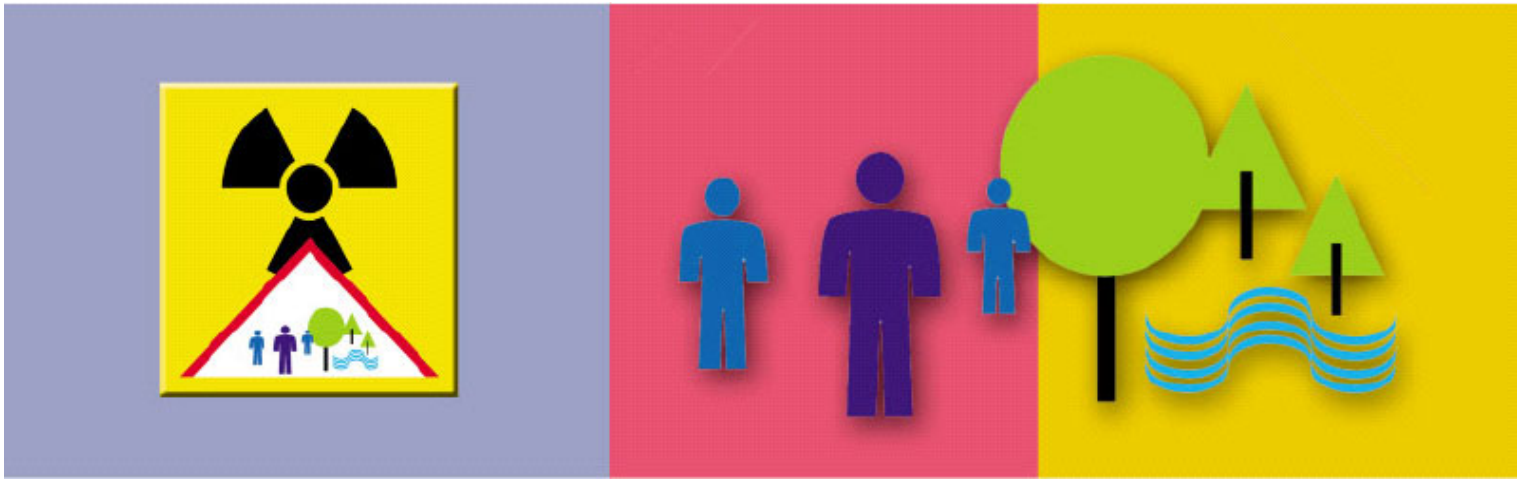
RADIATION PROTECTION



Evaluation of the application
of the concepts of exemption and clearance
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Volume 2: Appendices

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Volume 2: Appendices

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

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EC Project co-ordinator: Jean-Louis Daroussin

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 2: Appendices

by

MY Gerchikov[1], ZK Hillis[1], E.I.M. Meijne[2], W Oatway[3], S Mobbs[3], A van Weers[2]

[1]NNC Ltd, UK
[2]NRG, Netherlands
[3]NRPB, UK

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Appendix A - Title III of Council Directive 96/29/EURATOM

[OJ No L 159, 13.5.1996 p6-7]

Title III

REPORTING AND AUTHORISATION OF PRACTICES

Article 3

Reporting

1. Each Member State shall require the carrying out of the practices referred to in Article 2 (1) to be reported, except as provided for in this Article.

2. No reporting need be required for practices involving the following:

(a) radioactive substances where the quantities involved do not exceed in total the exemption values set out in column 2 of Table A to Annex I or, in exceptional circumstances in an individual Member State, different values authorised by the competent authorities that nevertheless satisfy the basic general criteria set out in Annex I; or

(b) radioactive substances where the concentration of activity per unit mass do not exceed the exemption values set out in column 3 of Table A to Annex I or, in exceptional circumstances in an individual Member State, different values authorized by the competent authorities that nevertheless satisfy the basic general criteria set out in Annex I; or

(c) apparatus containing radioactive substances exceeding the quantities or concentration values specified in subparagraphs (a) or (b), provided that:

  (i) it is of a type approved by the competent authorities of the Member State; and

  (ii) it is constructed in the form of a sealed source; and

  (iii) it does not cause, in normal operating conditions, a dose rate exceeding 1 $\mu Sv\ h^{-1}$ at a distance of 0,1 m from any accessible surface of the apparatus; and

  (iv) conditions for disposal have been specified by the competent authorities; or

(d) the operation of any electrical apparatus to which this Directive applies, other that referred to in subparagraph (e) provided that:

  (i) it is of a type approved by the competent authorities of the Member State; and

  (ii) it does not cause, in normal operating conditions, a dose rate exceeding 1 $\mu Sv\ h^{-1}$ at a distance of 0,1 m from any accessible surface of the apparatus; or

(e) the operation of any cathode ray tube intended for the display of visual images, or other electrical apparatus operating at a potential difference not exceeding 30 kV, provided that this operation does not cause, in normal operating conditions, a dose rate exceeding 1 $\mu Sv\ h^{-1}$ at a distance of 0,1 m from any accessible surface of the apparatus; or

(f) material contaminated with radioactive substances resulting from authorized releases which competent authorities have declared not to be subject to further controls.

