application in all EU Member States, evaluate this information and identify advantages and weaknesses of different national approaches. The final objective was to identify areas needing improvement (legal, practical application, additional guidance).

The extensive documentation was summarised into a number of tables and figures that should give the reader an overview of the way in which the Member States have been tackling the issue.

The information collected in this document will be used as a basis for the examination of this issue by a working party of the Group of Experts established under the terms of Article 31 of the Euratom Treaty. The views expressed in the current document are those of the contractor and the publication of this document does not imply endorsement by the Commission.

Augustin Janssens Acting Head of Unit DG TREN H4 Radiation Protection

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#### **Executive Summary**

The present study has been undertaken for the Directorate-General for Environment of the European Commission in order to provide information for Article 31 experts and EU Member States on the application of the concepts of exemption and clearance for practices according to Title III of Council Directive 96/29/EURATOM of 13 May 1996.

For this purpose NNC (UK) and its subcontractors, NRG (Netherlands) and NRPB (UK), implemented the following tasks:

- A compilation of information on legal instruments and application of exemption and clearance in all EU Member States
- Evaluation of collated information and identification of advantages and weaknesses
- Identification of needs for improvement.

Information on legal instruments and application of Exemption and Clearance by EU Member States was gathered primarily from specific responses to a questionnaire sent to regulators, and also from published papers and the national legislation itself.

The information was subsequently collated and then evaluated in order to identify particular measures which could be considered to improve the effectiveness of the existing provisions on Exemption and Clearance in the Member States.

It was found that most Member States in the EU have introduced new legislation to address the Directive within the past 2-3 years and so practical experience of implementing the new system is very limited. However, with regards to the exemption, it was found that provisions from Title III have been implemented by the majority of Member States in a way consistent with the provisions in the Directive.

The area of greatest variation relates to the introduction of clearance levels. The main findings on the implementation of clearance by EU Member States are:

- In most Member States clearance levels, when adopted, are not based on values published in guidance from the European Commission. This is because in a number of cases the guidance was not available until after the development and adoption of the new legislation. For certain radionuclides, there is a variation of up to four orders of magnitude between the clearance levels defined in Member states and those defined in the European Commission guidance. For example, the clearance level for Tritium varies from 0.4 Bq g<sup>-1</sup> in the UK to 1 000 000 Bq g<sup>-1</sup> in the Netherlands compared to the EU general clearance level of 100 Bq g<sup>-1</sup>. The list of radionuclides for which clearance levels exist also varies significantly between Member States. It should be noted that the introduction of such levels by Member States is discretionary.
- There is a need to encourage harmonisation of clearance levels for particular materials, such as metals, designated for recycling and so subject to international trade.

• Some of the countries with a large nuclear industry have approaches to clearance that predate the Directive. In particular, the approaches used in France and the UK are different from the European Commission's approach to clearance.

The overall conclusions are summarised below:

- Concepts of exemption and clearance are applied across the EU. The use of exemption by Member States is consistent with Title III of Council Directive 96/29/EURATOM of 13 May 1996. In some cases application of clearance in Member States encountered practical difficulties, which may be caused by the complexity, inconsistencies and gaps in the regulations, or by negative public perception and the refusal of the recycling industries to accept cleared materials. In many cases the regulations were adopted in the last 2 years and therefore only limited information is available on practical application of clearance under the new regulations.
- It is clear, following this review of implementation in Member States, that there is a need for additional guidance from the European Commission on various aspects of the implementation of the concepts of exemption and clearance; examples are the provision of guidance on surface contamination levels and decay storage. It is recommended that this advice should be in one publication in order to make it easy to find. Clearance guidance for small users such as universities and hospitals would be helpful.
- In order to gain good quality information on the benefits of the regulations in EU Member States it would be useful to carry out a Regulatory Impact Assessment. This can be done by liaising with the affected stakeholders (including the nuclear industry, the recycling industry and the regulators) to obtain information on and to carry out assessments of the social, economic and health impacts.

#### Synthèse de l'étude

La présente étude a été entreprise pour la Direction Générale pour l'Environnement de la Commission Européenne, afin de fournir aux experts de l'article 31 et des Etats Membres de l'Union Européenne (UE) des informations sur l'application aux pratiques, selon le Titre III de la Directive du Conseil 96/29/EURATOM du 13 mai 1996, des concepts d'exemption et de libération.

À cette fin, NNC (Royaume-Uni) et ses sous-traitants, NRG (Hollande) et NRPB (Royaume-Uni), ont effectué les tâches suivantes :

- compilation d'information sur les instruments juridiques et l'application de l'exemption et de la libération dans tous les Etats Membres de l'UE,
- évaluation de l'information collectée et identification des points forts et des points faibles,
- identification des besoins d'amélioration.

L'information sur les instruments juridiques et l'application de l'exemption et de la libération par les Etats Membres de l'UE a été recueillie principalement grâce aux réponses spécifiques à un questionnaire envoyé aux autorités réglementaires, et également au travers de l'étude de la littérature et des législations nationales.

L'information recueillie a été assemblée et évaluée afin d'identifier les mesures particulières qui pourraient être envisagées afin d'améliorer l'efficacité des dispositions existantes dans les Etats Membres sur l'exemption et la libération.

On a pu constater que la plupart des Etats Membres de l'UE n'ont adopté une nouvelle législation pour prendre en compte la Directive qu'au cours des 2 ou 3 dernières années et que, de ce fait, l'expérience pratique de mise en application d'un nouveau système est très limitée. Cependant, en ce qui concerne l'exemption, on a constaté que les dispositions du Titre III ont été mises en application par la majorité des Etats Membres de manière conforme aux dispositions de la Directive.

Le domaine où l'on a observé la plus grande disparité est celui de l'introduction de niveaux de libération. Les résultats principaux sur la mise en application du concept de libération par des Etats Membres de l'UE sont :

• Dans la plupart des Etats Membres, les niveaux de la libération, quand ils existent, ne sont pas basés sur des valeurs publiées dans les recommandations de la Commission Européenne. Ceci a été causé, dans un certain nombre de cas, par le fait que es recommandations n'ont été disponibles qu'après le développement et l'adoption de la nouvelle législation. Pour certains radionucléides, il y a une variation de jusqu'à quatre ordres de grandeur entre les niveaux de libération définis dans les Etats Membres et ceux définis dans les recommandations de la Commission Européenne. Par exemple, le niveau de libération pour le Tritium varie de 0,4 Bq g<sup>-1</sup> au Royaume-Uni à 1 000 000 Bq g<sup>-1</sup> en Hollande, pour un niveau général de libération de l'UE de 100 Bq g<sup>-1</sup>. La liste de radionucléides pour

lesquels les niveaux de libération existent change également de manière significative d'un Etat Membre à l'autre. Il convient de noter que l'introduction de tels niveaux par les Etats Membres est discrétionnaire.

- Il est nécessaire d'encourager l'harmonisation des niveaux de libération pour certains matériaux, tels que les métaux, destinés au recyclage et faisant l'objet pour cette raison d'un commerce international.
- Certains des pays dotés d'une industrie nucléaire importante ont des approches de la libération qui ont précédé la Directive. En particulier, les approches de la libération utilisées en France et au Royaume-Uni sont différentes de l'approche de la Commission Européenne.

Les conclusions générales sont récapitulées ci-dessous :

- Les concepts d'exemption et de libération sont appliqués à travers l'UE. L'utilisation de l'exemption par les Etats Membres est conforme au Titre III de la Directive du Conseil 96/29/EURATOM du 13 mai 1996. Dans certains cas, l'application de la libération dans les Etats Membres a rencontré des difficultés pratiques, qui peuvent être provoquées par la complexité, les contradictions et les lacunes dans les réglementations, ou par une perception négative du public et le refus des industries de recyclage d'accepter les matériaux libérés. Dans beaucoup de cas, les réglementations n'ont été adoptées qu'au cours des 2 dernières années et, de ce fait, une information limitée est disponible sur l'application pratique de la libération dans le contexte des nouvelles réglementations.
- A la suite de cet examen de la mise en application dans les Etats Membres, le besoin de recommandations supplémentaires de la Commission Européenne sur divers aspects de l'application des concepts d'exemption et de libération est apparu clairement; des exemples en sont la fourniture de recommandations sur les niveaux de contamination surfaciques et le stockage à des fins de décroissance. Il est recommandé que ces conseils soient rassemblés en une seule publication afin de les rendre faciles à trouver. Des recommandations en matière de libération pour les petits utilisateurs tels que les universités et les hôpitaux seraient utiles
- Afin d'obtenir une information de bonne qualité sur les bénéfices apportés par les réglementations dans les Etats Membres de l'UE, il serait utile d'effectuer une évaluation de l'impact réglementaire. Ceci peut être effectué par un travail en liaison avec les parties prenantes concernées (y compris l'industrie nucléaire, l'industrie du recyclage et les autorités réglementaires) afin d'obtenir des informations et d'effectuer des évaluations relatives aux impacts sociaux, économiques et sanitaires de ces recommandations.

#### Glossary of terms and abbreviations

#### Glossary

Clearance: release of material from a regulated practice/work activity from the requirements of the Directive for disposal, reuse or recycling if the radioactivity content is below so-called 'clearance levels' (European Commission, 2000a).

The term clearance is reserved for the release of material which does not require further regulatory control to ensure the actual destination of the material (European Commission, 2000a). Thus avoiding regulatory resources being wasted in situations where there would be little or no benefit (European Commission, 2000a).

Clearance levels: values established by the national competent authorities, and expressed in terms of activity concentrations and/or total activity, at or below which radioactive substances or materials containing radioactive substances arising from any practice subject to the requirement of reporting or authorization may be released from the requirements of the Directive for disposal, reuse or recycling (European Commission, 1996; European Commission, 2000a).

The notion of 'specific clearance levels' has been introduced for specific conditions which can be verified prior to release while 'general clearance levels' are for any possible application, there are no restrictions on the origin or type of material to be cleared (European Commission, 2000a).

With 'general clearance levels' the material does not require a specification in regard to future use, recycling, reuse or the final disposal. The destination is not defined and consequently these possibilities must be taken into account when deriving the clearance criteria and it must be ensured that the levels for *general* clearance are equal to or more restrictive than *specific* clearance levels for different options (European Commission, 2000a)

**Decay storage:** storage of radioactive material prior to clearance in order to allow decay of short-lived radionuclides.

**Dose constraint**: a restriction on the prospective doses to individuals which may result from a defined source, for use at the planning stage in radiation protection whenever optimisation is involved (European Commission, 1996).

**Dose limit:** maximum references laid down in Title IV for the doses resulting from the exposure of workers, apprentices and students and members of the public to ionising radiation covered by the Directive that apply to the sum of the relevant doses from external exposures in the specified period and the 50-year committed doses (up to age 70 for children) from intakes in the same period (European Commission, 1996).

**Exemption:** the Directive requires Member States to establish a procedure for regulatory control of practices by competent authorities. However, the concept of exemption allows for release from the requirement to report all practices, in specified circumstances (Article 3(2)). The Directive uses the concept of exemption only within the context of practices, and

indirectly the concept is applicable to waste generated by such practices (European Commission, 2000a).

The mechanism of exemption is used to avoid unwarranted regulatory efforts (Clarke R, 2001). Therefore the term means that the whole practice is exempt from the reporting requirement i.e. doesn't enter the regulatory system as opposed to clearance where materials originating from a controlled practice, but satisfying clearance requirements, are released from further regulatory oversight.

**Exemption Levels**: values given in Annex I of the Directive at or below which exemption applies. In exceptional situations EU Member States can vary levels from those given provided they satisfy the basic general criteria set out in Annex I (European Commission, 1996).

Note, values of activity corresponding to exemption from reporting do not imply exemption from prior authorisation in case of deliberate direct or indirect administration of radioactive substances to persons (Article 4.1 (b)(d)) (European Commission, 2000a).

**Effective dose:** the sum of the weighted equivalent doses in all the tissues and organs of the human body. The unit for effective dose is the sievert (Sv) (European Commission, 1996).

**Equivalent dose:** the absorbed dose, in tissue or organ weighted for the type of radiation. The unit for effective dose is the sievert (Sv) (European Commission, 1996).

**Exclusion:** sources which are not intrinsically amenable to control and so excluded from regulation these include <sup>40</sup>K in the body, cosmic radiation at ground level and unmodified concentrations of radionuclides in most raw materials (European Commission, 1996).

**NORM**: all naturally occurring radioactive materials where human activities have increased the potential for exposure in comparison to the unaltered situation. Activity concentrations may or may not be increased (Vandenhove et al, 2002). In this project the term NORM is preferred to other terms used in literature such as TENORM (Technically Enhanced NORM).

**Practice:** a human activity that can increase the exposure of individuals to radiation from an artificial source or from a natural radiation source where natural radionuclides are processed for their radioactive, fissile or fertile properties, except in the case of an emergency exposure (European Commission, 1996).

**Work Activities:** within the scope of the Directive with regard to natural radiation sources a distinction based on the intended use of a radionuclide is made. Where the presence of natural radiation sources leads to *a significant increase* in the exposure of workers or members of the public (and the material is not used because of its radioactive, fissile and fertile properties) these are referred to as work activities; had the material been used because of its radioactive, fissile or fertile properties it would be a practice (European Commission, 2001).

#### **Abbreviations**

- **'BSS'** International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (IAEA, 1996a).
- 'The Directive' Council Directive 96/29/EURATOM (European Commission, 1996).
- ${}^{\backprime}E_{\beta max}{}^{\backprime}$  maximum beta particles energy for a particular emission.
- **'10% summation rule'** For materials containing more than one radionuclide, when using the summation equation for the application of exemption and clearance levels, radionuclides may be disregarded from the summation calculation, provided this does not introduce an uncertainty in the summed activity or the contribution of the radionuclide to the activity concentration of the material is less than 10%.
- 'NPP' Nuclear Power Plant.
- 'na' not applicable.
- 'NK' unknown.
- '-' not given / not available to authors.
- **'+' or 'sec'** nuclides carrying these suffixes represent parent nuclides in equilibrium with their correspondent daughter nuclides as listed in Table B of Annex I of the Directive.

#### 1 Introduction

This report summarises the findings of a project initiated by the Radiation Protection Unit of DG Environment of the European Commission<sup>1</sup>. The objective of this project was to evaluate the application of the concepts of exemption and clearance for practices according to Title III of Council Directive 96/29/Euratom of 13<sup>th</sup> May 1996, which contains the basic safety standards for protecting the health of workers and the general public against the dangers arising from ionising radiation in all EU Member States.

The project was divided into three tasks:

- Task 1 Compilation of information from Member States.
- Task 2 Evaluation of advantages and weaknesses.
- Task 3 Identification of the need for improvement.

In Task 1, information was collected by analysing the relevant regulations and by means of a questionnaire to Member States in addition to a review of published reports in the area of regulatory experience.

Within Task 2, the project team carried out a comparison of regulations in individual Member States against provisions in Title III of the Council Directive 96/29/Euratom and the available guidance.

Recommendations provided in Task 3 are based on the analysis from Task 2 and expert opinion of the authors of this report.

The report summarises the key findings of this study. It has been structured as follows:

#### Part I: Main Report

 Section 2: Background, including a review of the Directive and associated recommendatory documents provided by the European Commission to assist Member States in the implementation of the concepts.

- Section 3: Summarising the implementation in Member States of the concept of exemption and evaluating any advantages and weaknesses of the existing systems.
- Section 4: Summarising the implementation in Member States of the concept of clearance and evaluating any advantages and weaknesses of the existing systems.
- Section 5: An identification of needs for improvement in the current legal provisions.

<sup>&</sup>lt;sup>1</sup> This unit has since been re-organised and now is part of DG Energy and Transport.

#### • Section 6: Conclusions

### Part II: Appendices

- Appendix A contains a copy of Title III from the Directive.
- Appendix B summarises some key points from European Commission guidance on the concepts.
- Appendix C includes copies of all the responses from Member States to the questionnaire.
- Appendix D summarises the evaluation of the implementation of exemption and clearance and subsequent suggested improvements on an individual Member State basis.

#### 2 Background

The mechanism of **exemption** is used to avoid unnecessary regulatory efforts by removing the reporting requirement from the whole practice. Materials from the exempt industry never enter the regulatory system.

The concept of **clearance**, on the other hand, is used to release material with low levels of radionuclide contamination from a regulated practice or work activity.

Safety Series No.89 (IAEA, 1988) was the first international publication on the subject of exemption principles and suggested two basic criteria for determining whether or not a practice can be a candidate for exemption namely:

- individual risks must be sufficiently low as not to warrant regulatory concern; and
- radiation protection, including the cost of regulatory control, must be optimised.

Nevertheless, the subject has continued to develop since then and at an IAEA meeting in Vienna on 'Exclusion, Exemption and Clearance' there was support for a single set of values for exemption and clearance (IAEA, 1997). Subsequently in 1998 the IAEA published IAEA-TECDOC-1000 (IAEA, 1998), in which generic clearance levels for moderate quantities of solid materials (generally less than 3 tonnes per year, per facility) were recommended which are numerically equal to the BSS (IAEA, 1996 (a)) exemption values. However, it was stated that they should be adjusted using a modifying factor of 1/10 when the amounts for clearance become larger.

The introduction of the concepts by the European Commission was in the context of international work in the area including IAEA Safety Series No 89 (IAEA, 1988), IAEA, 1997, IAEA TECDOC 1000 (IAEA 1998), ICRP 60 (ICRP, 1990) and ICRP 77 (ICRP, 1997). The Council Directive 96/29/Euratom (the Directive) followed the publication of ICRP 60 in 1990 (ICRP, 1990). Within the Directive the two concepts (see Figure 1) are included in Title III (see Part II, Appendix A), with a list of nuclide specific numerical exemption values contained in Table A of Annex I. In addition, non-numerical basic criteria in Annex I provide, in principle, flexibility for the release of materials from regulatory control as long as the radiological consequences are acceptable (see Part II, Appendix B for details of European Commission guidance).

The basis for the establishment of Annex I Table A were calculations using criteria detailed in the study published as RP 65 (Harvey et al, 1993). Among these criteria was that the calculated values applied to practices involving small-scale usage of activity where the quantities involved are, at most, of the order of a tonne (Harvey et al, 1993). However, this limiting factor has not been included in the text of Annex I of the Directive. Early drafts of the Annex did contain a statement on a limited applicability to bulk materials but this mass limit was felt not to be essential in the final formulation of the Directive.

Alongside the Directive there are 'recommendation' documents, see Figure 2 for details. Some key points from the major relevant technical reports have been outlined in Part II, Appendix B.