Article 4

Authorisation

1. Except as provided for in this Article, each Member State shall require prior authorisation for the following practices:

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

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

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

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

(e) the use of X-ray sets or radioactive sources for industrial radiography or processing of products or research of the exposure of persons for medical treatment and the use of accelerators except electron microscopes;

2. Prior authorisation may be required for practices other than those listed is paragraph 1.

3. Member States may specify that a practice shall not require authorization where:

(a) in the case of the practices described in paragraph 1 (a), (c) and (e), the practice is exempt from reporting; or

(b) in cases where a limited risk of exposure of human beings does not necessitate the examination of individual cases the practice is undertaken in accordance with conditions laid down in national legislation.

Article 5

Authorisation and clearance for disposal, recycling 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 authorization is subject to prior authorization.

2. However, the disposal, recycling or reuse of such substances or materials may be released for 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.

Appendix B - Summary of key points from European Commission guidance

Some of the key points relating to the application of the concepts of exemption and clearance from European Commission guidance documents have been outlined below. This summary is in no way comprehensive and for full details reference to the full reports is strongly recommended.

Exemption and clearance - the basic criteria

Values given in Table A of Annex I of the Directive relate only to exemption of practices (Title III, Article 3, 2 (a) and (b)). However, when establishing clearance levels (Article 5, para. 2) (or exceptionally when Member States are establishing their own exemption values (Article 3, para 2(b)) the basic criteria set out in Annex I must be followed.

Annex I [European Commission, 1996]

The basic criteria for the calculation of values in Table A are:

- the radiological risks to the individual from the exempt practice are of no regulatory concern; and
- the collective radiological impact of the exempt practice is of no regulatory concern under the prevailing circumstances; and
- the exempted practice in inherently without radiological significance, with no appreciable likelihood of scenarios that could lead to a failure to meet the criteria above.

Exceptionally, Member States may exempt practices even if they deviate from the exemption values in Table A if:

- the effective dose to members of the public is of the order of 10 μSv or less in a year; and
- either the collective effective dose in one year is no more than about 1 manSv or exemption is shown to be the optimum option.

The requirement for reporting can be waived for mixtures if the sum of the ratios for each nuclide of the total amount present, divided by the exemption value, is less than or equal to 1.

European Commission Guidance

To assist Member States when putting into effect the provisions of Title III of the Directive the European Commission has published a number of guidance documents, the recommendations within these documents are not mandatory. Some points taken from a number of these reports are given below.

Clearance

RP 113: Buildings and Building Rubble [European Commission, 2000(a)]

Criteria

- Three sets of clearance levels for buildings and building rubble were developed:
    - For Reuse (or Demolition)
    - For Demolition only
    - For Building Rubble
- The surface specific clearance levels in the tables apply to the total activity under the surface to be measured divided by its area. The surface area for averaging shouldn't exceed 1 m^2 or 1 t in the case of building rubble.
- A summation formula can be used for mixtures whereby if the sum of the all the ratios of the total activity per unit area (or mass) of each radionuclide to the clearance level is less than 1, the material complies with the clearance requirements. Short-lived progeny are included with parent nuclides.
- No restrictions on the activity cleared in a year need to be applied.
- The deliberate mixing of contaminated and uncontaminated building rubble in order to meet clearance levels should not be used.
- For building rubble in quantities not exceeding 100 t y^{-1} from one site, the clearance levels could be relaxed by a factor of 10.
- Clearance levels in tables should be verifiable by standard low-level measurement procedures.
- Clearance authorisation can be on a case-by-case basis or within the national legal framework.
- These recommendations do not apply to particle accelerators.

RP 89 Metals [European Commission, 1998]

- Recycling within the nuclear industry might be preferable to clearance to the public domain whenever it is economically sound to do so (European Commission, 1998). However, the clearance levels derived are for unrestricted release.
- The recommendations are not intended for composite materials such as electric cables or for scrap melted before clearance (because there is an assumption in the values that only a fraction of the scrap in the furnace comes from cleared scrap).

Criteria

- Two sets of clearance levels for metals were developed:
    - For metal scrap recycling (recycling by melting is reasonably assured).
    - For direct reuse
- The tables report the lowest value from all the metals studied i.e. copper, steel and aluminium. Short-lived progeny are included with parent nuclides.
- The mass specific clearance level allows for the total activity to be averaged over moderate (a few hundred kilograms) amounts of metal.
- The surface specific clearance levels apply to the total surface activity concentration, fixed and non-fixed averaged over moderate areas (several hundred cm^2).
- Both surface and mass limits must be met.
- A summation formula can be used for mixtures whereby if the sum of the all the ratios of the concentration of each radionuclide, to the clearance level is less than 1, the material complies with the clearance requirements.

RP 122 Part I General Clearance Levels [European Commission, 2000(b)]

<u>General points relating to clearance</u>

- Must be carried out under a system of reporting and prior authorisation.
- Once cleared material should require no further control i.e. no conditions on destination or traceability.
- Specific clearance levels have specific clearance pathways to clear it for a particular use or destination without further follow-up; traceability is limited to the first step ensuring it follows a prescribed scenario.

<u>Clearance Levels</u>

- Must be valid for a large class of materials and for all possible destinations.
- Triviality of risk must be guaranteed at time of release.
- Should be strictly forbidden to deliberately dilute in order to meet levels.
- In practice only the individual dose criteria are important in the establishment of levels.
- Should not exceed exemption values as laid down in Directive.

- General clearance levels should be equal to or more restrictive than specific clearance levels as the destination of the material is not defined so it could be recycled, reused or disposed of.

- A comparison between the general clearance levels given in RP122 with clearance levels given in RP89 for metals and RP113 for building rubble yielded the following results:

    - In only 17% of cases did the general clearance level exceed that given for metals, these were nuclides that are not usually the leading nuclide vector and only for 3% of that given for building rubble. Furthermore, the general clearance levels do not exceed the other sets by more than one order of magnitude.

    - The few cases where the general clearance level is higher than the specific clearance level could be adjusted in such a way that they are lower than or equal to the specific clearance levels for metals or building rubble for each nuclide.

    - Generally there is a considerable degree of consistency among the three sets of clearance levels with the general clearance level normally equal or a factor of 10 lower.

    - These values apply only to solid, dry material.

References:

European Commission, *Council Directive 96/29/EURATOM of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation*, Official Journal of the European Communities, OJ L159 1996 p19.

European Commission, Recommended Radiological Protection Criteria For The Recycling Of Metals From The Dismantling Of Nuclear Installations, *Radiation Protection No 89,* European Commission, 1998.

European Commission, Recommended Radiological Protection Criteria For The Clearance Of Buildings And Building Rubble From The Dismantling Of Nuclear Installations, *Radiation Protection No 113,* European Commission, 2000 (a).

European Commission, Practical Use of the Concepts of Clearance and Exemption – Part I Guidance on the General Clearance Levels for Practices, *Radiation Protection* No 122, European Commission, 2000 (b).

Appendix C - Responses to Questionnaire

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

BELGIUM (Belgique/België)

Provided by: Albert van Weers (NRG)

Further comment was sought from P. Smeesters, Article 31 Expert, Federal Agency for Nuclear Controls (FANC) in Belgium however no response was received within the period of the project.

Title III of Euratom Directive

1. Title III, Article 3 paragraph 2 and Title III, Article 5 paragraph 2 of Council Directive 96/29/Euratom define what practices may be exempt and what materials may be cleared. Have these articles been implemented in your country?

   Title III implemented? *Yes*

   Legislative document:

   Koninklijk Besluit van 20 juli 2001 houdende algemeen reglement op de bescherming van de bevolking, van de werknemers en het leefmilieu tegen de gevaren van ioniserende straling. ACRONYM: ARBIS

   Translated document title:

   Royal Decision of 20 July 2001 holding the general regulation of the protection of the population, the workers and the environment against the dangers of ionising radiation.

   Definition of Exemption? *Not provided in ARBIS Art. 2. Definitions.*
   Definition of Clearance? *Not provided in ARBIS Art.2 Definitions.*

   General exemption from scope of ARBIS

   The scope of ARBIS is defined in Article 1. In addition to the exemptions from the scope of the Council Directive (CD) specified in Title II, Art. 4, ARBIS also exempts from its scope:

   - *military equipment and installations, except with respect to the protection of workers from external companies present in those installations,*
   - *the transport under order of the National Defence Minister of equipment or materials that can emit ionising radiation.*

The exemption of practices from regulatory control is dealt with in Chapter II, Art. 3.1 of ARBIS. The exemption provisions cover practices as well as work activities and is implemented by describing a Class IV of establishments, exempted from reporting and prior authorization, containing one or more of the following installations:

1. the installations, with the exception of those installations described under 3.b and 3.d of Article 3.1.b of ARBIS, in which radioactive materials are used or possessed of which the total quantities or the activities per unit mass do not exceed the exemption levels laid down in Appendix 1A, taking into account the application criteria described in the same Appendix, amongst others with respect to mixtures of radionuclides.