The fundamental difference between clearance and exemption was described in European guidance RP 122 Part I (European Commission, 2000 (a)) as that:

While clearance levels may be defined generically the decision whether to apply clearance levels is an individual decision of the competent authorities on the basis of a case-by-case evaluation of the practice which gives rise to the contaminated or activated material. The undertaking can judge whether any of the waste streams comply with clearance levels and submit an application to the authorities, but it is for the authorities to decide. In the case of Exemption the holder/receiver makes the decision by looking into exemption rules. The receiver/holder must be in the position to unambiguously make the decision whether to notify his practice to the authorities based on published exemption rules. In the case of possible clearance the practice is already reported or authorised and therefore subject to regulatory control.

It is worth noting that the word 'clearance' has different meanings in English with no direct translation into other languages. It has, for example, been translated as 'liberation' in French and as 'desclasificación' in Spanish.

## 3 Evaluation of advantages and weaknesses in the implementation of exemption in EU national legislation

#### 3.1 Introduction

The information on which the present evaluation is based was obtained from questionnaires sent out to and returned by contact persons in the Member States (see Part II, Appendix C), on analysis of the content of the legislative documents (see Table 1) and on responses to specific requests for clarification. The evaluation is based on information received as of mid November 2002.

In brief, Title III of the Directive (see Part II, Appendix A) lays down exemption provisions for reporting:

- of practices where the radioactive substances involved do not exceed the levels specified in Annex I, or in exceptional circumstances, different values authorised by competent national authorities that nevertheless satisfy the basis general criteria set out in Annex I (Article 3, 2 (a) and (b));
- (ii) of apparatus containing radioactive substances as sealed sources (Article 3, 2 (c));
- (iii) of operation of electrical apparatus other than (iv) below emitting ionising radiation (Article 3, 2 (d));
- (iv) operation of any cathode ray tube for visual display or other electrical equipment operating at or below a specified maximum potential difference, provided that specified normal operation conditions are met (Article 3, 2 (e));
- (v) material contaminated with radioactive substances resulting from authorised releases which competent authorities have declared not to be subject to further control (Article 3, 2 (f)).

The evaluation therefore addresses the following questions:

- Have the principles and provisions of exemption of practices from regulatory control, as laid down in Title III of the Directive been adopted in the national legislation?
- In which specific provisions has the exemption principle been adopted?
- How has exemption been implemented?
- Does the implementation cover the requirements of the relevant Articles of Title III?
- Are there specific advantages or weaknesses identifiable in the implementations?

It should be noted in advance that new legislation incorporating the Directive has been implemented only very recently. In some cases the regulatory documents related to the implementation of certain provisions of the new national legislation have not yet been finalized and officially published. Therefore, practical experience with the implementation of Title III in national legislation is very limited indeed.

#### 3.2 Summary of conformity and deviations

Answers to the questionnaires have been summarised in table form in Tables 2 and 3. An overview of the implementation of the provision for exemption from Title III of the Directive is presented in Table 4. A more detailed evaluation for each individual Member State is contained in Part II, Appendix D where answers to the questions presented above are summarised. The approach followed in this section is to summarise key conclusions drawn from the evaluation:

- The provisions on exemption from Title III have been implemented by nearly all Member States (exceptions being Denmark and Portugal), (Figure 3).
- The implementations in nearly all Member States cover exemption from reporting and authorisations of practices involving sealed sources and apparatus emitting ionising radiation. This coverage comprises the exemptions from reporting and authorisation of such practices described in Article 3 of the Directive. Portugal has not implemented generally applicable exemption provisions for practices involving sealed sources and apparatus emitting ionising radiation.
- The Member States have, with a few exceptions (Denmark, Portugal and Italy), used Annex I Table A for defining exemption levels for practices involving radioactive substances. They did not adopt exemption levels different from Annex I Table A of the Directive, with only one exception: the Netherlands (Figure 4).
- Luxembourg and Spain have used exemption levels corresponding to Annex I of the Directive for classification of practices requiring different levels of regulatory requirements.
- Some Member States (for example Germany, Spain, Netherlands and UK), have added other radionuclides with exemption values derived on the same basis as used for Annex I of the Directive.
- Several Member States (for example Belgium and France), have limited the use of Annex I of the Directive to amounts of the order of 1 tonne.
- Only the Netherlands has changed several exemption levels relative to the Directive in reducing the values for <sup>228</sup>Ra, <sup>226</sup>Ra and <sup>60</sup>Co by a factor of 10 and increasing those for <sup>210</sup>Pb and <sup>210</sup>Po by the same factor (see Part II, Appendix C, p C-83 for details).

- The Netherlands is the only Member State that has chosen to regulate that the exemption levels of their respective annex apply to practices and work activities. In Denmark exemption levels exist for the naturally occurring radionuclides only. They equally apply to practices and work activities.
- The Netherlands and Denmark are the only Member States, which use, in their respective areas, practices or work activities, the same levels for exemption and clearance.

#### 3.3 Advantages and weaknesses

- As the concept of exemption has largely been implemented by Member States in a consistent and comparable way with the provisions of Title III, there is little reason for a detailed assessment of advantages and weaknesses in the national legislations. Moreover, there is very little experience with the practical application of the relatively new national legislations, in particular with the application of exemption of practices involving radioactive substances.
- Several Member States (Belgium and France) have limited the application of the exemption values for practices involving radioactive substances to amounts in the order of one tonne. However, the exposure scenarios used are the same as those used as the basis of the values provided in the Directive.

It should be evaluated whether this limitation is necessary to avoid situations in which unlimited amounts of material can in principle be exempted from reporting if the activity concentration criterion of Annex I is not exceeded.

According to the Directive, provided one of the criteria in Annex I, i.e. total activity **or** activity concentration, is not exceeded the practice will be exempt from reporting. So if the activity concentration exemption value is exceeded a limitation on amount automatically arises as a result of the exempted total activity exemption value, thus exemption is limited to practices involving a limited amount of radioactive substances. However, if the activity concentration exemption value is not exceeded then the amount of radioactive substances with which the practice is involved is not limited. Taking <sup>60</sup>Co as an example: at an activity concentration of 10 Bq g<sup>-1</sup>, the total activity criteria of 10<sup>5</sup> Bq is reached with 10 kg of material. Below 10 kg the practice and thus the material is exempted because only one criterion is reached.

Early drafts of the Annex indeed contained a statement on limited applicability to bulk materials, as did RP 65 (Harvey et al, 1993) on the principles and methods for establishing exemption values. The mass limit was felt not to be essential in the final formulation of the Directive since the effect of the mass limit is to ensure that exemption applies to small industries and users of radionuclides, not the nuclear industry, and this is already achieved by Article 4(1)(a), however, Member States may chose as a result of 4(3)(a) not to require such prior authorisation in cases where nuclear industry would be exempt from reporting under Article 3, in which case such a limitation may still be useful.

- Some countries have not just adopted Annex I of the Directive but have expanded the list of radionuclides on the basis of the Mobbs et al, 1999. In view of the already rather extensive list of radionuclides in the Directive it seems more appropriate to refer to that list for "missing radionuclides" than to recommend adaptation of each of the national annexes. The results for extra nuclides (Mobbs et al, 1999) were calculated after the Directive was finalised. However, they were presented to the Article 31 experts and accepted by them.
- In the German regulations if, even in the expanded list, the exemption values for a particular radionuclide are not provided, the use of default values for three categories of radionuclides is permitted (See Part II, Appendix D for details).
- The implementation of new legislation requires the development of official guidance from the competent authorities referred to in the legislation. The implementation of Title III in a consistent manner is not possible if that guidance is not available yet. This is for example the case with the Dutch regulations.

The comments below pertain to work activities.

Irrespective of their classification as advantage or weakness, attention must be drawn to the extensions of the exemption provisions for practices involving radioactive substances of Annex I of the Directive to work activities by the Netherlands. These provisions will bring work activities under reporting requirements at relatively low activity concentrations of <sup>238</sup>Usec, <sup>232</sup>Thsec, <sup>228</sup>Ra+ and <sup>226</sup>Ra+. The exemption concentration levels for these radionuclides in the Dutch legislation are however comparable to those given in Radiation Protection 122 Part II.

The provisions of the Netherlands will bring activities using materials with naturally occurring radionuclides, <sup>238</sup>Usec and <sup>232</sup>Thsec, under authorisation requirements relating to the possession and use of very small amounts (less than 100 g), at activity levels exceeding the weighted activity concentration sum of 10 Bq g<sup>-1</sup>.

Exemption of work activities from regulatory control depends on the results of the establishment by employers of exposures to workers or others required by provisions in the German RPO and the Dutch BS and in the Approved Code of Practice and Guidance, L121, to IRR 1999 in the UK (see Table 1 for details of regulatory documents). A dose criterion of 1 mSv is used for exemption from regulatory control.

## 4 Evaluation of advantages and weaknesses in the implementation of clearance in EU national legislation

#### 4.1 Introduction

As in the case for exemption, the information on which the present evaluation is based was obtained from questionnaires, sent out to and returned by contact persons in the Member States, on analysis of the content of the legislative documents and on responses to specific requests for clarification (see Part II, Appendix C). The evaluation is based on information received as of mid November 2002.

In Article 5 of Title III (see Part II, Appendix A), the following provisions are laid down on authorisation and clearance for disposal recycle or reuse:

- 1. The disposal, recycling or reuse of radioactive substances or materials containing radioactive substances arising from any practice subject to the requirement of reporting or authorisation is subject to prior authorisation.
- 2. However, the disposal, recycling or reuse of such substances or materials may be released from the requirements of this Directive provided they comply with clearance levels established by national competent authorities. These clearance levels shall follow the basic criteria used in Annex I and shall take into account any other technical guidance provided by the Community.

Title VII of the Directive deals with exposure due to natural radiation sources. Article 41 requires the Member States to set up for each work activity declared by them to be of concern, appropriate means for monitoring exposure and as necessary:

- (a) The implementation of corrective measures to reduce exposure pursuant to all or part of Title IX;
- (b) the application of radiation protection measures pursuant to all or part of Titles III, IV, V, VI and VIII.

In cases when Member States have chosen to apply the principle of clearance from Title III to work activities in addition to practices, and the information was supplied in their response to the questionnaire, this has been evaluated.

The summary of the key points in Section 4 and detailed evaluation in Part II, Appendix D therefore addresses the following questions:

- Have the principles of clearance of practices from regulatory control been adopted in the national legislation?
- In which specific provision has this principle been adopted?
- How has clearance been implemented?

- Does the implementation cover the requirements of the relevant Article 5 of Title III?
- Has clearance been applied to work activities and, if so, how?
- Are specific advantages or weaknesses identifiable in the implementations?

It should be noted in advance that new legislation incorporating the Directive has been implemented only very recently. In some cases the regulatory documents related to the implementation of certain provisions of the new national legislation have not yet been finalized and officially published. Therefore, practical experience with the implementation of Title III in national legislation is very limited indeed. Moreover, the provisions of Article 5 are of a general nature and leave much room for the development of specific national legal provisions. The levels set for cleared discharges from practices into air and water are not being addressed in this study.

#### 4.2 Summary of conformity and deviations

A summary of the answers to the questions relating to clearance from the questionnaire to Member States is contained in Table 5. A evaluation based on the questions posed above is detailed in Part II, Appendix D and a summary of the key conclusions is given in this section.

Table 6 provides an overview of the national implementation of clearance in their regulations. Clearance levels adopted by the countries in their current legislation are summarised in Table 7 for a limited number of key radionuclides. Values from European Commission guidance are also provided. Figures 5 to 10 illustrate clearance levels for selected radionuclides adopted by EU Member States. From these figures it can be seen that there is high degree of variation between the clearance levels defined in EU Member States and between the list of radionuclides for which these levels are defined

A benchmark example was also included in the questionnaire to investigate whether the practical application of the concept of clearance differed between Member States. Most Member States would not clear the material as specified (Table 5). A few stated that they might clear it after a period of decay storage or further cleanup (Figure 11). The most marked difference was for the surface contaminated steel, where no State said they would clear it but, for a number of States, they did not have legal provisions to allow clearance of surface contaminated material (Figure 11).

The key findings pertinent to all Member States are summarised below:

• The concept of clearance has been implemented by Member States in rather different ways ranging from no specific adaptations of previously existing regulations (United Kingdom) to detailed new provisions involving the principles from Title III, as well as the setting of a series of levels for general and specific clearance as well as levels for release of residues from work activities from regulatory control (Germany).

- All countries have implemented the authorisation requirement laid down in Article 5 of the Directive with respect to disposal, recycling or reuse of radioactive substances or materials containing radioactive substances from practices requiring authorisation.
- Provisions on clearance of such substances and materials from practices have been implemented by the Member States at very different levels of detail. Even the inclusion of a definition of clearance is not universal (Figure 12).
- France and Austria, which have not adopted clearance levels in their regulations, did, however, adopt the basic criteria as for exemption as required by Article 5 of the Directive.
- Those countries that have adopted clearance levels for substances and materials from practices in their regulations have based these levels on the basic criteria for exemption as required by Article 5 of the Directive (Figure 13) (PA in Table 6).
- Several countries could not comply with the requirement of Art. 5, i.e. for national competent authorities to take into account any other (meaning other than Annex I of the Directive) technical guidance provided by the Community in the establishment of clearance levels, as that guidance partly only became available after new legislation implementing the Directive had been adopted (Figure 14).
- Clearance levels adopted by countries are not consistently based on the values published in guidance from the Commission. As previously stated it is important to note that in a number of cases the said guidance only became available after the development and adoption of the new legislation.

The key findings from individual Member States are as follows:

- Belgium has adopted, for materials from practices, the general clearance levels from RP 122, Part I.
  - (i) In adopting RP 122, Part I, in Belgian legislation the number of radionuclides has been reduced significantly by deleting radionuclides of very little or no practical significance in clearance, including a number, but not all, short-lived radionuclides from natural decay chains.
  - (ii) It is also stated that the clearance levels for naturally occurring radionuclides do not apply to materials from work activities but this still would imply that these levels do apply to materials from practices. This deviates from RP 122, Part I, which explicitly recommends treating these naturally occurring radionuclides resulting from practices on a case-by-case basis.

- (iii) In adopting RP 122, Part I, in Belgian legislation a value of 1 Bq g<sup>-1</sup> is kept for <sup>40</sup>K. This would imply that an ordinary laboratory chemical KCl could not be unconditionally cleared from a practice. This is not likely to be an intended consequence of the new legislation.
- (iv) In view of the very low clearance levels for naturally occurring radionuclides in materials from practices, adopted in Belgian legislation, it should be made clear how this should be handled, for instance, in clearance of building material from practices. These low clearance levels, compared to normal levels in building material, indicates either a significant degree of conservatism in the scenario's used to derive the levels or a dose criterion of 10 μSv y<sup>-1</sup> not being appropriate for the naturally occurring radionuclides.
- (v) Clearance of residues from authorised work activities requires prior authorisation. No clearance levels have been set.
- 2 Denmark has not adopted clearance values but has adopted the principles for application on a case-by-case basis.
  - (i) The exemption levels in Bq g<sup>-1</sup> for natural radionuclides in Annex 2 of Order No. 192 can also be regarded as general clearance levels for materials from work activities. With <sup>40</sup>K as the only exception, these are identical to the rounded general clearance levels from RP 122, Part II (see clarification given by Denmark to Qu 1 in Part II, Appendix C).
- 3. Germany has implemented the most detailed provisions on clearance of materials from practices, comprising values for general clearance for different materials as well as for specific clearance. The levels are based on recommendations of the Strahlenschutzkommission (SSK).
  - (i) General clearance levels deviate from RP 122 Part I, being lower for some, higher for others. The higher levels for naturally occurring radionuclides, compared to RP 122 Part I, are still moderate compared to levels normally occurring in building materials. It is not clear how in practice this is dealt with.
  - (ii) Clearance levels for building rubble in excess of 1000 t y<sup>-1</sup> deviate from RP 114, in particular being lower for some naturally occurring radionuclides (<sup>226</sup>Ra, <sup>210</sup>Pb and <sup>210</sup>Po) for which the clearance levels are relatively close to normal levels in building materials. It is not clear how this is dealt with in practice.
  - (iii) Clearance levels for metal scrap deviate from RP 89, being lower by a small factor for some man-made radionuclides and substantially lower for naturally occurring radionuclides.

- (iv) The provisions for release from surveillance of materials from work activities (not in Table 7) deviate significantly from the general clearance levels in RP 122 Part II but should be regarded as specific release levels.
- 4. Greece has adopted clearance levels for waste only, which are, with some exceptions, identical to those in RP 122, Part I.
  - (i) It is not clear how these clearance levels were developed.
  - (ii) Many short-lived radionuclides, man-made and natural, are included which doesn't seem meaningful for solid waste.
- 5. Spain has used the exemption levels of Annex I of the Directive for the classification of practices requiring different levels of regulatory control (Royal Decree 1836/1999 Appendix I, Art 3). Guidance has been published, CSN Guide 9.2, which contains clearance levels for waste from non-nuclear practices from IAEA-TECDOC 1000, which are identical to Table A of Annex I of the Directive, but only cover a limited number of radionuclides. These clearance levels can only be applied in category 2 and 3 premises using unsealed sources. This corresponds to small industries and users of radionuclides such as universities and hospitals.
  - (i) CSN Guide 9.2 is in the form of a recommendation to potential users, and for use would require a legal dispensation to be in force. The inclusion of IAEA-TECDOC-1000 clearance levels in Spanish legislation is presently under consideration, but a decision has not yet been made.
  - (ii) The limited nuclide coverage, based on the TECDOC would require a case-by-case approach when other radionuclides are known to be present, irrespective of their concentration.
  - (iii) Clearance of materials from Nuclear Power Plants (NPP) is organised under the "Common Project" for each potentially clearable waste stream (see Part II, Appendix C for a flow-chart of the process). These clearance levels are then incorporated within the site authorisations.
- 6. In France information obtained suggests a novel approach. It is not envisaged that threshold levels for the clearance of radioactive wastes will be established in France. Instead a methodology for the preparation of waste management plans for waste produced inside nuclear installations has been introduced which do not resort to clearance levels. The approach is based on geographical zoning of nuclear sites according to the potential waste that would be produced there and the application of Best Practical Environmental Option (BPEO) and Best Practical Means (BPM) assessments to waste treatment and disposal pathways (see Part II: Appendix C p C-45-46 for details). If the impact of the waste needs to be assessed then the doses are compared to a dose criterion of 10 μSv y<sup>-1</sup>.

- 7. Italy has set in a specific case, clearance levels for materials from an NPP at values equal to those in RP 89, RP 113 and RP 122, Part I for some radionuclides but lower for others.
  - (i) The levels set for metal scrap are much lower than in RP 89 for <sup>55</sup>Fe, <sup>59</sup>Ni, and <sup>63</sup>Ni (all at 1 Bq g<sup>-1</sup>). In practice, it is expected that it would be difficult to prove compliance.
  - (ii) It is not clear whether these specific clearance levels are also to be adopted for new cases.
- 8. In Ireland the concept of clearance levels was deliberately excluded from the new legislation implementing the Directive, The Radiological Protection Act, 1991, (Ionising Radiation) Order, 2000 (S.I. No. 125 of 2000) (IRO). Clearance of materials from licensed practices is instead approached on a case-by-case basis.
- 9. Luxembourg has adopted levels for general clearance expressed as activity concentrations and surface contamination values based on recommendations of the German SSK with a few adjustments for naturally occurring radionuclides. Amounts are limited to 1 t.
- 10. The Netherlands has adopted Annex I, Table A of the Directive as a basis for values for general clearance, except in the case of discharges, with few numerical changes. As a result the clearance levels are significantly higher than the values recommended in RP 122 Part I. However, the Dutch Government retains the right to refuse clearance if the potential exposures are expected to be unacceptably high.
  - (i) Under the present Dutch BS, the amount of material that can be cleared is not limited as long as the activity concentration limit is not exceeded. This is the same as in clearance guidance RP 122 Part I (and Part II) and in the exemption provisions within the Directive.
  - (ii) Small amounts with higher activity concentrations can be cleared as long as the total activity limit is not exceeded. For example, for <sup>60</sup>Co activated scrap with an activity concentration <u>equal</u> to the limit of 1 Bq g<sup>-1</sup>, the quantity would be limited to 100 kg. This derived amount applies to annual clearance from an establishment.
  - (iii) The clearance levels adopted in Dutch legislation are, in principle, for general clearance. The activity concentration levels for man-made radionuclides are considerably higher than provided for general clearance in RP 122, Part I and adopted by other countries. However, the amounts that can be cleared are small when the clearance levels for activity concentrations are exceeded.

(iv) The clearance levels apply also to materials from work activities for which the activity concentration levels are the relevant criteria because of the usually large amounts involved.

The comments below pertain to clearance from work activities.

- (v) By setting concentration as well as total activity limits the Dutch regulators allow small amounts of material at or above the clearance level for activity concentration to be cleared provided that the total activity is not exceeded. By setting the levels for <sup>210</sup>Pb+ and <sup>210</sup>Po at 100 Bq g<sup>-1</sup> the Dutch regulators allow general clearance of amounts not exceeding 100 g. This deviates from RP 122, Part II that recommends a clearance level of 5 Bq g<sup>-1</sup> for the same radionuclides but without limitations on amounts. As stated in (i), the amount of material that can be cleared under Dutch regulations is unlimited provided the activity concentration limit is not exceeded. If for instance the activity concentration of <sup>210</sup>Pb+ is below 100 Bq g<sup>-1</sup>, unlimited amounts of that material can, in principle, be cleared according to the Dutch regulations.
- (vi) By having concentration as well as total activity limits the total amount that can be cleared is automatically limited when the activity concentration limit is reached or exceeded. The amount that still can be cleared depends on the ratio between the actual activity concentration in the material to be cleared and the total activity limit. For example, the amount of material with an activity concentration of 500 Bq g<sup>-1</sup> <sup>210</sup>Pb+ that can be cleared unconditionally each year is just 20 g.
- (vii) By setting the levels for both <sup>228</sup>Ra+ and <sup>226</sup>Ra+ at 1 Bq g<sup>-1</sup> the Dutch regulators allow general clearance of amounts not exceeding 100 kg and 10 kg on the basis of exempted activities of 10<sup>4</sup> Bq and 10<sup>5</sup> Bq respectively. This deviates slightly from RP 122, Part II that recommends a clearance level of 1 and 0.5 Bq g<sup>-1</sup> respectively for the same radionuclides but without limitations on amounts.
- (viii) The sample amounts given in (v) and (vii) above apply to material with activity concentration levels <u>equal</u> to their respective activity concentration limits (100 Bq g<sup>-1</sup> for <sup>210</sup>Pb+ and 1 Bq g<sup>-1</sup> for <sup>228</sup>Ra+ and <sup>226</sup>Ra+) with total activity limits of 10<sup>4</sup>, 10<sup>5</sup> and 10<sup>4</sup> Bq respectively. As explained earlier, if the activity concentration is less than the limit there would be no limit on the quantity permitted to be cleared. If the activity concentrations are higher that the clearance limits the amounts that can be cleared are smaller than the calculated example amounts.
- (ix) At concentration levels up to 10 times the clearance levels the Dutch legislation requires reporting of the fate of the materials and assessments of the radiation exposures resulting from processing, reuse

or disposal. This can be regarded as specific clearance on a case-by-case approach.

- 11. In Austria the new Radiation Protection Ordinance (RPO), (Strahlenschutzverordnung), was expected to come into force January/February 2003 and at the time of this evaluation was still an incomplete draft. Provisions for clearance of materials from practices were given in Par. 13a of the draft RPO. In cases of clearance of solids for disposal, for buildings to be demolished and for metal scrap for recycling, there must be no doubts about the acceptability of the intended processing or disposal with regard to the legal requirements for the waste. This requirement includes written consent from the receiver.
- 12. In Portugal new legislation implementing the Directive is laid down in Legislative Decree 165/200 (LD). The LD adopts the same scope as the Directive but contains no provisions on clearance.
- 13. Finland provides particularly detailed guidance on the application of clearance. It adopted radionuclide clearance levels for waste from nuclear power based on the type of emission and provides values for both surface and volumetric contamination (YVL 8.2) (See Part II, Appendix C). Consistency with the European Commission guidelines is ensured as it is specified that the activity concentrations of the materials to be cleared must not exceed the clearance levels set out in the guidelines issued by the European Community (ST 1.5).
- 14. Sweden has adopted non-nuclide-specific general clearance levels as well as specific clearance levels for waste disposal and incineration of oil based on IAEA-TECDOC-855 (IAEA, 1996 (b)).
- 15. The UK has provisions equal or close to clearance in RSA 1993 and in the Exemption Orders
  - (i) The UK exclusion level of 0.4 Bq g<sup>-1</sup> for solid waste specified in EO(SoLA) is likely to be regarded as general clearance.
  - (ii) The application of the clearance level in the UK of 0.4 Bq g<sup>-1</sup> for all man-made radionuclides, results in significant differences with the levels specified in the European Commission Guidance. For example, the UK's clearance level for tritium is just 0.4 Bq g<sup>-1</sup> compared to 100 Bq g<sup>-1</sup> specified in RP 122 Part I and 1 000 000 Bq g<sup>-1</sup> specified in the Netherlands.
  - (iii) Clearance by means of the Exemption Orders and Schedule 1 of RSA93 has been stated as being consistent with the criteria for exemption from the Directive (see Martin, 1999).

- (iv) However, conditions within EO(SoLA) mean that it is not applicable to solids which are not substantially insoluble in water which must receive authorisation in accordance with 6(1) and (3) of RSA93.
- (v) Other EOs relate to specific industries or materials such as the Radioactive Substances (Phosphoric Substances, Rare Earths etc) Exemption Order 1962 which, under section 5, excludes radioactive waste from the provisions of section 13(1) and 13(3) of RSA93 which relates to disposal. In this limited manner these other EOs can be used for 'clearance'.
- (vi) Solid substances containing natural radionuclides up to the levels specified in Schedule 1 of the RSA 1993 are not regarded as radioactive substances and may be disregarded. The same levels in are given in the EO(SoLA). At these levels the materials are outside the scope of the regulations, these levels can be used as general clearance levels, either from practices or from work activities or both, often referred to as 'free release'.
- (vii) Schedule 1 of RSA 1993 and EO(SoLA) both define activity concentrations as element activities. Guidance commissioned by the Department of the Environment, Transport and the Regions (DETR), Hill et al, 2000, recommends that only the longer-lived radionuclides from the decay chains of <sup>238</sup>U and <sup>232</sup>Th have to be summed to element activity concentrations for assessing compliance of solid materials with Schedule 1. However, the need to sum concentrations of long and short lived radionuclides is not ruled out entirely and might be necessary for materials containing unusual mixtures of radionuclides in the natural decay series (Hill et al, 2000).
- (viii) Schedule 1 of RSA 1993 defines discharges of natural radionuclides into air of no regulatory concern as elemental activity concentration levels per unit mass of discharged air. It is noted that this is a unique way of expressing discharge levels of no regulatory concern. It is assumed that these levels are regarded as cleared discharge levels, regardless of the discharge rate in terms of m³ per unit of time and therefore bear no clear relationship to exposures resulting from such cleared discharges.

# 4.3 Practical experience under new legislation

Through the questionnaires, information from the countries was sought on the practical experience with clearance of radioactive materials. The responses received are summarised below:

Belgium: no information received; experience under previous legislation exists. However, experience under new legislation is probably limited or absent altogether.

- Denmark: no experience under new legislation but some experience under previous legislation, when there were instances of problems with acceptance of cleared NORM contaminated scrap.
- 3 Germany: considerable experience under previous legislation exists.
- 4 Greece: steel cleared for recycling under specific clearance provisions based on European Commission guidance.
- 5 Spain: experience with specific clearance from NPP under previous legislation, some negative political and social responses in specific cases.
- France: experience with clearance of metal scrap from nuclear facility in conventional smelter.
- Ireland: lack of clearance levels did not pose difficulties. In the past, contaminated material has been returned to the country of origin, the example cited was of scrap contaminated as a result of a melted orphan source in scrap which resulted in the scrap being returned to country of origin. It is worth noting that Ireland no longer has any smelting plant.
- 8 Italy: limited practical experience with clearance of scrap, buildings and other material from one NPP.
- Duxembourg: limited experience under previous legislation, reluctance observed among industrial receivers to recycle or reuse material because of principle, political reasons or fear of confrontation with employees, labour unions or other opposition. No experience under new legislation.
- Netherlands: Experience under previous legislation exists; problems have been experienced with NORM on recycled steel; there is a strong reluctance to accept radioactivity associated with metal scrap by the recycling industry. Under the new legislation, experience is still very limited or absent altogether; acceptability of residues and waste by processors or disposers is not self-evident.
- Austria: positive experience under previous legislation limited to waste from hospitals and research establishments; no known experience with NORM; inclusion of clearance levels in new legislation not decided yet.
- 12 Portugal: no information available.
- Finland: experience under past and prevailing regulations pertains to repeated clearance of batches of metal scrap, ferrous and non-ferrous. There have been cases of incidental refusal of scrap metal after the radiation monitor at the smelter has been triggered. There is increasing reluctance to accept radioactivity associated with metal scrap by the recycling industry.

- Sweden: significant experience with general and specific clearance under past and still prevailing legislation; amounts of 200 t as waste and 500 t as scrap or ingots cleared annually. There appears to be an increasing reluctance by the recycling industry to accept radioactivity associated with metal scrap, but no refusals have been reported.
- United Kingdom: experience with clearance under SoLA Exemption Order, aluminium was cleared from Capenhurst and lead from Harwell.

#### 16 All countries

- (i) There is very little information for evaluation of practical application of clearance, in particular under the new legislation.
- (ii) Consequently, there is little proof that the implementation of Title III is, in practice, resulting in a harmonised approach across the Member States of the European Community.
- (iii) The most relevant aspects of the application of clearance at Community level are expected to be the clearance of materials that may be or are likely to be involved in transborder transport for reuse, recycling or as waste. Such materials comprise:
  - Scrap from dismantling of nuclear installations for recycling,
  - Scrap contaminated with NORM from industrial work activities for recycling,
  - Residues from industrial work activities for disposal,
  - Bulk residues from work activities applicable directly as material in the construction of roads or other civil works or as constituent in the production of building materials,
  - Residues from work activities to be used as raw material for extraction of valuable components in a country other than the country of origin.
- (iv) As these materials largely comprise residues from work activities there is a clear need for guidance on how to assess the levels of natural radionuclides, in an effective and economic way, for the purpose of clearance.
- (v) It seems to be essential that the process of clearance of materials from practices and work activities not only comprises assessment of compliance with clearance criteria but also incorporates steps to ascertain acceptance of the material by the envisaged receiver for processing, recycling or disposal of the materials.

# 5 Identification of needs for improvement

#### 5.1 Introduction

The aim of this section is to review the implementation of the concepts of exemption and clearance in national legislation in order to identify examples of good practice and areas that need improvement. The responses to the questionnaire were reviewed to give general observations on similarities, differences, areas of general improvement and good practice, (sub-section 5.2). These observations were used as the basis for the suggestions given in Part II, Appendix D, which considers each Member State in turn, highlighting good points but also pointing out problem areas. General conclusions are given in sub-section 5.3.

## 5.2 General improvement and good practice

# 5.2.1 Affect of experience of nuclear power generation on the degree of implementation of Title III

EU Member States are almost equally divided between those that have nuclear power plants (NPPs) and those that don't and this may be a significant factor in implementation. The Member States without NPPs are Denmark, Greece, Ireland, Luxembourg, Austria and Portugal. However, all of these countries do have research reactors with the exception of Ireland and Luxembourg who have neither research nor nuclear power reactors. In a number of countries, including Greece, Ireland and Austria, the lack of a nuclear industry was highlighted in their responses. Ireland, for example, chose not to include provision for clearance levels due to the perceived lack of demand for such provisions. Although Greece has included provision for clearance levels, application has been limited.

The remaining EU nations without a nuclear power industry include Denmark and Luxembourg. Denmark has introduced legislation that only allows for the exemption and clearance of natural radionuclides, there is no provision for exemption of manmade radionuclides. Luxembourg, on the other hand, has introduced clearance levels but has used guidance from the German Radiation Protection Commission (SSK) rather than that of the European Commission available at the time they were drafting their legislation (see 5.2.4 for further details).

Due to international trade, particularly in scrap metal and thus the possibility of cross-border movements of cleared material, matters which may in the first instance appear irrelevant to Member States without nuclear power reactors, could still be important. In particular, radionuclides are used in the medical sector and clearance could be an important concept for this sector.

France and the UK have the greatest number of nuclear power reactors in the EU and their approach to clearance differs from European Commission guidance. This is because they had developed procedures and criteria prior to the publication of the Directive and guidance. In the UK, the existing provision was found to be consistent with the Directive dose criterion for clearance and hence it was considered unnecessary to replace it. In France the concept of clearance exists but the process of determining what waste can be cleared is by the use of optioneering and direct

regulatory input. The use of zoning of an area defined by the type of waste that is potentially generated there, and hence the likely impact of that waste, is also used. This is an important point as it also takes into account other characteristics of the waste, such as its chemical properties, that could effect how the waste is handled.

#### 5.2.2 Harmonisation

One of the key themes underlying the Directive is the concept of harmonisation of definitions and regulations across the EU Member States in order to protect the health of the population. Harmonisation has two facets: harmonisation of concepts and harmonisation of values. The first is essential and the second is desirable. *Setting common values for exemption and clearance reduces the complications that arise when moving materials and waste from Member State to Member State*. In the context of exemption, the Directive specifies the dose criteria to be used and the exemption levels. However, it does allow Member States to derive their own exemption levels (using the dose criteria) under exceptional circumstances. Hence, although harmonisation is the ideal, there is an appreciation that each Member State has its own needs.

In the context of clearance, the Directive defines the concept and specifies the dose criteria, but does not give clearance levels. The Directive advises that European Commission advice on clearance levels should be taken into account when deriving clearance levels but leaves it up to Member States to derive their own levels. Obviously, this flexibility means that it is more difficult to achieve harmonisation across Member States for clearance. Thus, cleared material in Member State A may fail to satisfy the definition of cleared material in Member State B. *This lack of harmonisation could, for some Member States, be reduced by further consideration of advice from the European Commission.* However it is noted that some of the European Commission guidance (see Figure 2) on clearance principles and levels has been published quite recently. This pertains in particular to the guidance in Radiation Protection 122, Part I and Part II. This guidance could therefore not be taken into account by all countries even if they had wished to (Figure 14).

**Recommendation:** The harmonisation of exemption and clearance levels between Member States is important to reduce complications for cross border movement of materials. Thus the use of common values (as recommended by the European Commission) by all Member States is strongly recommended.

#### **5.2.3** Implementation in legislation

It is apparent when reviewing the answers to the questionnaires sent to Member States that the implementation of Article 3 (exemption from reporting) has been largely carried out (although there appear to be a few notable exceptions), and the majority of States have included the exemption levels in Annex I of the Directive in their national legislation. However, Article 5 appears to have only been partly implemented in several Member States. Article 5 contains two parts:

• the first part requires prior authorisation for disposal, recycle or reuse of waste and this has been implemented

• the second part introduces the option of the adoption of clearance levels, and has been implemented in significantly fewer countries.

The level of detail varies significantly between Member States and this is discussed further in greater detail in Part II, Appendix D.

The Directive was published in 1996 and the deadline for adoption of the Directive was the 13<sup>th</sup> May 2000. However, the relevant European Commission guidance on clearance and clearance levels was not published before 1999, with the latest guidance on general clearance, RP122 Part II, published in 2001. As a result, implementation of clearance levels in many Member States is quite varied. In general, all Member States have introduced new or amended existing legislation or guidance between 1999 and 2002 relating to the provisions of the Directive.

# 5.2.4 Concept of clearance

As mentioned above, the European Commission guidance on clearance levels is recent and therefore was not available to be taken into account when some Member States were formulating their legislation. As a result, the implementation of the concept of clearance varies quite widely. Some have not implemented clearance levels, some have adopted dose criteria only, some have specified only general clearance levels and some have specified levels for clearance of specific materials for specific destinations.

In addition, the clearance levels themselves are based on a number of sources, including the European Commission guidance and IAEA reports, and therefore differ from Member State to Member State. Luxembourg chose to base its clearance levels on recommendations from the German Commission on Radiological Protection (SSK) since they considered that the European Commission scenarios for clearance apply to 'work place scenarios', 'landfill scenarios' or being linked to the dismantling of nuclear installations and were unsuitable for general clearance of radioactive materials. However, the European Commission scenarios were chosen to be representative of the most restrictive scenarios and hence are suitable for general clearance.

The concept of clearance is most relevant to the decommissioning of power plants and buildings where radioactive materials were used e.g. research labs. In most cases clearance will be for disposal within national boundaries and hence the use of different levels is not a problem. However, for specific clearance, e.g. for metals for recycling, the industry is international and therefore harmonisation of clearance levels is preferred.