Appendix IA of ARBIS provides numerical exemption values for concentrations and total activities to be used in connection with Art. 3.1.d of ARBIS. The Appendix is largely identical to Annex 1 of the CD and also provides the same basic criteria for calculation of exemption values. In Point 1 of the Appendix IA it is stated that the values:

- *can only be applied to moderate amounts of material (of the order of maximum one tonne),*
- *are not applicable to materials related to Art. 4 of ARBIS (Work activities involving natural radiation sources).*

2. The installations in which apparatus is used or possessed containing radioactive materials in quantities or concentrations higher than those referred to in point 1 above if all of the following requirements are fulfilled:

- *the apparatus of a type approved by the Agency;*
- *the apparatus has the properties of a sealed source;*
- *the apparatus does in normal operation at no point at 0.1 m distance a dose rate higher than 0.1 microsievert per hour.*

3. the installations in which cathode ray tubes are used for the display of visual images or where any other electric apparatus is used operating at a potential difference not exceeding 30 kV under the condition that they under normal operation at no point at 0.1 m of their accessible outer surface cause a dose rate exceeding 0.1 microsievert per hour.

4. the installations in which other apparatus are used than described in point 3 of this Class which produce ionising radiation, but do not contain radioactive substances, if all of the following conditions are fulfilled:

- *the apparatus of a type approved by the Agency*
- *the apparatus causes at no point from its accessible outer surface and in normal operation a dose rate exceeding 0.1 microsievert per hour.*

5. In Art. 3.2, Additional provisions, the exempted Class IV of installations is extended to:

- *Establishments in which the radioactive nuclides Nd-144, Sm-147, Rb-87, In-115 and Re-187 are being used or possessed independent of the activities under consideration.*

- *Establishments in which natural and depleted uranium and natural thorium are being used or possessed as far as the quantities involved are less or equal to 5 Mb and 50 kBq respectively. If the quantities involved are higher than these installations fall under the not exempted Class III establishments.*

Incorporation of Clearance for disposal, recycling or reuse (Title III, Art. 5, par. 2)

The clearance for disposal, recycling or reuse of solid radioactive waste materials from Class I, II and III establishments requires prior authorization (Art. 18, par 18.1) when these materials do not comply with the clearance levels and conditions specified in annex IB. This authorization requirement also applies to materials arising from work activities authorized under application of Art. 9 of ARBIS which provides the regulatory framework for work activities involving natural radiation sources described in Art. 4 of ARBIS. However, the clearance levels for natural radionuclides provided in Annex IB do not apply to materials from work activities unless the Agency decides otherwise (point 5 of Annex IB). They also do not apply to food contaminated in a radiological emergency situation and in intervention situations.

The basic radiological principles for clearance are described in point 1 to 6 of Annex IB. They are identical to the criteria specified for the calculation of exemption levels presented in Annex IA of ARBIS and Annex I of the CD. However, the numerical clearance levels, provided as kBq/kg without limitation of total activity, are one to three orders of magnitude lower than the corresponding exemption levels in Annex IA. In addition Annex IB covers a smaller number of radionuclides than Annex IA. Other differences between Annex IA and Annex IB pertain to the daughter nuclides considered to be included in the values for the long-lived mother.

Clearance of materials arising from the dismantling of facilities of Class I, Class II or Class III authorized practices, and from facilities from authorized work activities requires prior authorization (Art. 17.1 of ARBIS). Art. 17.2 specifies the general requirements for the application of an authorization. Art. 18.1 and 18.2 specifies the requirements for the application for authorised clearance to dispose or remove for recycling or reuse solid materials from Class I to Class III facilities and from authorized work activities. Art. 18.3 specifies on what basis FANC will take its decisions on the application. Activity concentrations in solid radioactive wastes should be as low as reasonably achievable and may not exceed the levels specified for materials in exempted practices specified in annex IA of ARBIS. In addition, the disposals should comply with the radiological protection criteria specified in point 2 of Appendix IB.

Clearance of liquid radioactive discharges

The discharge of liquid waste from all installations authorized under the provisions of Chapter II of ARBIS is subject to the provisions of Part IV of ARBIS (radioactive wastes)
Discharge of liquid radioactive waste into the ground is not allowed (Art. 34.1).
The discharge of liquid radioactive effluent in surface water or sewers is not allowed when the concentration of radionuclides exceeds the values specified in Table H1 of Appendix III (Art. 34.2). Authorizations obtained by Class 1 and II facilities may deviate from this provision.
The total activity of the radioactive waste to be discharged must be kept as low as reasonably achievable. FANC can impose, by an officially published general Directive, limits on total activities discharged within a specified period from a given establishment.