There is a need to encourage harmonisation of clearance levels. One solution is for National guidance documents to explicitly refer to European Commission advice.

**Recommendation:** All Member States should implement the concept of general clearance levels where they do not at present exist. Reference to European Commission advice should be made in order to harmonise values between Member States.

#### 5.2.5 Radionuclides considered

The Directive gives exemption levels for about 300 nuclides in Annex I and specifies that for others, the dose criteria should be applied. The radionuclides listed in national legislation differ from Member State to Member State. Many only list those specified in Annex I of the Directive, whereas some include only naturally occurring radionuclides (Denmark), and some have included exemption levels for extra artificial radionuclides (Germany, Netherlands, UK).

Exemption levels for extra nuclides are available in NRPB R306 (Mobbs et al, 1999) and have been used by Germany and UK in their legislation. The Spanish Official Journal, BOE of 10<sup>th</sup> April 2003, has also published the exemption values for extra nuclides from this NRPB report. It is suggested that where Member States have not included these extra radionuclides then reference is made to this document as a supplement to existing legislation.

Obviously, new uses of radionuclides occur and new radionuclides need to be considered so it is important to harmonise the values for these extra nuclides as far as possible. Harmonisation facilitates cross border trade and would also ensure that the practical criteria for exemption or clearance are more clearly defined in terms of activity or concentration limits. This would help to underpin these concepts and prevent accusations that some Member States are allowing too much uncontrolled use or release of material containing radionuclides.

In the interests of harmonisation, if any Member State calculates exemption or clearance levels for extra radionuclides currently not considered in either the Directive or the Radiological Protection Reports and different from NRPB R306 report then these levels should be provided to all Member States for information. They should also be submitted to the European Commission so that they can be considered for adoption in forthcoming guidance.

As stated previously some Member States have used recommendations on clearance from the German SSK. However, these are apparently intended to cover all the radionuclides from Annex I of the Directive. Examples are the inclusion of <sup>99m</sup>Tc, <sup>90</sup>Y, <sup>69</sup>Zn and <sup>60m</sup>Co as man-made radionuclides and <sup>228</sup>Ac, <sup>212</sup>Pb, <sup>212</sup>Bi and <sup>210</sup>Bi as naturally occurring radionuclides. Inclusion of short-lived man-made radionuclides may have some meaning in setting exemption levels but much less so in defining clearance levels. *All man-made radionuclides with half lives of up to a week or so can be removed and their coverage replaced by a requirement for a limited storage time before actual clearance*. The proof of absence of these radionuclides then becomes rather simple. The inclusion of short-lived radionuclides from natural decay chains like <sup>228</sup>Ac, <sup>212</sup>Pb, <sup>212</sup>Bi and <sup>210</sup>Bi, even at considerably higher clearance levels than their mothers, also has no practical meaning as it is highly improbable that these radionuclides can occur at concentrations higher than their mothers at the time of clearance.

European Commission guidance on levels for clearance of materials for practices provided in RP 89, RP 114 and RP 122, Part I, contain more realistic sets of manmade radionuclides as does RP-122 Part II on clearance of natural radiation sources. The latter contains a special set of clearance levels for wet sludges from oil and gas

production. However, the reasons why only these wet sludges are treated as a special case don't appear to be convincing. In addition, the derived clearance levels include <sup>238</sup>U and <sup>232</sup>Th, known to be virtually absent from these sludges relative to <sup>228</sup>Th, <sup>226</sup>Ra, <sup>226</sup>Ra and <sup>210</sup>Pb.

**Recommendation:** Where not mentioned already, reference to documents such as NRPB-R306 should be made in legislation so that as many radionuclides as possible can be brought into the system with the minimum of effort. If values for other radionuclides are calculated in case-by-case studies then these should be made available to the European Commission for promulgation to other Member States. This will allow the experiences of Member States in setting levels to be distributed so decreasing the amount of duplication by Member States when determining levels.

#### **5.2.6** Surface contamination

It is apparent that few countries explicitly allow clearance of surface contaminated material i.e. they do not have 'activity per unit area' concentration limits in the legislation. However, in practice, clearance of some surface contaminated material could be allowed in specific cases. There is an obvious need for surface contamination to be addressed in national legislation or guidance. In the interests of harmonisation, there is need for advice from the European Commission with regards to levels of surface contamination that would meet the dose criteria for clearance. Although advice exists for metals and buildings, such advice does not exist for general clearance.

**Recommendation:** The European Commission should provide advice on the clearance of surface contaminated materials as soon as possible. Member States should incorporate this advice when provided as soon as practical.

#### 5.2.7 Mass limit

Some Member States have introduced mass limits in conjunction with the exemption activity and activity concentration levels in the Directive. Thus the legislation is more restrictive than the Directive. (The Directive states that compliance is with the activity limit OR the activity concentration limit, not with both, and does not specify a mass limit. However, the ratio of the activity limit and the activity concentration limit is often interpreted as an implied mass limit, even though this does not follow from the methodology used to calculate them). In fact, the reason for this mass limit is essentially the timing of the development of the legislation: the draft Directive included a mass limit of 1 t to reflect the scenarios that were used to develop the exemption levels, as described in RP65. This mass limit was felt not to be essential in the final formulation of the Directive. It is felt that for consistency across all Member States, no mass limits should be set for exemption levels but that this is not a priority area.

A mass limit appears also to have been introduced for clearance levels in one Member State (Luxembourg). For clearance, no mass limit was implied in the scenarios used for the calculations in RP122 and therefore there is no need for a mass limit in national legislation where this guidance has been used; the intention was to allow

large masses of low-level material to leave the system when it poses no significant danger to health.

**Recommendation:** It is recommended that where mass limits exist for clearance then this should be reviewed and removed if possible. For those countries which either have clearance levels equal to the exemption levels or that use clearance levels from other sources, it is recommended that a review is conducted to ensure that the dose criteria are still met if those countries are to dispose of large quantities of material.

#### 5.2.8 Decay storage

Some Member States allow storage in order to decay short-lived radionuclides prior to clearance and others apparently do not. Also, the definition of 'short lived' differs between Member States. This needs to be remedied so that a consistent approach and definition is used in all Member States. It is thus recommended that Member States should include the option of storage for allowing decay of short-lived radionuclides in their legislation or guidance. Recommendations from European Commission on appropriateness of decay storage would be welcomed to increase harmonisation on the application of the concept of clearance. It is also recommended that the European Commission should give advice on the definition of which radionuclides should be allowed to be included for decay storage.

Clearance levels are not needed in practice for very short-lived nuclides as waste contains aged contamination and hence short-lived nuclides will have decayed away. This is reflected in European Commission guidance and could be used to rationalise the number of clearance levels specified by some Member States (see section 5.2.5). A half-life cut off of about a week would appear to be appropriate.

**Recommendation:** European Commission advice is needed on the concept of decayed storage. Member States should incorporate the recommendations of the European Commission as soon as practical once this is given.

#### 5.2.9 Practical experience

Often, with the changes being relatively recent, the application or impact of the new provisions has not yet been fully explored and so experience is limited. However, it is true to say that both the concepts of exemption and clearance are actively used. Exemption was implemented in all Member States. It was not possible to obtain information on how much material was exempt or could be exempt from the responses to the questionnaires. Twelve countries reported past experience with clearance and the concept was felt to be valuable by the regulators in those countries. There is little information on how much has been cleared although several Member States reported clearance of material amounting to hundreds of tonnes per year.

It was not possible to determine the extent of regulatory follow up or monitoring of clearance from the questionnaires and legislation. Since clearance applies to material leaving a regulated facility, regulators will have access to records of material sent for clearance and could carry out spot checks. In the UK the operator has to demonstrate to the regulator that the clearance criteria are met for a particular waste stream before clearance of that waste stream is allowed. This is an example of good practice.

#### 5.2.10 Acceptability of cleared material

Actual clearance of materials that meet clearance criteria and clearance levels, based on European Commission guidance and/or developed nationally, are not self-evident. The experience in various countries has been that materials like contaminated scrap, for instance, have been refused by intended receivers on principle or for political reasons. This is commonly seen in the case of scrap metal where the gate monitors have been activated and material sent back to the originator. Six countries experienced problems with acceptance of scrap (Denmark, Spain, Italy, Luxembourg, Finland, UK); four countries have cleared metal scrap successfully (Greece, Austria, Sweden and the UK).

Given that scrap metal is the most common material that companies wish to be cleared for recycling, it might be possible to develop guidance for the scrap metal industry itself so that their concerns are addressed. However, this is a complicated issue and stakeholder dialogue would be required. In some Member States (Denmark, Germany, Austria), agreements are required between the originator and receiver of the cleared material. This is one way in which misunderstandings can be resolved.

The same problem of acceptance arises when waste or residues that were regarded as non-radioactive materials under previous legislation get 'labelled' as being radioactive at a level requiring reporting of their destination. Therefore, it seems to be essential that the process of clearance of materials from practices and work activities not only comprises assessment of compliance with clearance criteria, but also incorporates steps to ascertain acceptance of the material by the envisaged receiver for processing, recycling or disposal of the materials.

The comments directly above pertain particularly to clearance of residues from industrial work activities, as their radioactive content is only one characteristic of the material. They can contain non-radioactive contaminants like heavy metals and toxic hydrocarbons. An example of such materials are the sludges from oil and gas production which contain naturally occurring radionuclides at widely varying concentrations but also heavy metals like lead, zinc and mercury and polycyclic aromatic hydrocarbons. The general or specific clearance of such materials on the basis of radiological criteria alone leaves these potentially overriding aspects unaddressed. It is understood that the clearance provisions of Germany, for materials from practices as well as for releases from surveillance of residues from work activities, explicitly include the consideration of these non-radiological aspects. This is an example of good practice.

**Recommendation:** The European Commission should consider providing advice to recipient industries who may come into contact with cleared material in order to allow greater acceptance of such material.

#### 5.2.11 Need for guidance

It is often possible to interpret the practical implementation of exemption and clearance levels in different ways, especially when a mix of radionuclides are involved. Similarly, where the legislation does not specifically mention the situation (e.g. surface contamination) then in some conditions material could be cleared and in

others not, even within the same Member State. This type of situation calls for both a set of values in the legislation and a set of guidance documents to explain the legislation for both general users and those concerned with the regulation of the legislation.

As the implementation of the Directive is relatively new, most Member States do not have this guidance documentation in place, or they have only a few documents covering a small area of the legislation. Thus it is recommended that Member States should review any guidance documentation they have issued with regard to legislation implementing the Directive and issue any outstanding documents as soon as possible.

**Recommendation:** Member States should provide guidance on the legislation as soon as practical in order to ease the use of the concepts of exemption and clearance.

# 5.2.12 Application to NORM

The application of the principles of exemption and clearance to NORM is not the main purpose of this report and it is only considered since some Member States have explicitly mentioned NORM in their responses to the questionnaires. However, it is obvious from the information that has been provided on how the principles are applied to NORM by some Members States that the regulation of NORM is treated differently in different Member States. Some have applied all the Title III provisions, including Article 3, the exemption levels in Annex I and Article 5; some apply the provisions only if the doses are 'not insignificant' and this is generally set at a level of  $1 \text{ mSy y}^{-1}$ ; and some apply the RP 122 exemption and clearance levels.

The Annex I exemption levels for naturally occurring nuclides are not intended for NORM industries; the recently published RP122 Part II gives the corresponding exemption and clearance levels for NORM. However, this was not available in time for some Member States to incorporate it into their legislation.

There is a complication relating to the levels of naturally occurring materials in building materials. This was discussed in RP122 Part II.

Harmonisation of legislative regimes cannot be expected in view of the recent inclusion of NORM in the scope of the Directive. *Practical guidance in one document addressing all the issues by the European Commission and a review in five years time is recommended.* In the meantime, Member States could refer to the guidance given in RP122 Part II in their national guidance. It is expected that a considerable amount of NORM material will be available for clearance in the future. As stated previously in the report (see Section 4.3), the most relevant aspects of the application of clearance at European Union level are expected to be the clearance of materials that may be or are likely to be involved in transborder transport for reuse, recycling or as waste. These materials largely comprise of residues from work activities and so there is a clear need for guidance on how to assess the levels of natural radionuclides in an effective and economic way for the purpose of clearance.

**Recommendation:** Guidance should be prepared on how to assess the levels of natural radionuclides in an effective and economic way for the purpose of clearance.

#### 5.2.13 Regulatory impact assessment

EU Member States use several different approaches, particularly in respect to the clearance concept. A view has been expressed that 'a plethora of levels, each specific to a material or industry, will lead to confusion' (Cooper et al, 2000). There is some evidence that the practical application of the concept encounters difficulties, as has been highlighted in the answers to questionnaires. It is not known, however, if it is the complexity of the clearance concept that has contributed to these difficulties.

In addition to the issue of acceptance of cleared materials, it can be argued that unnecessarily high analytical costs are imposed in some cases, particularly in countries that do not implement the 10% summation rule for consideration of nuclides.

In order to gain good quality information on the benefits of the regulations in EU Member States, it would be useful to carry out a Regulatory Impact Assessment. This can be done by liaising with the affected stakeholders (including nuclear industry, recycling industry and regulators) to obtain information on and carry out assessments of the social, economic and health impacts. Such a regulatory impact assessment would get feedback from the regulators and the industry on the likely effect of new regulations.

**Recommendation:** The European Commission should consider conducting a Regulatory Impact Assessment in order to assess the use and ease of the regulations set up by Member States with regard to exemption and clearance.

#### 5.3 General observations

The suggested improvements for individual Member States are summarised in Table 8, with the detail, as stated earlier, in Part II, Appendix D.

Collective experience to date is limited but has been used to identify good practice and problems likely to be encountered. *Examples of good practice relating to exemption and clearance from Member States are listed in Table 9.* 

There is a need for additional guidance from the European Commission on various aspects of the implementation of the concepts of exemption and clearance; examples are values for nuclides not included in the Directive or current advice, surface contamination levels and decay storage. This advice should be in one publication to make it easy to find. A number of Member States also suggested a need for guidance in certain areas, these requests have been listed in Table 10.

Further European guidance on the exemption and clearance of NORM, with some examples, would also be beneficial.

Another issue is the concept of specific clearance. This is complicated and leads to a number of clearance levels. Do we really need it? Could this be dealt with on a national basis under the existing system of authorisations? There is merit in having a simple system of general clearance because it is more transparent and hence helps the concepts gain more general acceptance.

The review of the legislative instruments demonstrated that for many Member States the legislation does not appear to be easy to use and transparent. *The provision of national guidance documents is therefore essential. In particular, hospitals need guidance on clearance and exemption and how it applies to them.* 

The timetable by which the Articles 3 (exemption) and 5 (clearance) should have been implemented has expired. It is recommended that in those countries where these Articles are not yet implemented in legislation, or are not fully implemented, then action should be taken to implement them.

# 6 Conclusions

## 6.1 Exemption

- Provisions on exemption from Title III have been implemented by the majority of Member States in a way consistent with the provisions in the Directive.
- New legislation to incorporate the provision on exemption has been recently introduced in several Member States. Legislation in other Member States relating to exemption predates the Directive. However, the definitions are, in most cases, consistent with the requirements of the Directive.
- Some instances exist where Member States have not implemented the provisions in the Directive fully: a possible waste of resources in regulating material that has a low radiological hazard may result.
- The concept of exemption is widely used in the Member States. There are many examples of its use in a manner consistent with the provisions defined in the Directive. It should be noted that the concept had been used in the EU prior to the issue of the Directive.

#### 6.2 Clearance

- Provisions on clearance of materials and substances from practices have been implemented by the Member States using different approaches.
- In most Member States clearance levels, when adopted, are not based on values published in guidance from the European Commission. In a number of cases the guidance was not available until after the development and adoption of the new legislation. There is a variation of up to four orders of magnitude between the clearance levels defined in Member states and those defined in the European Commission guidance.
- There is a need to encourage harmonisation of clearance levels, in particular for specific clearance which most often relates to metals and other materials designated for recycling and so is subject to international trade.
- There is very little information available on practical application of clearance, particularly under the new national legislation that has been introduced in many of the countries. Several countries experienced problems with acceptance of cleared scrap by recycling companies.
- A particularly good example of good practice is the situation in Finland where the Regulator STUK issues numerous guides, namely the ST (non-nuclear practices) and YVL (nuclear power) guides to assist users. These guides are relatively short and are written in plain language making it easy to understand when they apply and how. Making the process of clearance readily understood by possible users could increase effective use of the concept.

• Some of the countries with a large nuclear industry have approaches to clearance that predate the Directive. In particular the approaches used in France and the UK were developed before the Directive and therefore the concepts are realised in a different way.

#### 6.3 General

- It is clear, following this review of implementation in Member States, that there is a need for additional guidance from the European Commission on various aspects of the implementation of the concepts of exemption and clearance; examples are provision of guidance on surface contamination levels and decay storage. It is recommended that this advice should be in one publication to make it easy to find. Clearance guidance for small users such as universities and hospitals would be helpful.
- In order to gain good quality information on the benefits of the regulations in EU Member States it would be useful to carry out a Regulatory Impact Assessment. This can be done by liasing with the affected stakeholders (including nuclear industry, recycling industry and regulators) to obtain information on and to carry out assessments of the social, economic and health impacts.
- The present study had very limited success in obtaining information on the practical application of the principle of clearance, especially under the new regulatory provisions of the Member States. This should be pursued further in order to determine the success or otherwise of the existing approaches.

#### 6.4 Recommendations

- The harmonisation of exemption and clearance levels between Member States is important to reduce complications for cross border movement of materials. Thus the use of common values (as recommended by the European Commission) by all Member States is strongly recommended.
- All Member States should implement the concept of general clearance levels where they do not at present exist. Reference to European Commission advice should be made in order to harmonise values between Member States.
- Where not mentioned already, reference to documents such as NRPB-R306 should be made in legislation so that as many radionuclides as possible can be brought into the system with the minimum of effort. If values for other radionuclides are calculated in case-by-case studies then these should be made available to the European Commission for promulgation to other Member States. This will allow the experiences of Member States in setting levels to be distributed so decreasing the amount of duplication by Member States when determining levels.
- The European Commission should provide advice on the clearance of surface contaminated materials as soon as possible. Member States should incorporate this advice when provided as soon as practical.