Appendix III, point D explains that the maximum concentrations in liquid discharges are derived on the basis of an annual dose limit for members of the public of 1 mSv. The activity of a radionuclide (Bq) that would upon ingestion result in a committed dose of one thousands of the dose limit is expressed as the clearance limit in Bq/l. The dose coefficients in Sv/Bq for adults are taken from Table A of Annex III of ARBIS. The resulting values are given in Table H1. The list of radionuclides in Table H1 is not completely identical to Table A of Annex IA or Table A of Annex IB. In the case of mixtures of radionuclides a summation rule has to be applied.

Clearance of gaseous radioactive effluents

Discharge of radioactive substances into the atmosphere is not allowed when the concentration of the radionuclides, expressed as Bq/m^3, exceeds at the point of discharge the derived limits for concentrations in air calculated for members of the public according to the rules defined in Appendix III, point D. The values are given in table H2 of that Appendix (Art. 36.1).
Appendix III, point D explains that the maximum concentrations in aerial discharges are derived on the basis of an annual dose limit for members of the public of 1 mSv. The activity concentration of a radionuclide (Bq/m^3) that would upon inhalation during 8000 hrs/year result in a committed dose of one thousands of the dose limit is expressed as the clearance limit in Bq/m^3. The dose coefficients in Sv/Bq for adults are taken from Table B of Annex III of ARBIS. The resulting values are given in Table H2. The list of radionuclides in Table H2 is not completely identical to Table A of Annex IA or Table A of Annex IB.

2. Which organisation(s) is responsible for issuing regulatory documentation, including exemption and clearance levels and overseeing the practical application of the concepts?

Federaal Agentschap voor Nucleaire Controle (FANC) = Federal Agency for Nuclear Control.

The Agency has been founded by the law of 15 April 1994 concerning the protection of the public and the environment against from ionising radiation and concerning the Federal Agency for Nuclear Control. The Agency is fully operational since 1

September 2001 when the Royal Decision of 20 July 2001 came into force. The general mission of the Agency is the care for the protection of the public and the environment against the dangers from ionising radiation.
The main tasks of the Agency to fulfil this mission are:

- *to propose laws and regulations*
- *to control the observance of the laws and regulations*
- *to examine, propose and take decisions on applications for a variety of authorizations*
- *to ensure supervision, control and inspections on all practices and work activities involving the use of ionising radiation.*

FANC is supported in its responsibilities by a Scientific Council which provides general advice on supervision policy and, more specific, is consulted prior to the issue of authorizations or to renewal of authorizations.

3. What guidance has been issued to ensure compliance with statutory provisions e.g. approved codes of practice?

Guidance as referred to in this question is largely provided in the articles of ARBIS. These articles specify the requirements:

- *for authorization of practices in Class I, II and III practices: in Art. 6, Art. 7 and Art. 8 of ARBIS respectively,*
- *for reporting of work activities described in Art. 4 of ARBIS: in Art 9 of ARBIS*
- *for clearance of solid radioactive waste material from authorized practices to disposal, recycling or reuse: in Art. 18 and Art. 35 of ARBIS,*
- *for clearance of solid radioactive waste material from authorized work activities to disposal, recycling or reuse: in Art. 18 of ARBIS,*
- *for treatment and cleared discharge of gaseous radioactive effluents from authorized practices Class I to III in: Art. 36 of ARBIS,*
- *for treatment and cleared discharge of liquid radioactive waste from authorized practices Class I to III in: Art. 34.*

4. Please describe the processes of exemption and clearance for nuclear installations and other practices i.e. hospitals, research establishments etc.

See answers to question 1.

The following provisions describe the process of clearance of materials from practices of Class I to III.

1. Application for authorization Class I

a. *Art. 6.2 requires from the applicant to register at NIRAS and to come to an agreement with NIRAS on the management of all radioactive waste materials.*

b. Art. 6.2 requests from the applicant for authorization of a Class I practice a preliminary safety report that includes the description of de expected amounts of radioactive waste materials, including those from dismantling, their treatment and/or temporary storage before disposal or transfer to NIRAS.

2. Application for authorization Class II

Art. 7.2 requires from the applicant to provide a description of the treatment and/or storage of possible radioactive waste materials, including those from dismantling, prior to transfer to NIRAS. In particular the description should

a. include detailed information on expected liquid discharges, arisings of solid wastes to be disposed or store and gaseous effluents.

b. Art. 7.2 also requires from the applicant to register at NIRAS and to come to an agreement with NIRAS on the management of all radioactive waste materials.

3. Notification of work activities with natural sources

Work activities as meant by Art. 4.2 have to be notified to FANC. The notification must include a description of the natural radiation sources involved, of processes that can lead to enrichment of radionuclides present and, if applicable, the physical state of the natural radiation sources, their amounts, radioactivity level, their destination, and the places where they are held, used or stored.

4. Prior authorization for disposal, recycling or reuse

Art. 18 specifies that prior authorization is required for disposal, recycling or reuse of solid radioactive wastes from Class I to Class III establishments that do not comply with clearance conditions and levels of Annex IB. This provision also applies to solid radioactive wastes from work activities authorized under application of Art. 9.

5. Record keeping

Art. 34.5 specifies the following requirements:

a. The concentrations of the various radioactive substances present in the solid radioactive wastes, their chemical and physical characteristics, their origin, volume and mass, as well as their destination have to systematically registered by the operator of Class I to III establishments and kept available for FANC and NIRAS.

b. At the latest on 1 March of every year the operators or their substitutes provide FANC with an overview of all waste materials that were cleared in the previous year.

c. The destination of substances and materials for which disposal at a disposal site, recycling or reuse where foreseen has to be verified and guaranteed by the operator and to be proven with appropriate documentation.

5. Was Annex 1 (of BSS Euratom) used for defining exemption levels? If not, what are these other levels. Please describe the reasoning/methodology in their derivation.

*Exemption of **practices** involving radioactive substances from reporting is based on Art. 3.1.d of ARBIS that refers to Annex 1A of ARBIS containing a description of the radiological principles underlying the application of exemption and a Table A, "Exemption levels" providing recommended nuclide specific exemption concentrations and total activities. Both the radiological criteria for exemption and the numerical values for activity and activity concentration are directly based on Annex 1 of the CD. This includes the summation rule to be applied in the case of mixtures of more than one radionuclide. However, Annex 1A of ARBIS in its first paragraph specifies:*

"The following table A provides the exemption levels to be used for the application of article 3.1.d. These values can only be used when the materials, that contain radioactive substances, are present in moderate quantities (of the order of maximum one tonne)." These are not applicable in relation to article 4. Art. 4 of ARBIS deals with work activities involving natural radiation sources!!!

6. Was EC guidance used in the derivation of clearance levels? Please indicate which guidance and for which materials and practices.

The clearance of solid waste materials for reuse or recycling from authorised Class I to III practices, referred to in Art. 3 of ARBIS, is, according to the provisions Art. 35.2 of ARBIS, dealt with in Annex IB of ARBIS. This Annex is titled "Solid radioactive waste: conditions and clearance levels" The underlying basic radiological criteria are the same as those specified for exemption in ANNEX 1 of the CD and Annex IA of ARBIS. However, in the conditions it is noted that when radionuclides with half-lives of less than 6 months are used it is not sufficient to observe the clearance levels. In those cases the provisions of Art. 35.3 regarding decay storage apply. The clearance levels are generic (unconditional) but do not apply to residues from work activities.

Although the generic clearance levels provided in Table A of Annex IB are stated to be consistent with the basic radiological protection criteria for exemption in ANNEX 1 of the CD, it is not clear from Annex IB on the basis of what scenario's the nuclide specific clearance levels were derived. They are 1 to 4 orders of magnitude lower than the exempted concentration levels for the same radionuclides in Annex IA and are apparently applicable to unspecified amounts of material. Most of the clearance levels are identical to those in Radiation Protection 122 Part I. Therefore the conclusion is that the guidance provided by the European Commission in RP 112 Part I is used for establishing Annex IB of ARBIS.

The clearance levels for some natural radionuclides, Pb-210, Po-210, Ra-226 etc., in Annex 1B are lower than encountered in many types of soil and building materials. It is not clear how would this be dealt with in practice, for example how clearance of

Cs-137 contaminated concrete from dismantled facilities of a former practice would be approached.

Annex IB states that surface contamination needs not to be assessed unless the materials will be manipulated after clearance. How it is not clear what surface contamination criteria would apply in such cases.

Annex IB states that the clearance levels do not apply to materials from work activities as indicated in Art. 4 of ARBIS.

7. Please give specific situations, sources, waste streams to which exemption and clearance have been applied. Please list exempt practices. Have both general and specific clearance levels been applied in your country (i.e. after clearance, is material cleared for all uses or are restrictions imposed)? Please give examples.

   No answer.

8. Has clearance been a useful concept or have cleared materials still been rejected as radioactive? Please give details.

   No answer.

9. Please identify needs for improvement (legal, practical application, additional guidance) in this area

   No answer.

Benchmark Example:

In order to fairly and simply compare the approaches of different EU Member States it is our hope to analyse the responses Authorities would take to a sample situation. Thus could you consider the following and justify the appropriate proposed course of action:

- Operator of a nuclear installation in your country hopes to clear about 5,000 t steel in the course of decommissioning the site.