- It is recommended that where mass limits exist for clearance then this should be
  reviewed and removed if possible. For those countries which either have
  clearance levels equal to the exemption levels or that use clearance levels from
  other sources, it is recommended that a review is conducted to ensure that the
  dose criteria are still met if those countries are to dispose of large quantities of
  material.
- European Commission advice is needed on the concept of decayed storage.
   Member States should incorporate the recommendations of the European Commission as soon as practical once this is given.
- The European Commission should consider providing advice to recipient industries who may come into contact with cleared material in order to allow greater acceptance of such material.
- Member States should provide guidance on the legislation as soon as practical in order to ease the use of the concepts of exemption and clearance.
- Guidance should be prepared on how to assess the levels of natural radionuclides in an effective and economic way for the purpose of clearance.
- The European Commission should consider conducting a Regulatory Impact Assessment in order to assess the use and ease of the regulations set up by Member States with regard to exemption and clearance.

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 Table 1
 Relevant national legislation and associated guidance

Country	Document
Belgium	Royal Decision of 20 <sup>th</sup> July 2001 (ARBIS)
Denmark	Ministry of the Interior and Health Order No 192 of 2 <sup>nd</sup> April 2002 on exemption from law on
	the use of radioactive substances.
	National Board of Health Order No 954 of 23 October 2000 on the use of unsealed
Commons	radioactive sources in hospitals, laboratories etc.  Radiation Protection Ordinance (Strahlenschutzverordnung) 20 <sup>th</sup> July 2001 (RPO)
Germany	Nuclear Law (Atomgesetz) 3 <sup>rd</sup> May 2000
Greece	Radiation Protection Regulations Joint Ministerial Order No 1014 (ΦΟΡ) 94, Official Gazette
Greece	No 216B, 06/03/01 (RPR).
Spain	Nuclear and Radioactive Installation Royal Decree (RD 1836/1999)
•	Nuclear Energy Act 25/1964 of 29 April 1964 as modified by Electric Sector Law 54/1997
	and RD 1836/1999
	CSN Safety Guide 9.2 Clearance of residual material generated by radioactive installations.
France	Ordinance No 2001-270 of the 28 <sup>th</sup> March 2001
	Decree No 2002-460 of the 4 <sup>th</sup> April 2002
Ireland	The Radiological Protection Act, 1991 (Ionising Radiation) Order 2000 (S.I. No 125 of 2000) (IRO)
Italy	Legislative Decree nr 230 of 17 <sup>th</sup> March 1995, published in the Official Journal No 136 of the
•	13 <sup>th</sup> June 1995, as modified inter alia by Legislative Decree No 241 of 26 <sup>th</sup> May 2000
	published in Official Journal No 136 of 31 <sup>st</sup> August 2000 (ordinary supplement 140/L) (LD)
	Italian National Standards Body (UNI) Technical guidance:
	UNI 9498 Part 6 Decommissioning of nuclear plants - Radiological characterisation
	and classification of materials resulting from decommissioning activities in view of their final destination.
	UNI 9498 Part 7 Decommissioning of nuclear plants - Criteria for partial release of a
	nuclear plant site.
Luxembourg	Regulations of the Grand Duchy, 14 December 2000. (RDG).
Netherlands	Royal Decision of 16 <sup>th</sup> July 2001 (BS)
Austria	Radiation Protection Act (146 Strahlenschutz-EU-Anpassungsgesetz 2002) 20 <sup>th</sup> August 2002
	(RPAL)
	Radiation Protection Ordinance (draft) (RPO)
Portugal	Decree No 165/2002 of 17 <sup>th</sup> July (LD)
Finland	Radiation Act (592/1991) as amended by 1142/1998 (RA-1991)
	Radiation Decree (1512/1991) as amended by 1142/1998
	Nuclear Energy Act (990/1987) as amended in 1994, 1995 and 1996
	Nuclear Energy Decree 1988 as amended in 1993, 1994, 1995 and 1996
	ST 1.5 (July 1999) Exemption of the use of radiation from the safety licence and reporting
	obligation
	ST 5.4 (October 2000) Trade in Radiation Sources
	ST 6.2 (July 1999) Radioactive Wastes and Discharges
	YVL 8.2 (March 2002) Exemption from regulatory control of nuclear wastes
Sweden	Radiation Protection Act (1988/220)
Swedell	Radiation Protection Act (1988/220)  Radiation Protection Ordinance (1988/293) as amended 1 <sup>st</sup> Sept 2001 (RPO)
	, , , , , , , , , , , , , , , , , , , ,
	SSI FS 1983:7 General regulations on clearance levels for material from laboratories
	SSI FS 1996:2 General regulations on clearance levels for material from nuclear installations

# Table 1 (cont'd)

Country	Document
UK	Ionising Radiation Regulations 1999 SI 1999 No 3232 (IRR99)
	Approved Code of Practice and Guidance for IRR99 L121
	Radioactive Substances Act 1993 (RSA93)
	Exemption Orders (18 of) (see Part II, Appendix C for details)
	Radioactive Substances (Basic Safety Standards) (England and Wales) Direction 2000, 9 <sup>th</sup> May 2000
	Radioactive Substances (Basic Safety Standards) (Scotland) Regulations 2000 SI 2000 No 100
	Radioactive Substances (Clocks and Watches) (England and Wales) Regulations 2001 SI 2001 No 4005
	Radioactive Substances (Basic Safety Standards) (Northern Ireland) Regulations 2003 SR 2003 No 208
	Hill M. and Wakerley MW., An Interpretation of Schedule 1 of the Radioactive Substances Act 1993 and Related Issues, DETR/RAS/00.003, Department of the Environment, Transport and
	the Regions Commissioned research for Radioactive Substances Division, UK, September 2000.
	(NB This report has no legal weight but has been published to assist users)

Table 2 Responses to questionnaire - overview questions

Country	Has Title III been enacted? (Qu 1a)	Who is the responsible authority in the Member State?	Has additional guidance been published to accompany legislation? (Qu 3)	Are there any changes expected/needed in this area? (Qu 9)
Belgium (not confirmed)	Yes – Royal Decision 20 <sup>th</sup> July 2001 (ACRONYM: ARBIS)	Federal Agency for Nuclear Control (FANC)	Guidance is contained within the articles of ARBIS.	1
Denmark	Yes – Order No 192 (2 <sup>nd</sup> April 2002) however only in a limited way because it only relates to naturally occurring materials. All other radioactive materials require authorisation.	National Institute of Radiation Hygiene (NIRH)	In Annex 3 of the Order users are referred to EU reports RP 89, RP 113, RP 114, RP 117, RP 122 Part I and Part II for the principles for setting and calculating clearance.	1
Germany	Yes – Radiation Protection Ordinance 20 <sup>th</sup> July 2001 (RPO)	Ministry of Environmental Protection	No.	No
Greece	Yes – Radiation Protection Regulation 6 <sup>th</sup> March 2001. (RPR)	The Greek Atomic Energy Commission (GAEC)	Guidance for exemption and clearance for steel beams is currently with the GAEC for approval.	1
Spain	Yes – Nuclear and Radioactive Installation Royal Decree (RD1836/1999)	Ministry of Economy (for issuing of authorisations) Nuclear Safety Council (CSN) (inspections and assessments)	Plant specific 'Technical Instructions' have been issued by CSN and in addition Safety Guides have been produced including CSN SG 9.2, guidance on clearance from hospitals, research and industrial applications.	CSN is preparing a plan for the review of the rules and guides in the area of waste management including clearance.

Table 2 (cont'd)

Country	Has Title III been enacted?	Who is the responsible	Has additional guidance	Are there any changes
	(Qu 1a)	authority in the	been published to	expected/needed in this
		Member State?	accompany legislation?	area?
		(Qu 2)	(Qu 3)	(Qu 9)
France (not confirmed)	Yes – Ordinance No 2001-270,	Directorate-General of	1	1
	Public Health Code (cf art	Nuclear Safety and		
	L1333-11 with L1333-20) and	Radiation (DGSNR) is		
	the Fair Labour Standards Act	responsible for		
	(cf act L231-7-1)	implementing regulatory		
		documents.	* & .	
Ireland	Yes – The Kadiological	Kadiological Protection	No specific document on	Further clarification on
	Protection Act 1991 (Ionising	Institute of Ireland (RPII)	either exemption or	how clearance would
	Radiation) Order 2000 (SI		clearance has been	work in practice would be
	No 125 of 2000)		issued.	useful however the lack
				of clearance levels has
				not posed any particular
				difficulties in the Irish
				context.
Italy	Yes - Legislative Decree 230 of	Agency for Protection of	The Italian National	Clarification of the scope
	1995 as modified by Legislative	the Environment and for	Standards Body (UNI)	of the Directive might
	Decree 241 of 2000.	Technical Services	issues technical guidance	bring improvements to
		(APAT) - inspection	on various aspects of	the application of the
		powers for nuclear safety	decommissioning and a	radiation protection
		and radiation protection.	draft concerning	system as it has been
		Other bodies also have	clearance of solid	argued that exemption
		inspection powers under	material is at an advanced	levels from reporting are
		the legislation - see Part	approval stage.	not explicitly stated as the
		II, Appendix C for		scope of the Directive's
		details.		requirements.

Table 2 (cont'd)

Country	Has Title III been enacted?	Who is the responsible	Has additional guidance	Are there any changes
	(Qu 1a)	authority in the	been published to	expected/needed in this
		Member State?	accompany legislation?	area?
		(Qu 2)	(Qu 3)	(On 9)
Luxembourg	Yes – Réglement grand-ducal du	Ministry of Health	No written official code	A code of practice for
	14 décembre 2000.		of practice exists in	guidance on
			addition to the	determining/evaluating
			regulations. However all	specific activity of
			use of radioactive sources	materials to be cleared
			requires a licence and	resulting from use of
			instructions for	unsealed sources is
			compliance is usually	needed in Luxembourg.
			included in that licence.	In addition a common
				European Commission
				policy for exemption and
				clearance of consumer
				products containing
				radioactive substances is
				needed.
Netherlands	Yes – Royal Decision 16 <sup>th</sup> July	Joint responsibility of	General explanatory	The system will have to
	2001 (referred to as BS)	'Our Ministers', see	notes and specific notes	be evaluated in a few
		Part II, Appendix C for	with each article of the	years time; it was only
		details.	BS. In addition	introduced in 2001.
			Ministerial regulations	
			have been issued on	
			specific topics.	

Table 2 (cont'd)

Country	Has Title III been enacted? (Qu 1a)	Who is the responsible authority in the Member State?	Has additional guidance been published to accompany legislation?	Are there any changes expected/needed in this area? (Qu 9)
Austria	Yes- Radiation Protection Law (146 Strahlenschutz-EU-Anpassungsgesetz 2002).	The Federal Ministry for Agriculture, Forestry, Environment and Water Management.	Usually no official guidance documents are issued in Austria. Recommendatory Austrian Standards often issued however due to the only very recent introduction of the new legislation no such standards have yet been prepared for exemption and clearance.	The system is too new to identify needs for improvement at this stage.
Portugal (as of May 2002)	Not implemented yet.	Likely to be the Directorate General of Health (DGS), Ministry of Health.	None	There is a need to implement suitable legislation.
Finland	Yes – Radiation Act (592/1991) but see Part II, Appendix C for details.	Radiation and Nuclear Safety Authority (STUK).	A number of ST and YVL Guides exist including: ST 1.5 Exemption from reporting ST 5.4 Trade in Radiation sources. ST 6.2 Radioactive Waste and discharges YVL 8.2 Exemption of nuclear wastes (Clearance)	EU harmonisation of exemption for some commonly used consumer products such as smoke detectors should be considered perhaps at the first stage by means of recommendations.

Table 2 (cont'd)

Country	Has Title III been enacted?	Who is the responsible	Has additional guidance	Are there any changes
	(Qu 1a)	authority in the	been published to	expected/needed in this
		Member State?	accompany legislation?	area?
		(Qu 2)	(Qu 3)	(Qu 9)
Sweden	Yes – Ordinance on Radiation	Swedish Radiation	Some guidance is given	SSI has identified the
	Protection (1988:293 as amended	Protection Authority	in supplementary	need for regulations on
	1st September 2001.)	(ISSI)	regulations such as SSI	clearance of materials
			FS 1996:2 general	from non-nuclear
			regulations for clearance	activities and clearance of
			levels from nuclear	large amounts of material
			installations, and from	from decommissioning of
			laboratories -	nuclear facilities. SSI has
			SSI FS 1983:7	also identified the need
				for review of existing
				regulations in light of
				European Commission
				recommendations on
				clearance.
				See Part II, Appendix C
				for more details.

Table 2 (cont'd)

Country	Has Title III been enacted? (Qu 1a)	Who is the responsible authority in the Member State? (Qu 2)	Has additional guidance been published to accompany legislation? (Qu 3)	Are there any changes expected/needed in this area? (Qu 9)
United Kingdom	Yes – Ionising Radiation Regulations 1999 (IRR99) and the Radioactive Substances Act 1993 (RSA93)	Environment Agency (EA) (England and Wales and its equivalents in Scotland and N.Ireland) - regulates waste and discharges i.e. RSA93.  Health and Safety Executive (HSE) regulates exposure of workers and the public from work practices i.e. IRR99.	Approved code of practice has been issued to support the IRR99. Generic authorisations have been issued by HSE for exemption of practices.  No guidance with legal weight has been issued to accompany the RSA93. However DEFRA has published a report which aims to provide assistance in application of the legislation.	Following the conclusion in Martin, 1999 recommending an update of the Exemption Orders a report was commission by DEFRA to propose revisions of the Exemption Orders under the RSA93. The report Thorne and Smith-Briggs, 2002 was approved in July 2002 by DEFRA however it is not clear that any decisions regarding its implementation have since been made.

Table 3 Questionnaire responses - exemption

Country	Is a definition of exemption provided and where? (Qu 1b)	Has Annex I Table A of the Directive (exemption levels) been transposed into national legislation? (Qu 5)	Description of exemption process (Qu 4)
Belgium (not confirmed)	Not provided in ARBIS Art 2 Definitions but covered in the scope in Art 1 and Chapter II, Art 3.1. It covers both practices and work activities.	Yes, see Chapter II, Art 3.1.d and Appendix 1A. Calculation criteria and values the same as in the Directive but are limited in the ARBIS to moderate amounts of material of the order of 1 tonne. (These are not applicable to NORM see Art 4).	Exemption provisions cover practices as well as work activities and is implemented by describing Class IV establishments exempted from reporting and prior authorisation. Exemption levels are provided in Appendix IA of ARBIS. (See Part II, Appendix C, Qu 1 for details.)
Denmark	A definition is not given but exemption levels ('undtagelsesniveau') and clearance levels are the same in Order 192.	No Order 192 only lists exemption/clearance levels for naturally occurring radionuclides based upon RP122 Part II. In theory all practices involving even the smallest man-made radionuclides should come under regulatory control. However under §12.2 of the Order the authorities have the possibility to clear radioactive material after assessment of the radiological impact.	Table 1 of Annex 2 of Order 192 gives exemption levels for naturally occurring radionuclides and below these levels users are exempt from reporting the practice to the authorities. (See Part II, Appendix C, Qu 1 for further details).

Table 3 (cont'd)

Country	Is a definition of exemption provided and where? (Qu 1b)	Has Annex I Table A of the Directive (exemption levels) been transposed into national legislation? (Qu 5)	Description of exemption process (Qu 4)
Germany	Definition not provided but described as possession of materials, practices or work activities not requiring prior authorisation. Definition of exemption values given in point 16 of RPO.	Yes, the first three columns providing exemption limits are based on Annex I Table A of the Directive however it has been expanded to include additional radionuclides.	General exemptions from the scope of the RPO are specified in par 2(2). Exemption from reporting and authorisation for apparatus is given in par 12(3). Exemption of practices from authorisation is given in par 8. Par 95 deals with work activities. (See Part II, Appendix C, Qu 1 for details)
Greece	The concept of exemption is to be found in para 1.1.6 of the RPR and the same wording as in Title III, Art 3 para 2 of the Directive was used.	Yes, Annex I was used in defining the exemption levels and is incorporated in part 12, para 12.1 of the RPR.	There is no nuclear industry in Greece and so the process has only been applied to scrap metal processing.
Spain	The concept is in Art 35 and Annex I of RD 1836/1999. It is applied to radioactive installations with the same radiological criteria as in the Directive.	Yes, Annex I of the Directive was fully adopted in the definition of exemption levels for practices with low quantities of materials (below 3 tonnes per year). Note that the 3 tonnes per year restriction is not stated in any legal/regulatory document.	Annex I of RD 1836/1999 states which installations the regulations will not apply to and these follow the pattern of the Directive e.g. substances, equipment, apparatus etc, etc.

Table 3 (cont'd)

Country	Is a definition of exemption provided and where? (Qu 1b)	Has Annex I Table A of the Directive (exemption levels) been transposed into national legislation? (Qu 5)	Description of exemption process (Qu 4)
France (not confirmed)	Concept included.	Yes, see Annex II Table A of Decree 2002 - 460 of 4 <sup>th</sup> April 2002	Authorisation is only necessary when exemption levels in Annex I Table A in the Directive are exceeded but this exemption won't apply to medical situations.
Ireland	Subject to Art 5 (Exemptions), Art 4(1) of the Order requires all practices to be licensed except where the quantities are below the exemption values.	Yes, Schedule 5 of the Order is Annex I of the Directive.	Exemptions are set out in Art 5 of the Order and cover substances, apparatus and equipment as in the Directive. (See Part II, Appendix C for details)
Italy	Requirements laid down in Annex I, para 0.1 to 5 of Decree 230. It is important to note that Italian legislation introduces a distinction between exemption of practices (Art 2 para 1 of Directive) and exemption from prior reporting (Art 3 para 2 of the Directive). See Part II, Appendix C Qu 1 for details.	Exemption from reporting levels (Art 22 and Annex VII para 4 and Tables VII-1 and VII-2) are the same as those in Annex I of the Directive however there are additional exemption levels to exempt practices completely from the radiation protection controls.	Decree 230 Art 22 para 1 require that local authorities be notified in advance of commencement of practices where exemption levels (from reporting) are likely to be exceeded. However if below these levels but above the thresholds for exemption the provisions of the radiation protection legislation still apply. See Part II, Appendix C, Qu 1 for details.

Table 3 (cont'd)

Country	Is a definition of exemption provided and where? (Qu 1b)	Has Annex I Table A of the Directive (exemption levels) been transposed into national legislation? (Qu 5)	Description of exemption process (Qu 4)
Luxembourg	No specific definition is given however the exemption levels given in the Directive are used for the classification of industries in three classes II-IV (Article 2 of Decree). See Part II, Appendix C Qu 1 for details.	Yes, it is given as Table A in the Decree. See Part II, Appendix C Qu 5 for details.	Exemption levels are used to determine the licensing class. Below 1/100 of the exemption level they are excluded from reporting. Those between this exclusion level and the exemption level require reporting while those above the exemption level require prior authorisation. See Part II, Appendix C Qu land 4 for details.
Netherlands	Yes, provided in par 4.4 of the Explanatory notes: A practice or work activity not subject to reporting or authorisation but still subject to other obligations following from BS.	The principles of Annex I and Table A have been used to derive Annex I Table 1 of the BS however the numerical values apply to both exemption and clearance and so the values are different for <sup>228</sup> Ra, <sup>210</sup> Pb, <sup>210</sup> Po and <sup>60</sup> Co. See Part II, Appendix C Qu 5 for details.	There are general exemptions from the scope and other detailed provisions relating to exemptions, see Part II, Appendix C Qu 1 for details. Note that the same levels are used for both exemption and clearance and for all practices and work activities.
Austria	Article 3 para 2 of the Directive has been implemented into the Radiation Protection Act.	Yes, these will be incorporated into the new Ordinance.	Legislation only came into force on the 1st January 2003 so detail not available.
Portugal (as of May 2002)	No	No	Not established.

Table 3 (cont'd)

Country	Is a definition of exemption provided and where? (Qu 1b)	Has Annex I Table A of the Directive (exemption levels) been transposed into national legislation? (Qu 5)	Description of exemption process (Qu 4)
Finland	Not a definition but section 17 of the Radiation Act outlines those activities which are licence-free operations i.e. are exempt practices. See Part II, Appendix C Qu 1 for details.	Yes, Appendix A of ST Guide 1.5 is the same as Annex I of the Directive.	Provided the activity or activity concentration of the radioactive substance associated with the practice is less than or equal to the exemption value neither a safety licence nor a report is required. See Part II, Appendix C Qu 1 and 4 for details.
Sweden	Yes, see §2 of the Ordinance where it states that exemption from licensing is valid for practices where activity levels are lower than the values from the Directive is handled, and also that SSI is allowed to exempt devices from licensing if they fulfil the demands of the Directive.	Yes, see appendix to the Ordinance.	SSI have regulations to exempt the use of smoke detectors and the use of compasses and binoculars containing tritium from licensing in addition to exempting practices according to the levels contained in the appendix to the Ordinance.

Table 3 (cont'd)

Country	Is a definition of exemption provided and where? (Qu 1b)	Has Annex I Table A of the Directive (exemption levels) been transposed into national legislation? (Qu 5)	Description of exemption process (Qu 4)
United Kingdom	Not provided in IRR99 Reg 2 Interpretation, however regulations given in terms of what it applies to as opposed to what is exempt. The work with ionising radiation not requiring notification under Reg 6 is given in Schedule 1 of IRR99. See Part II, Appendix C Qu 1 for details.	Annex I was not used to determine levels in Schedule 8 for the exemption of practices however Schedule 8 does contain the Annex I values plus others.	Exemption from reporting is defined in Schedule 1 with levels given in Schedule 8. In addition Exemption Orders under the RSA93 give exemption from specified provisions of the Act. See Part II, Appendix C Qu 1 for details.

Table 4 Overview of the implementation of exemption provisions from the Directive

Company	Practices, Exemption from	reporting and authorisation
Country	Apparatus and sealed sources	Unsealed sources
Belgium	As in Directive	As in Directive but with a 1 tonne limit
Denmark	Information incomplete.	Directive not fully implemented in legislation only applying to naturally occurring radionuclides.
Germany	As in Directive	As in Directive, expanded list of nuclides
Greece	As in Directive	As in Directive
Spain	As in Directive	As in Directive
France	As in Directive	As in Directive but with a 1 tonne limit
Ireland	As in Directive	As in Directive
Italy	As in Directive	≤ 1 Bq/g and Directive
Luxembourg	As in Directive	Annex I used for classification, including exemption
Netherlands	As in Directive	Some Annex I values changed and list expanded
Austria	Expected to be as in Directive	Annex I likely to be implemented
Portugal	Directive not fully implemented in present legislation	Directive not implemented fully in present legislation
Finland	As in Directive	As in Directive but only for non-nuclear industry practices
Sweden	As in Directive	Values as in Directive but principles not explicitly adopted
United Kingdom	As in Directive	As in Directive, expanded list of nuclides

NB: See Part II Appendix D for more detail.

Table 5 Questionnaire responses - clearance

Country	Is a definition of clearance provided and where? (Qu 1b)	Have clearance levels been established? (Qu 4)	Was European Commission guidance used in the derivation of clearance levels? (Qu 6)	Examples of application of clearance? (Qu 7)	Has cleared material still been rejected? (Qu 8)	Benchmark a) Surface contaminated steel. b) Activated steel
Belgium (not confirmed)	Not provided in definitions but covered in Art 18(1) and Annex IB of ARBIS.	Yes, prior authorisation is required unless there is compliance with these limits set out in Annex IB (solid material) for liquids and gases reference must be made to Tables H1 and H2 in Appendix III. See Part II, Appendix C	Yes, underlying basic radiological criteria are the same as those for exemption in Annex I of the Directive. Most clearance levels given for solids are equal to those from RP122 Part I.	1	ı	a) No regulatory basis for clearance of surface contaminated material. b) Exceeds clearance levels for both <sup>60</sup> Co and <sup>54</sup> Mn - can't be cleared.
		for details.				

Table 5 (cont'd)

Country	Is a definition of	Have clearance	Was European	Examples of	Has cleared	Benchmark
	clearance provided	levels been	Commission	application of	material still	a) Surface
	and where?	established?	guidance used in	clearance?	been rejected?	contaminated
	(Qu 1b)	(Qu 4)	the derivation of	(Qu 7)	(Qn 8)	steel.
			clearance levels?			b) Activated steel
			(Qn 6)			
Denmark	Yes,	Yes, but only for	Yes, RP122 Part	Clearance has	No experience of	a) + b) No general
	'Frigivelsesniveau'		II was used to	ied	rejected cleared	clearance for man-
	level adopted	occurring	prepare Table 1 of	in a very few	materials under	made
	whenever a	materials;	the Order. In	cases and all	present rules but	radionuclides
	radioactive material	handling of all	addition reference	before the	cleared scrap was	however specific
	can in practice be	radioactive	is made in	implementation	rejected in the past	clearance might be
	regarded as non-	material requires	Annex 3 para 5 to	of present	from a smelter	granted if a
	radioactive - Order	prior	RP89, RP113,	regulations. To	because of	disposal plan was
	192, Art 1(2).	authorisation see	RP114, RP117	date the total	radionuclides from	presented to the
		Table 1 of Order	and RP122 Parts I	amount of	the U and Th	NIRH.
		192 (p C-10).	and II.	NORM sand,	decay chain.	
		See also Annex 3		metal scrap and		
		(p C-14) for the		concrete that has		
		principles of		been cleared		
		clearance. See		amount to less		
		Part II, Appendix		than 100 t.		
		C Qu 6 for				
		details.				

Table 5 (cont'd)

Country	Is a definition of clearance provided and where? (Qu 1b)	Have clearance levels been established? (Qu 4)	Was European Commission guidance used in the derivation of clearance levels?	Examples of application of clearance? (Qu 7)	Has cleared material still been rejected? (Qu 8)	Benchmark a) Surface contaminated steel. b) Activated steel
Germany	Yes, see point 15 of RPO par.3, Definitions.	Yes, levels set out in RPO, see Section 9, Art 29. However material requires a statement of clearance from authorities before release (even if clearance levels have been used). See Part II, Appendix C for details	Levels based on or consistent with European Commission guidance – RP 89, 101,113, 114, 117 and 122 Part I	Considerable application of clearance in the decommissioning of NPPs.	No.	a) + b) Uncertain from regulations due to possibility of specific as well as general clearance however it appears that clearance for recycling is not possible.

Table 5 (cont'd)

Country	Is a definition of clearance	Have clearance levels been	Was European Commission	Examples of application of	Has cleared material still been	Benchmark a) Surface
	provided and	established?	guidance used in	clearance?		contaminated
	where?	(Qu 4)	the derivation of	(Qu 7)	(Qu 8)	steel.
	(Qu 1b)		clearance levels? (Qu 6)			b) Activated steel
Greece	Yes, included in	Yes, general	Yes – RP 122	General clearance		a) Surface
	'definitions' of	clearance levels	Part I, RP 117,	levels have been		contaminated
	the RPR	given in RPR,	114 and 89 were	applied to		material
	paragraph 1.9.	Tables 6.1 and	used to derive	discharges from		considered for
		6.2.	levels.	medical, research		disposal.
				and industrial		Decontamination
				applications.		not considered.
				Levels for steel		
				beams are have		b) Active steel
				been developed		stored for
				but not yet		3 months and then
				approved.		sent for recycling.

Table 5 (cont'd)

Country	Is a definition of clearance provided and where?	Have clearance levels been established? (Ou 4)	Was European Commission guidance used in the derivation of	Examples of application of clearance? (Ou 7)	Has cleared material still been rejected? (Ou 8)	Benchmark a) Surface contaminated steel.
	(Qu 1b)		clearance levels? (Qu 6)			b) Activated steel
Spain	No, but the	Yes, but on a	Yes, it is used in	Scrap metal,	Clearance has	a) + b) Not cleared
	definition of	site-specific basis	terms of	buildings and	been applied very	for recycling or
	radioactive waste	through licences.	radiological	used oil have all	successfully,	reuse.
	provides the	The clearance	criteria for the	been cleared	however there are	
	necessary legal	system adopted	deviation of	using specific	examples such as	Decontamination
	framework see	for NPPs is	clearance levels	clearance levels.	the clearance of	could be
	Part II, Appendix	based on	and specific	Both general and	very low	considered for
	C Qu 1 for	elaboration by	clearance levels	specific clearance	radioactive waste	surface
	details. General	producers of a	from RP 89 and	levels have been	coming from the	contaminated steel
	and specific	Common Project	RP 113 were used	applied to very	Acerinox accident	with the activated
	clearance levels	for each	for metals and	low activity	when there has	steel sent for
	exist. But only	potentially	rubble.	residual	been a political	disposal.
	specific clearance	clearable waste.		materials.	and social	
	levels in use.	See Part II,			reaction.	
		Appendix C Qu				
		4 for details.				

Table 5 (cont'd)

Country	Is a definition of clearance provided and where? (Qu 1b)	Have clearance levels been established? (Qu 4)	Was European Commission guidance used in the derivation of clearance levels? (Ou 6)	Examples of application of clearance? (Qu 7)	Has cleared material still been rejected? (Qu 8)	Benchmark a) Surface contaminated steel. b) Activated steel
France (not confirmed)	Concept included.	No general clearance levels have been issued; waste management is based on geographical zoning as opposed to measurement. See Part II, Appendix C Ou 4 for details.	No, clearance is incorporated into licences and involves detailed specific impact assessments.	A smelting plant has been authorised to receive metal scrap from a nuclear facility.	1	National clearance levels not defined, optioneering applied.

Table 5 (cont'd)

Country	Is a definition of clearance provided and where?	Have clearance levels been established? (Qu 4)	Was European Commission guidance used in the derivation of clearance levels? (Qu 6)	Examples of application of clearance? (Qu 7)	Has cleared material still been rejected? (Qu 8)	Benchmark a) Surface contaminated steel. b) Activated steel
Ireland	The concept of clearance levels has been deliberately excluded from the legislation. (Order - Reg 5(2)(d)) All disposal, recycling or reuse of radioactive substances or materials arising from any licensed practice must be licensed by RPII.	No, decided on a case-by-case basis as required.	No clearance levels have been set.	1	na	No nuclear installations and so no clearance levels have been set.

Table 5 (cont'd)

Country	Is a definition of	Have clearance	Was European	Examples of annication of	Has cleared	Benchmark a) surface
	provided and where?	established? (Ou 4)	guidance used in the derivation of	clearance? (Ou 7)		contaminated steel.
	(Qu 1b)		clearance levels? (Qu 6)			b) activated steel
Italy	The definition of	A general rule of	It is explicitly	See Part II,	Caorso NPP case	Steel would not be
	release 1s addressed in	unrestricted release has been	stated in Art 30	Appendix C Qu 7 for details of the	is the sole example of application of	cleared, see Part II Annendix C for
	Decree 230 of	established in	para 3-bis, that	levels used for	current clearance	further details.
	1995 in Art 30	Art 154 para 2	reference will be	clearance	rules. No mention	
	para 1 and in	and other	made when	(authorised	of rejection was	
	Art 154 para 3-	releases not	defining technical	release) of	made.	
	bis, as being any	meeting the two	specifications in	metals, building		
	act of discharge,	conditions of	authorising	materials and		
	clearance,	mass activity	releases, inter alia,	other material		
	disposal, recycle	concentration <=	to the European	from the Caorso		
	or reuse of	1 Bq/g and half-	Union's relevant	NPP.		
	radioactive	life $<$ 75 days	directives,			
	requirements.	must be	technical			
	Art 4 para 2q)	authorised.	recommendations			
	addresses release		and reports.			
	levels.					

Table 5 (cont'd)

Country	Is a definition of clearance provided and where?	Have clearance levels been established? (Qu 4)	Was European Commission guidance used in the derivation of clearance levels? (Qu 6)	Examples of application of clearance? (Qu 7)	Has cleared material still been rejected? (Qu 8)	Benchmark a) surface contaminated steel. b) activated steel
Luxembourg	It is not defined specifically in the definitions. In Art 2.12.2 of the Decree a description applicable to clearance is given: disposal or reuse of materials released from prior authorisation.	Yes, see Table A and B in the Decree.	No, used levels recommended by German Commission on Radiological Protection (SSK) because European Commission scenarios for clearance apply to 'workplace scenarios' or 'landfill scenarios' or are linked to dismantling of nuclear installation. These scenarios were felt to be unsuitable for general	Dismantling of a facility processing natural ores with a high content of natural radioactivity. The facility and slag was sent to an agreed special waste disposal site.	Experience has been rather limited, however, there are problems of acceptance with fears of contamination and of linking their company with radiation in public perception etc.	No nuclear installations therefore hypothetical.  a) Surface contaminated material would be refused clearance and sent for disposal though further decontamination could be considered.  b) Active material is likely to be sent for disposal though export for recycling could be
			radioactive materials.			considered.

Table 5 (cont'd)						
Country	Is a definition of clearance provided and where? (Qu 1b)	Have clearance levels been established? (Qu 4)	Was European Commission guidance used in the derivation of clearance levels? (Qu 6)	Examples of application of clearance? (Qu 7)	Has cleared material still been rejected? (Qu 8)	Benchmark a) surface contaminated steel. b) activated steel
Netherlands	Yes, provided in par. 4.4 of Explanatory Notes. See Part II, Appendix C Qu 1.	Yes, in Annex 1 of the BS. It is important to note that the same levels apply to exemption and clearance and to both practices and work activities.	No, for the assessment of the clearance levels for natural sources different scenarios were used. These scenarios were based on the scenarios used for calculating the exemption levels.	No specific examples given.	Legislation very recent; don't know yet but the Dutch steel industry doesn't accept (yet) steel contaminated with radionuclides even if below the Exemption levels/Clearance levels.	a) Surface contaminated material either decontaminated if practical, or sent for disposal.  b) Active material could be cleared for recycling if accepted by steel industry, otherwise sent for disposal.
Austria	Title III, Article 5 para 2 of the Directive has been implemented into the new Act.	Limits for clearance under discussion, decision not yet made; currently clearance is on a case-by-case basis with levels prescribed by the authorities within individual	RP122 Part I under consideration.	Clearance has been applied but, up to now, only on an individual case-by-case basis e.g. waste from hospitals and research establishments after the decay of short-lived radionuclides.	No rejection has occurred.	No clearance limits yet.

Table 5 (cont'd)

Country	Is a definition of clearance	Have clearance levels been	Was European Commission	Examples of application of	Has cleared material still been	Benchmark a) surface
	provided and where?	(Qu 4)	guidance used in the derivation of	(Qu 7)	rejecteu: (Qu 8)	steel.
	(QI nA)		clearance levels? (Qu 6)			b) activated steel
Portugal (as of May	No, legislation	No, no materials	na	na	na	No clearance
2002)	not implemented,	have been				levels.
	no process of	cleared.				
	clearance exists.					
Finland	Section 24 of the	Yes see Guide	Initially no,	Scrap metal from	There has been	a) Disposal or
	4.	ST 1.5 and YVL	however reference	NPP (up to	fairly little public	cleared if
		8.2. The process	is made in Guide	10 t/NNP/ year)	concern about	decontamination
		is prescribed in	ST 1.5 to a	cleared	clearance of	of the
	and	Section 10 of the	requirement to	unconditionally.	nuclear wastes,	contaminated
		Nuclear Energy	comply with	Specific	however the metal	portion below the
	determine if a	Decree. See Part	European	clearance permits	recycling industry	levels given in
	waste is	II, Appendix C	Commission	have been	tends towards a	YVL8.2 is
	radioactive. See	Qu 1 for details.	technical guides in	granted for waste	policy of not	practicable.
	Part II, Appendix		addition to Finnish	oil, larger	accepting any	
	C Qu 1 for		limits.	quantities of	radioactive	b) Disposal, as
	details.		Furthermore	metal and for	substances, where	concentrations
			RP 122 was used	trash.	the alarm at the	exceed limits in
			in preparation of		gate is triggered	YVL 8.2.
			YVL 8.2		the waste is sent	
					back.	

Table 5 (cont'd)						
Country	Is a definition of clearance provided and where? (Qu 1b)	Have clearance levels been established? (Qu 4)	Was European Commission guidance used in the derivation of clearance levels? (Qu 6)	Examples of application of clearance? (Qu 7)	Has cleared material still been rejected? (Qu 8)	Benchmark a) surface contaminated steel. b) activated steel
Sweden	It is not defined specifically. It is mainly regulated by general regulations issued by SSI in accordance with \$7-8 of the Ordinance and on a case-by-case basis as in \$4 of the Ordinance.	Yes, see SSI FS 1996:2 (nuclear installations) and SSI FS 1983: 7 (hospitals and research establishments).	No, clearance levels were based on IAEA TECDOC-855 and Swedish studies; the individual dose criterion was 10 µSv y <sup>-1</sup> .	NNPs: 200 t y <sup>-1</sup> of low activity material is disposed of in municipal dumps, 60 t y <sup>-1</sup> of oil and hazardous waste and about 500 t y <sup>-1</sup> of metal are cleared. See Part II, Appendix C Qu 7 for more details.	The steel industry has expressed reluctance to accept metals from nuclear facilities, but SSI has not got any information on cleared materials that have been rejected.	a) Surface contaminated steel would require either decontamination or controlled smelting before release. b) Activated steel would require smelting and some years of decay storage before release.
United Kingdom	Not provided in RSA93 definitions, nor is the term recognised in UK legislation. However there are provisions in RSA93 (reg 13, 14 and 15) to release material from control.	Yes, these are in the form of Exemption Orders, there are 18 such orders largely industry specific. See Part II, Appendix C Qu 1 for details.	No, and the only clearance levels are given in Schedule 1 of RSA93 and in the Exemption Orders.	Aluminium and Lead have been cleared (referred to as 'free release') using the Substances of Low Activity Exemption Order.	No examples of rejection cited.	a) No surface contamination clearance criteria; not cleared. b) Above 0.4 Bq g <sup>-1</sup> so couldn't be cleared.  None of the steel would be released.