- Half the material has surface contamination while the other half is activated.

- The typical surface contamination and activity is given below:

Radionuclide	Surface Contamination (Bq/cm^2)
Cs-137	80
Ce-144	50
Sr-90	15

Answer: *ARBIS does not provide a basis for clearance of surface contaminated scrap or other materials.*

Radionuclide	Specific Activity (Bq/g)
Co-60	1
Zn-65	0.5
Mn-54	1.2

Is the steel likely to be cleared? What conditions may be applied?

From ARBIS it is concluded that this material cannot be cleared unconditionally on the basis of Annex 1B because the clearance levels of both Co-60 and Mn-54 (0.1 Bq/g) are exceeded.

June 2002

DENMARK (Danmark)

Provided by: Carsten Israelson, Specialist in Natural Radiation, National Institute of Radiation Hygiene (NIRH)

1. Title III, Article 3 paragraph 2 and Title III, Article 5 paragraph 2 of Council Directive 96/29/Euratom define what practices may be exempt and what materials may be cleared. Have these articles been implemented in your country?

   A new Order no. 192 of April 2nd, 2002 from the Danish Ministry of the Interior and Heatlh on exemption levels from law on the use of radioactive substances came into force May 1st, 2002. The Order will implement exemption levels for natural occurring radionuclides.

   Further clarification received in November 2002:

   In Order 192 it gives a definition for release level 'Frigivelsesniveau' as the level adopted whenever a radioactive material can in practice be regarded as non-radioactive. This level is stipulated by the National Institute of Radiation Hygiene. Could you tell me what that level is and where it is expressed i.e. in which piece of legislation or guidance or other document?

   'Frigivelsesniveau' which translates directly to clearance level is given in Order 192 in Table 1. Clearance levels and exemption levels ('undtagelsesniveau') is the same in Order 192. Note that there are only exemption levels for reporting to the authorities for natural radionuclides. This means that there is no level below which users of man-made radionuclides are exempt for reporting a practice to the authorities. Order 192 is the only piece of legislation that describes exemption and clearance levels.

   Annex 2 of Order 192:

   Table 1, Exemption level for naturally occurring radionuclides

Nuclide	***Concentration BqIg -***
U-238sec incl. U-235sec[1]	*0.5*
U-238natural[2]	*5*
Th-230	*10*
Ra-226+	*0.5*
Pb-210+	*5*
Po-210	*5*
Th-232sec	*0.5*
Th-232	*5*
Ra-228+	*1*
Th-228+	*0.5*
K-40	*20*

1) U-238 and U-235 correspond to their natural content (99.3% and 0.7%).
2) natural uranium corresponds to the two uranium-nuclides in their natural state

2. Which organisation(s) is responsible for issuing regulatory documentation, including exemption and clearance levels and overseeing the practical application of the concepts?

   National Institute of Radiation Hygiene (NIRH).

3. What guidance has been issued to ensure compliance with statutory provisions e.g. approved codes of practice?

   A copy of the above mentioned Order no. 192 is enclosed (not available in English).

4. Please describe the processes of exemption and clearance for nuclear installations and other practices i.e. hospitals, research establishments etc.

   The regulations as written in Order no. 192 only list exemption levels for natural occurring radioactive material. Handling of all other radioactive material requires prior authorisation from NIRH regardless of the amounts and concentrations

5. Was Annex 1 (of BSS Euratom) used for defining exemption levels? If not, what are these other levels. Please describe the reasoning/methodology in their derivation.

   No, see 6.

6. Was EC guidance used in the derivation of clearance levels? Please indicate which guidance and for which materials and practices.

   The publication: 'Practical use of the concepts of clearance and exemption, Part II, Radiation Protection 122, European Commission 2001', was used to define exemptions and clearance levels. Order no 192 only lists exemption levels for natural occurring radionuclides. This means that there are no exemption or clearance levels for man-made radionuclides.

   Further clarification received in November 2002:

   Table A of Annex I of the Council Directive 96/29/EURATOM gives total activities and activity concentrations for a long list of radionuclides for the purposes of exemption from reporting of practices i.e. if the material or substance being used contains radionuclides below the level stated it need not be reported so doesn't come within regulatory control. As I understand it when transposing the Directive into Danish legislation only levels for naturally occurring radionuclides where included as in Table 1 of Bilag 2 of Order 192. How does Denmark exempt practices using materials that may use materials containing very low levels of man-made radionuclides, materials that have been cleared for example from other EU Member States?