Table 6 Summary of implementation of clearance by country

Country		Non-nuclear practices (NNP) and nuclear practices (NPG)	ar practices (NPG)
		Materials	Discharges
Belgium	PA	UCL: RP 122, Part I	CL liquid and aerial
Denmark	PA	CCL solid waste (NNP) CC: CG;	CL sewer and incineration
Germany	PA	UCL and CCL: SSK	CL liquid and aerial. Dose limit of 0.3 mSv y <sup>-1</sup> effective dose.
Greece	PA; $CL = EL$ ;	CCL: W ≅ RP 122 Part I	CL liquid and aerial
Spain	PA	CC with CCL: W, IAEA (NNP) CC: CG (NPG)	20
France	PA	CC (NNP and NPG)	33
Ireland	No provisions, CC	na	2)
Italy	PA	ncT NCT	သ
		CC: CG CCL, ≅ RP 89, 113, 122 (NPG)	
Luxembourg	PA	UCL: SSK	2)
Netherlands	PA	UCL, CL = EL = Directive (with exceptions)	CCL liquid and aerial, DC = $10 \mu \text{Sy y}^{-1}$
Austria (as of November 2002)	PA	No UCL or CCL yet	22
Portugal (as of May 2002)	No provisions	na	No provisions
Finland	PA	CC: CG	20
Sweden	PA	UCL, CCL (NPG) CCL: W (NNP)	CL, liquid, aerial (NNP)
United Kingdom	Clearance concept not defined explicitly.	CC: Exemption Order SoLA $\cong$ DC 10 $\mu$ Sv $y^{-1}$	CL, liquid and aerial
NB: CC = case by case app	oroach; CCL = specific clear	NB: CC = case by case approach; CCL = specific clearance levels; CG =European Commission guidance consulted; CL = clearance levels; CRL = specific	nsulted: CL = clearance levels; CRL = specific

rob: CC = case by case approach; CCL = specific clearance levels; CG = European Commission guidance consulted; CL = clearance levels; CC = clearance levels levels

Comparison of clearance levels in current regulations of EU Member States for key radionuclides in Bq g-1

${f g}^{-1}$	Luxembourg, RGD 14 December 2000, general clearance, practices and work activities.	12	5.0E-02	4.0E-02	5.0E-01	2.0E+00	1.0E-01	5.0E-01	1.0E+02 1.0E+03	}	<i>હેહેહે</i>	3.0E-02	1.0E-01	7.0E-02	3.0E-02	4.0E-02 4.0E-02
levels in current regulations of EU Member States for key radionuclides in Bq	Italy, specific clearance levels for building materials from MPP Caorso (in addition surface contamination levels were set).	11			1.0E+00	1.0E+00	1.0E-01		1.0E+00							
key radionu	Italy, specific clearance levels for metals from MPP Caorso (in addition surface contamination levels were set).	10			1.0E+00	1.0E+00	1.0E+00		1 0E+00							
States for <b>k</b>	Greece, RPR 6 March 2001, clearance of non-reusable waste from practices.	6	1.0E-01	1.0E-01	1.0E+00	1.0E+00	1.0E-01	1.0E+00	1.0E+01 1.0E+03		1.0E+00	1.0E-02	1.0E-01	1.0E-02	1.0E-02	1.0E-02 1.0E-02
Member 5	Germany, Strahlenschutzverordnung, 20 July 2001, specific clearance of metal scrap for recycling, practices.	8	3.0E-01	2.0E-01	6.0E-01	9.0E+00	6.0E-01	5.0E-01	1.0E+03 1.0E+03		4.0E-02	1.0E-01	4.0E-01	7.0E-01	4.0E-01	6.0E-02 1.0E+00
tions of EU	Germany, Strahlenschutzverordnung, 20 July 2001, specific clearance solids and liquids for disposal, practices, except column 5.	7	1.0E+00	1.0E+00	1.0E+01	2.0E+00	4.0E+00	1.0E+01	3.0E+02 1.0E+03		1.0E-01	1.0E+00	1.0E+00	8.0E+00	1.0E-01	1.0E+01 1.0E+01
ent regula	Germany, Strahlenschutzverordnung, 20 July 2001, general clearance, practices, surface soil.	9	6.0E-02	4.0E-02	6.0E-02	2.0E-03	3.0E-02	1.0E-02	3.0E+00 3.0E+00							
els in curr	Germany, Strahlenschutzverordnung, 20 July 2001, general clearance, practices, building rubble, soil in excess of 1000 t y <sup>-1</sup> .	5	5.0E-02	8.0E-02	4.0E-01	2.0E+00	9.0E-02	4.0E-01	8.0E+00 6.0E+01		4.0E-01	3.0E-02	7.0E-02	1.0E-01	3.0E-02	3.0E-02 4.0E-02
	Germany, Strahlenschutzverordnung, 20 July 2001, general clearance, practices, solids, liquids, except column 5.	4	5.0E-02	4.0E-02	5.0E-01	2.0E+00	1.0E-01	5.0E-01	1.0E+02 1.0E+03	}	9.0E-03	2.0E-02	1.0E-01	7.0E-02		2.0E-02 4.0E-02
Comparison of clearance	Denmark, Order 192, clearance levels for naturally occurring radionuclides, (bold includes daughters).	3									5.0E-01	5.0E+00	5.0E-01	1.0E+00	5.0E-01	<b>5.0E+00</b> 5.0E+00
Compa	Belgium, ARBIS, general clearance, practices, (bold not applicable to work activities).	2	1.0E-01	1.0E-01	1.0E+00	1.0E+00	1.0E-01	1.0E+00	1.0E+01 1.0E+02		1.0E+00	1.0E-02	1.0E-01	1.0E-02	1.0E-02	1.0E-02 1.0E-02
Table 7	(s) abilau/	П	$^{241}$ Am	$^{239}$ Pu	$^{137}$ Cs	$^{90}$ Sr	°Co	$^{ m uZ_{co}}$	<sup>31</sup> Cr <sup>3</sup> H	1	$^{238}$ U	$^{232}$ Th	$^{228}$ Th	<sup>228</sup> Ra+	226Ra+	$^{210}_{ m PPo}$

	European Commission Guidance, general clearance level natural sources, RP 122, Part II, 2001.	20									5.0E-01	5.0E-01	5.0E-01	1.0E+00	5.0E-01	5.0E+00	5.0E+00
	European Commission Guidance, specific clearance level, metal scrap, practices, Rp 89, 1998.	19	1.0E+00	1.0E+00	1.0E+00	1.0E+01	1.0E+00	1.0E+00		1.0E+03	1.0E+00	1.0E+00	1.0E+00	1.0E+00	1.0E+00	1.0E+00	1.0E+00
	European Commission Guidance, rounded derived general clearance level, practices, RP 122, Part I, 2000.	18	1.0E-01	1.0E-01	1.0E+00	1.0E+00	1.0E-01	1.0E+00	1.0E+01	1.0E+02	1.0E+00	1.0E-02	1.0E-01	1.0E-02	1.0E-02	1.0E-02	1.0E-02
	European Commission Guidance; derived clearance level building rubble, practices, RP 114, May 1999.	17	9.1E-02	7.7E-02	4.0E-01	1.5E+00	8.9E-02	3.8E-01		6.2E+01	4.3E-01	3.8E-02	7.3E-02	1.2E-01	8.3E-02	8.7E-02	1.1E+00
	UK, general clearance for solids, EO(SoLA), (based on radioelements)	16	4.0E-01	4.0E-01	4.0E-01	4.0E-01	4.0E-01	4.0E-01	4.0E-01	4.0E-01	1.11E+01	2.59E+00	2.59E+00	3.70E-01	3.70E-01	7.40E-01	3.70E-01
	Sweden, general clearance, SSI FS 1996:2, for nuclear installations.	15	1.0E-01	1.0E-01	5.0E-01	5.0E-01	5.0E-01	5.0E-01	5.0E-01	5.0E-01	1.0E-01	1.0E-01	1.0E-01	5.0E-01	1.0E-01	5.0E-01	1.0E-01
	Finland, General clearance levels for nuclear energy sources, YVL 8.2, $25^{th}$ March 2002, (maximum of 100 t $y^{-1}$ per installation) <sup>2</sup> .	14	1.0E-01	1.0E-01	1.0E+00	1.0E+00	1.0E+00	1.0E+00	1.0E+01	1.0E+01	1.0E-01	1.0E-01	1.0E-01	1.0E+01	1.0E-01	1.0E+01	1.0E-01
(p,	Netherlands, BS 16 July 2001, exemption = (general) clearance, practices and work activities.	13	1.0E+00	1.0E+00	1.0E+01	1.0E+02	1.0E+00	1.0E+01	1.0E+03	1.0E+06	1.0E+00	1.0E+00	1.0E+00	1.0E+00	1.0E+00	1.0E+02	1.0E+02
Table 7 (cont'd)	Nuclide (s)	-	$^{241}$ Am	$^{239}$ Pu	$^{137}$ Cs	$^{90}$ Sr	$^{\circ}$ Co	$^{ m e2}_{ m c9}$	J <sub>1</sub> Cr	$^{3}\mathrm{H}$	$^{238}$ U	$^{232}\mathrm{Th}$	$^{228}$ Th	$^{228}$ Ra+	$^{226}$ Ra+	$^{210}$ Pb	<sup>210</sup> Po

<sup>2</sup> Clearance levels must not exceed guide values set in European Commission technical reports (ST 1.5). NB YVL 8.2 is for nuclear energy waste and is based on the following criteria: α-emitters 0.1 Bq g<sup>-1</sup>; significant  $\beta$  and  $\gamma$  emitters 1 Bq g<sup>-1</sup>; and weak  $\beta$  and  $\gamma$  emitters 10 Bq g<sup>-1</sup>.

Table 8 Summary of suggested improvements to Member States regulations relating to exemption and clearance of practices

Country	Exemption	Clearance
Belgium	Removal of the mass limit.	Introduce further guidance on
		application.
	Introduction of guidance including on	
	extra nuclides and a 10% rule for	Consider introducing provision for
	summation calculations.	clearance of surface contaminated
		material.
Denmark	Suggest including Annex I from the	Introduce further guidance on
	Directive for man-made nuclides.	application e.g. in the case of extra
	Inter-denting of and Income	nuclides, averaging volumes etc.
	Introduction of guidance including on extra nuclides and a 10% rule for	
	summation calculations.	
Germany	Guidance on consideration of decay	Consider giving guidance on decay
Germany	chains.	storage.
Greece	Introduction of guidance including on	Introduce further guidance on
	extra nuclides and a 10% rule for	application e.g. in the case of extra
	summation calculations.	nuclides, averaging volumes etc.
Spain	Introduction of guidance including on a	Consider existing levels with a view to
	10% rule for summation calculations.	harmonising with European
		Commission guidance.
France	Removal of mass limit.	Consider the introduction of clearance
	Introduction of avidence including an	levels with additional guidance on
	Introduction of guidance including on extra nuclides and a 10% rule for	application to extra nuclides, decay chains etc.
	summation calculations.	chams etc.
Ireland	Introduction of guidance including on	Consider a wider application of
	extra nuclides and a 10% rule for	clearance possibly clearance levels
	summation calculations.	
Italy	Review existing values with to ensure	Introduction of guidance including on
	consistency with current Euratom	extra nuclides and a 10% rule for
	values.	summation calculations.
	Introduction of guideness including on	Consider existing levels with a view to
	Introduction of guidance including on extra nuclides and a 10% rule for	Consider existing levels with a view to harmonising with European
	summation calculations.	Commission guidance.
Luxembourg	Introduction of guidance including on	Consider removing mass limit
Lancinoung	extra nuclides and a 10% rule for	Consider removing mass mint
	summation calculations.	Introduce guidance on application
Netherlands	Introduction of guidance including on	Consider introducing provision for
	extra nuclides and a 10% rule for	clearance of surface contaminated
	summation calculations.	material.
	Whore exemption values differ from	Introduction of avidence including an
	Where exemption values differ from Annex I of the Directive harmonisation	Introduction of guidance including on extra nuclides and a 10% rule for
	is recommended.	summation calculations.
	15 100011111011dCd.	barrination carculations.

## Table 8 (cont'd)

Country	Exemption	Clearance
Austria	Recommend introduction of guidance.	Recommend introduction of guidance.
Portugal	Annex I values should be adopted.	Implement concept
	Recommend introduction of guidance.	
Finland	Introduction of further guidance	Introduction of further guidance
	including on extra nuclides and a 10% rule for summation calculations.	including on extra nuclides and a 10% rule for summation calculations.
Sweden	Recommend further increased guidance	Regulation for large volumes and non-
	on the progeny details to be considered.	nuclear industry needed.
	Introduction of further guidance	
	including on extra nuclides and a 10%	
	rule for summation calculations.	
UK	Introduction of further guidance	Consider introducing provision for
	including on extra nuclides and a 10%	clearance of surface contaminated
	rule for summation calculations.	material.
		Consider changing to nuclides as opposed to existing elemental limits.
		Harmonise existing values with European Commission guidance where possible.
		r

NB: See Part II Appendix D for more details.

# Table 9 Summary of examples of possible good practice adopted by Member States for exemption and clearance

### **Examples of good practices for exemption**

Harmonisation of levels with European Commission guidance

Inclusion of extra radionuclides

Issuing of guidance documents

#### **Examples of good practices for clearance**

Harmonisation of levels with European Commission guidance

Issuing of guidance documents

Levels specified for all practices (nuclear power generation, hospitals, universities etc)

Explicit consideration of non-radiological aspects of waste before clearance (e.g. heavy metal content).

Exclusion of very short-lived radionuclides (i.e. half-life of a week or less) from lists of clearance levels.

Use of specific and general clearance levels

Provision for general clearance of alpha/beta emitters for radionuclides where no formal levels are set

Use of the 10% summation rule

No mass limits

Use of decayed storage

Advising on how to include daughter ingrowth in assessments

Measuring volumes/masses specified

Clearance allowed for surface contaminated materials

Advice on disposal routes available for materials cleared at certain contamination levels

Definition of a methodology for assessing clearance for case-by-case applicability

Use of zoning to characterise waste with respect to radiological and other hazards (chemical/biological etc), use of BPEO

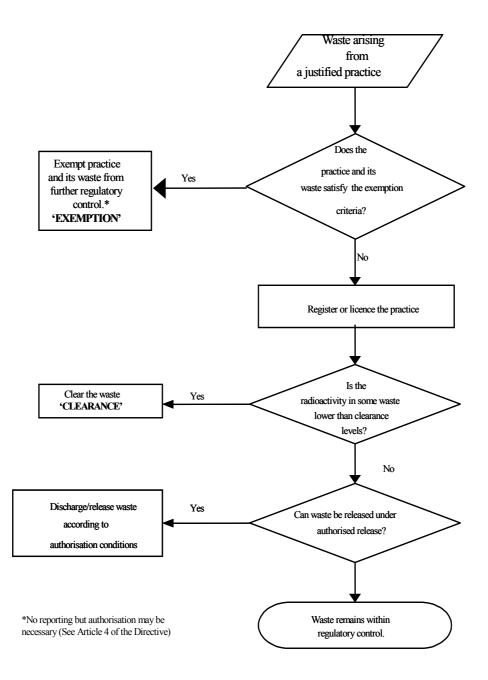
Requirement of waste producer to talk to waste receiver before delivery in order to ensure acceptability

Table 10 Summary of requests made by questionnaire respondents (Qu 9)

Country	Request / Comment
Spain	Guidance in the definition of standard requirements for radiological characterisation of materials before clearance would be welcomed i.e. methodology, required level of confidence, etc.
	Additional guidance for the clearance of hazardous waste streams, considering that regulations in this matter are common in the EU, would be very useful.
	Clearance guidance for small users such as universities and hospitals would be helpful and welcomed in line with the objective of harmonisation.
Ireland	It is not exactly clear how clearance would work in practice and further guidance in this area would be useful.
Italy	One aspect that might be clarified is the definition of the scope in Directive 96/29/Euratom. In fact, Article 2, paragraph 1, of the Euratom Directive states "This Directive shall apply to all practices which involve a risk from ionising radiation"; Article 3 lays down conditions for exemption from reporting and Article 5, paragraph 2, states conditions for exemption from authorisation of releases.
	It can certainly be argued that careful reading of Article 2, paragraph 1, Article 3, paragraph 1, and Article 5, paragraph 2, of the Directive indicates that the scope is determined by levels of exemption from reporting. Nonetheless, some might argue, and have actually done so, that the Directive does not explicitly indicate exemption levels for reporting as the scope of the Directive's requirements. Clarification on this would certainly bring improvements to the application of the radiation protection system.
Luxembourg	A common EC policy for exemption or exclusion of consumer goods containing radioactive substances is needed, e.g. timepieces incorporating radioluminous paint, items incorporating gaseous tritium light sources, items containing uranium and/or thorium (ophthalmic lenses, glassware, tableware, ceramics, dental products), electronic devices containing radioactive materials, etc would be welcomed.
Finland	Although Title III and Annex I of the BSS give common criteria for exemption, the final decision on exempting a single equipment or device may vary from country to country. It could be considered whether exemption of the use of some commonly used equipment containing radioactive substances could be harmonised within EU (e.g. smoke detectors, EC detectors). This "harmonisation" would not necessary require heavy instruments like regulation or directive but even a recommendation could be adequate at the first stage.
	On the other hand some flexibility is also needed to effectively fit the requirements of the BSS to different types of legislation in Member States. The overall approach of exemption as stated in BSS is good and effective as such.
Sweden	It might be helpful to us if the EC also issued recommendations on clearance levels for waste that can be treated as non-radioactive waste (recycled, incinerated or deposited).

Figure 1 Diagram of the concepts

[modified from Cooper et al, 2000]



European Commission guidance<sup>3</sup> documents and technical reports<sup>4</sup> relevant to clearance and exemption Figure 2

	dismantling of n installations)  RP 122 Part I (For practices)
RP 96 (Principles and methods for establishing exemption levels)  RP 96 (Enhanced radioactivity of building materials)  exemption levels)  RP 101 (Surface contamination clearance levels for recycling)  recycling / re-use)  RP 43 (Radiation protection decided for elevels for recycling of recycling of contamination for elevels for nethelials from the foreign for elevels for ele	ear
(Natural radioactivity of building materials)  RP 117 (Methodology and models for dose calculations)  RP 114 (Clearance levels)	

 $<sup>^3</sup>$  Highlighted in bold.  $^4$  These were the basis for the guidance established by the Article 31 Experts and are shown in italics.

#### **Notes:**

- **RP 43<sup>5</sup>.** Radiological protection criteria for the recycling of materials from the dismantling of nuclear installations: guidance from the Group of Experts set up under the terms of Article 31 of the Euratom Treaty. Luxembourg, 11/1988 (Doc. XI-3134/88 EN). [Guidance].
- **RP 65**<sup>6</sup>. Principles and Methods for Establishing Concentrations and Quantities (Exemption values) Below which Reporting is not Required in the European Directive. M. Harvey, S. Mobbs, J. Cooper, A.M. Chapius, A. Sugier, T. Schneider, J. Lochard, A. Janssens. Luxembourg, 1993 (XI-028/93). [Technical report].
- **RP 89**. Recommended Radiological Protection Criteria for the Recycling of Metals from the Dismantling of Nuclear Installations. Luxembourg, 1998. [Guidance].
- **RP 96**<sup>7</sup>. Enhanced radioactivity of building materials. STUK, December 1997, published 1999. [Technical report].
- **RP 101**<sup>8</sup>. Basis for the definition of surface contamination clearance levels for the recycling or reuse of metals arising from the dismantling of nuclear installations. Luxembourg, 1999. [Technical report].
- **RP 112.** Radiological protection principles concerning the natural radioactivity of building materials. February 2000. [Guidance].
- **RP 113.** Recommended radiological protection criteria for the clearance of buildings and building rubble arising from the dismantling of nuclear installations. Luxembourg, 07/2000. [Guidance].
- **RP 114**<sup>9</sup>. Definition of Clearance Levels for the Release of Radioactively Contaminated Buildings and Building Rubble Final Report. Luxembourg, 07/2000. [Technical report].
- **RP 117<sup>10</sup>.** Methodology and models used to calculate individual and collective doses from the recycling of metals from the dismantling of nuclear installations. Luxembourg, 07/2000. [Technical report].
- **RP 122**. Practical use of the concepts of clearance and exemption
- **Part I:** Guidance on general clearance levels for practices. Luxembourg, 2000. [Guidance].
- **Part II:** Application of the concepts of exemption and clearance to natural radiation sources. Luxembourg, 2001. [Guidance].

<sup>&</sup>lt;sup>5</sup> Note that RP 43 is partially superseded: detailed calculations for 300 radionuclides have since been completed replacing the mass specific activity of 1 Bq g<sup>-1</sup> but surface contamination values are still valid.

<sup>&</sup>lt;sup>6</sup> Technical contribution for the establishment of the exemption values in Annex I of the Directive.

<sup>&</sup>lt;sup>7</sup> Used to establish RP 112 -recommendations.

<sup>&</sup>lt;sup>8</sup> Used to establish RP 89 recommendations.

<sup>&</sup>lt;sup>9</sup> Used to establish RP 113 recommendations.

<sup>&</sup>lt;sup>10</sup> Used to establish RP 89 recommendations.

Figure 3 Status of implementing Title III of the Directive in Member States (based on answers to Question 1 of the Questionnaire and analysis of the legislation).

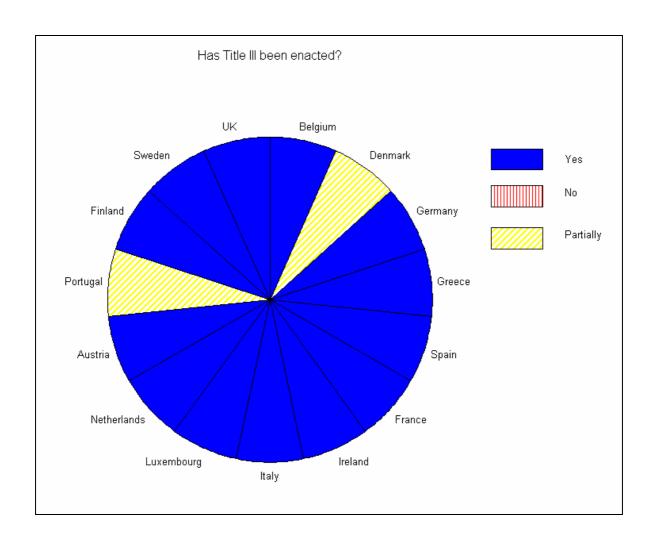


Figure 4 Transposition of the exemption levels for practices from the Directive into national legislation (based on answers to Question 5 of the Questionnaire).

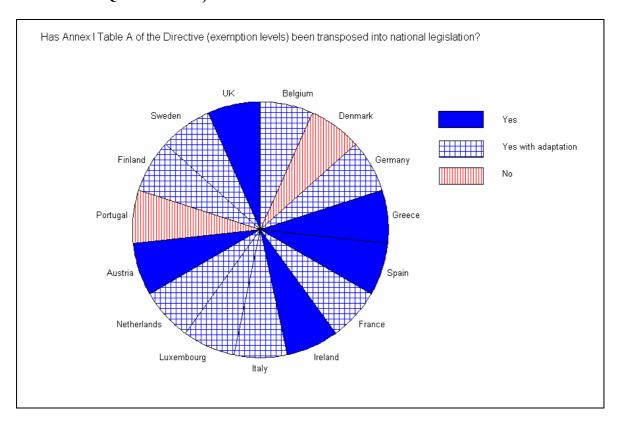


Figure 5 General clearance levels for <sup>239</sup>Pu (assuming no multi-nuclide contamination)

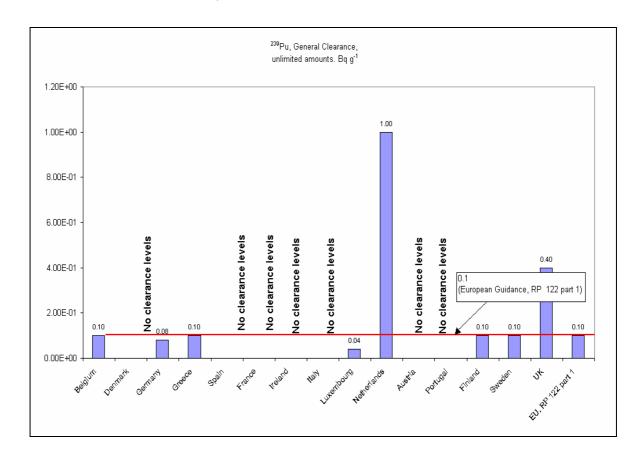


Figure 6 General clearance levels for <sup>137</sup>Cs (assuming no multi-nuclide contamination)

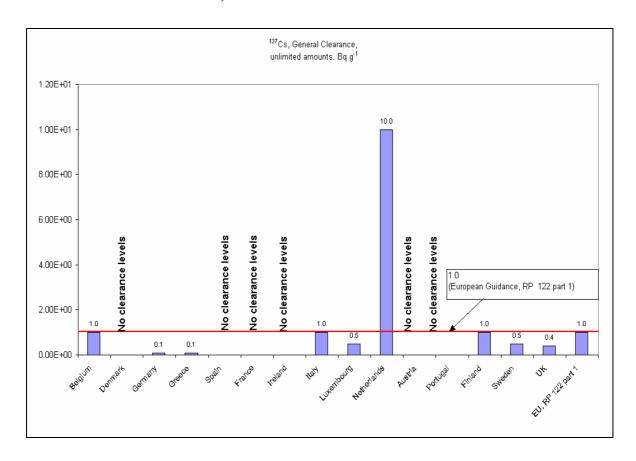


Figure 7 General clearance levels for <sup>90</sup>Sr (assuming no multi-nuclide contamination)

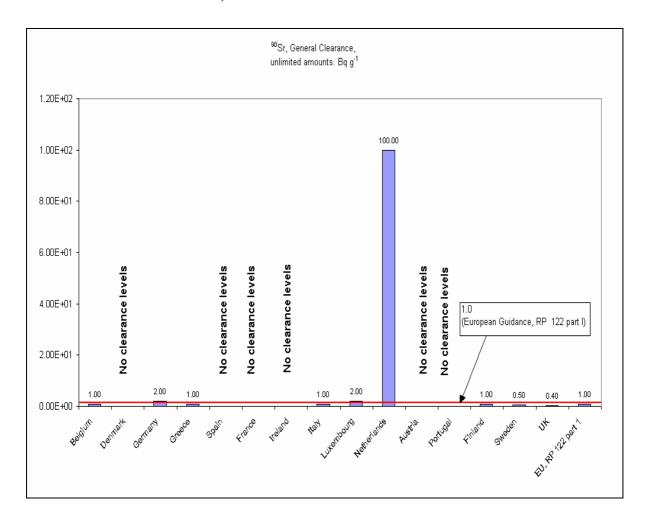


Figure 8 General clearance levels for <sup>65</sup>Zn (assuming no multi-nuclide contamination)

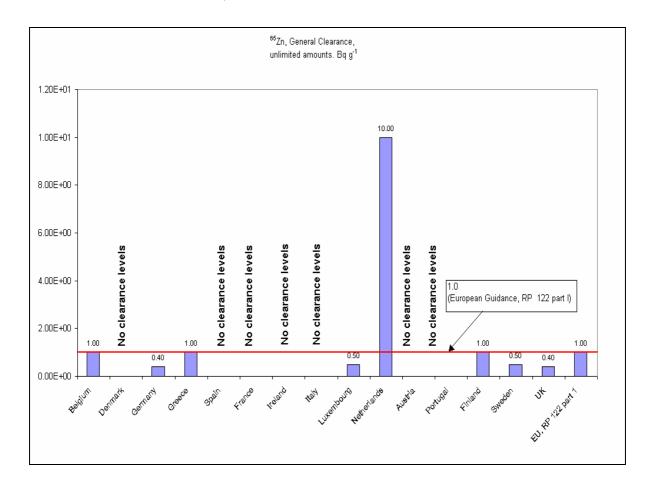


Figure 9 General clearance levels for <sup>60</sup>Co (assuming no multi-nuclide contamination)

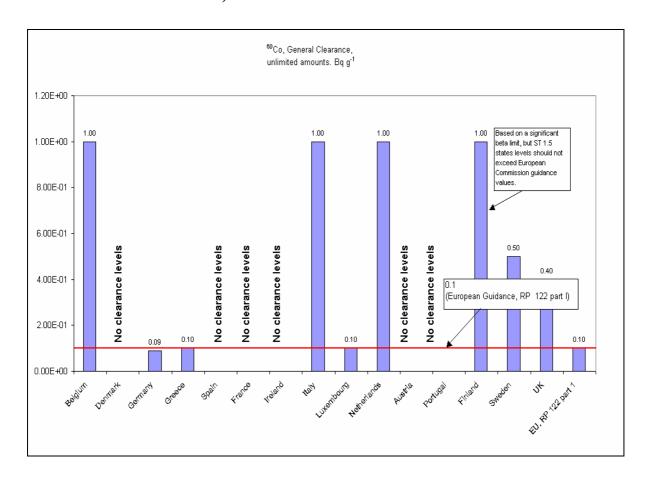
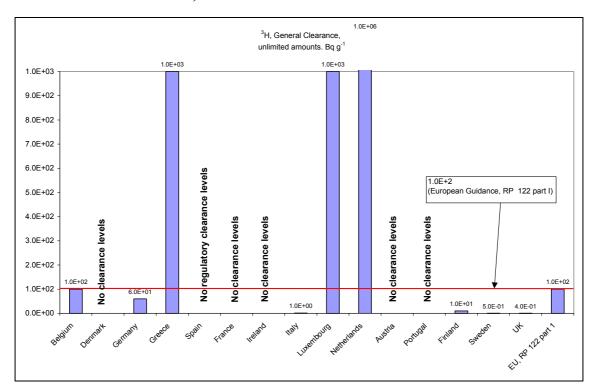


Figure 10 General clearance levels for tritium (<sup>3</sup>H) (assuming no multi-nuclide contamination)



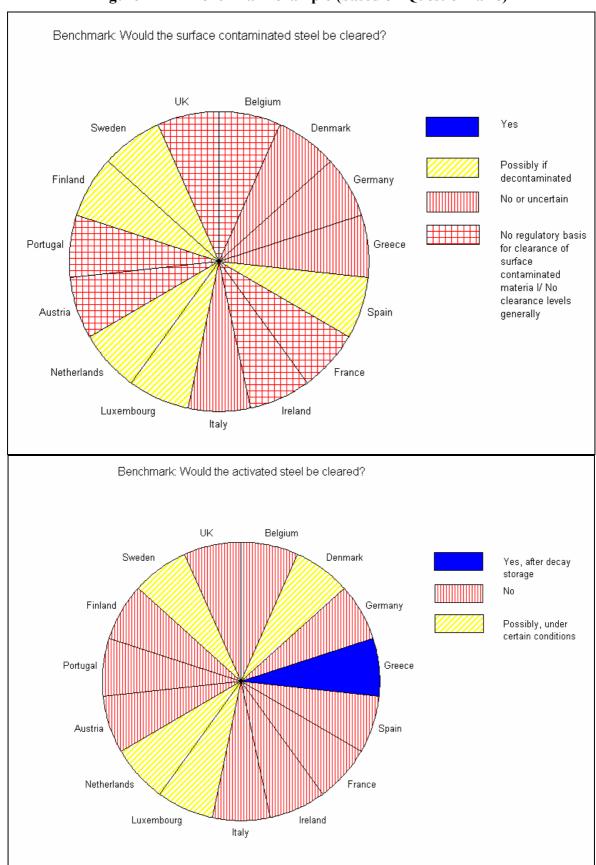


Figure 11 Benchmark example (based on Questionnaire)

Figure 12 Status of the clearance concept (based on answers to Question 1 of the Questionnaire).

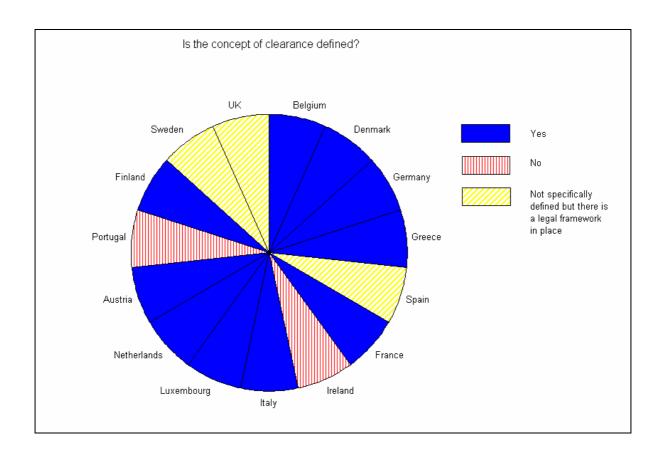


Figure 13 Use of clearance levels (based on answers to Question 4 of the Questionnaire).

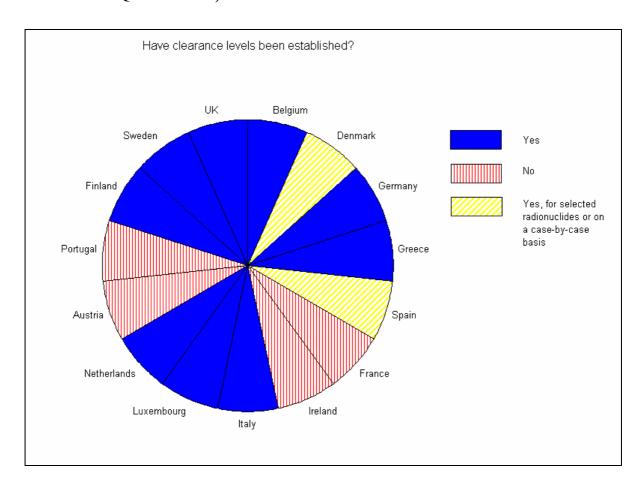
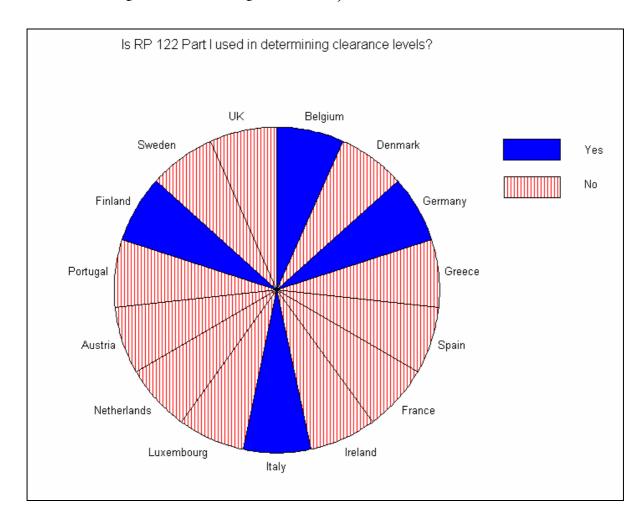


Figure 14 Transposition of the clearance levels from the latest European Commission Guidance on clearance for practices (based on answers to Question 6 of the Questionnaire).



#### Abstract

This document summarises the findings of a project commissioned by DG Environment of the European Commission. The project's primary objective was to provide information for Article 31 experts and EU Member States on the application of the concepts of exemption and clearance for practices according to Title III of Council Directive 96/29/EURATOM of 13 May 1996.

For this purpose information on legal instruments and application of exemption and clearance in all EU Member States was collated and then evaluated in order to identify particular measures that could be considered to improve the effectiveness of the existing provisions on Exemption and Clearance in the Member States.

It was found that most Member States in the EU have introduced new legislation to address the Directive within the past 2-3 years. Exemption has been implemented by the majority of Member States in a way consistent with Title III of the Directive.

The application of clearance in some Member States has encountered practical difficulties and the area of greatest variation relates to the setting of clearance levels. There is a need to encourage harmonisation of clearance levels especially for particular materials, such as metals, designated for recycling and hence subject to international trade.

Available on: Europa, <a href="http://europa.eu.int/comm/energy">http://europa.eu.int/comm/energy</a> in the Publications of the Radiation Protection section.