   You have understood Order 192 correctly. In theory, all practices that involve even the smallest amounts of man-made radionuclides should come under regulatory control. However, according to § 12, 2 in Order 192, the authorities have the possibility to clear radioactive material after assessment of the radiological impact. Principles for clearance are given in Bilag 3 (attached in an English translation). In

general, Bilag 3 opens the possibility for clearance of material if the effective doses to any person in the public is under 0.01 mSv per year for man-made radionuclides and under 0.3 mSv per year for natural radionuclides.

7. Please give specific situations, sources, waste streams to which exemption and clearance have been applied. Please list exempt practices. Have both general and specific clearance levels been applied in your country (i.e. after clearance, is material cleared for all uses or are restrictions imposed)?

So far, clearance has only been applied in very few cases. All cases were before the present regulations were implemented. Clearance was at that time applied to sand waste from the oil industry, to scrap metal from the smelting industry and to steel scrap and concrete from Risø nuclear installations.

Further clarification received November 2002:

Clearance:
Clearance from nuclear activities: On what quantitative criteria have conditional clearance been granted for materials from Risø and under what conditions (prescribed route of disposal):

- metal scrap (recycling)?
- sewage sludge (disposal, incinerator)?
- crushed concrete (reuse or disposal)?

Nothing has yet been cleared from Risø after Order 192 came into force. It has not yet been decided under which circumstances clearance from nuclear activities will be made.

Clearance from non-nuclear practices (activities):

a. Municipal dumping: is summing of all activity concentrations required?
b. Liquid discharges to sewers:
   i. How are the radionuclides ranked?
   ii. Is there any requirement for decay storage of short-lived nuclides?
c. Solid waste to incinerators: Has there been no problems of refusal of waste by the incinerator operator as has been the case with contaminated metal scrap from Risø?

As for nuclear activities, there is not yet a practise for clearance under the new Order 192.

Could you estimate the quantity of material that has been cleared using the current case-by-case situation?

Using the present case-by-case clearance situation material has been cleared in only a few cases. The total amount of NORM sand, metal scrap and concrete that have been cleared amount to less than 100 t of material.

8. Has clearance been a useful concept or have cleared materials still been rejected as radioactive?

   NIRH has no experience with rejected cleared materials under the present rules. However, cleared steel scrap containing radionuclides from the U and Th decay series has previously been rejected from a smelter because of its radioactive content.

9. Please identify needs for improvement (legal, practical application, additional guidance) in this area

   No answer.

Benchmark Example:

In order to fairly and simply compare the approaches of different EU Member States it is our hope to analyse the responses Authorities would take to a sample situation. Thus could you consider the following and justify the appropriate proposed course of action:

- Operator of a nuclear installation in your country hopes to clear about 5,000 t steel in the course of decommissioning the site.

- Half the material has surface contamination while the other half is activated.

- The typical surface contamination and activity is given below:

Radionuclide	Surface Contamination (Bq/cm^2)
Cs-137	80
Ce-144	50
Sr-90	15

Radionuclide	Specific Activity (Bq/g)
Co-60	1
Zn-65	0.5
Mn-54	1.2

Is the steel likely to be cleared? What conditions may be applied?

Following the new Order no. 192 on exemption levels, the steel material in the example cannot be generally cleared, since there are no clearance levels for man-made radionuclides. However, specific clearance might be granted if a disposal plan from the producer is presented to NIRH.

May 2002 (with added clarification November 2002)

Principles for clearance of radioactive substances

(Unauthorized translation of annex 3 in Ministry of the Interior and Health Order no. 192 of 2 April 2002 on exemptions from act on use etc. of radioactive materials)

1. Radioactive substances or materials containing radioactive substances may be cleared from their regulatory control due to their radioactivity, when special radiation protection requirements regarding activity levels etc. are fulfilled. This mean in practice that cleared materials can be treated and handled as non-active materials. Clearance can include disposal as non-active materials, recycling and reuse of the materials in question.

2. The special radiation protection requirements are defined, cf. article 12 in the order, by the National Board of Health (National Institute of Radiation Hygiene) either in a specific authorisation or in regulations for a given area of application. The special radiation protection requirements shall ensure:

a) That the radiological risk to individuals caused by the cleared materials are sufficiently low,
b) That the collective radiological impact is sufficient low, and
c) That the activity of the cleared materials from a radiation protection point of view is without significance with no appreciable likelihood of scenarios that could lead to a failure to meet the criteria in (a) and (b).

3. For materials containing man-made radionuclides, the special radiation protection requirements shall among others be based upon, that the following dose criteria are met in all feasible circumstances:

a) The effective dose expected to be incurred by any member of the public due to the cleared material is of the order of 0.01 mSv or less per year, and
b) Either the collective committed effective dose per year due to the clearance is of the order of 1 man Sv or less or an assessment of the optimisation of protection shows that clearance is the optimum solution.

4. For materials containing natural radionuclides, the special radiation protection requirements shall among others be based upon, that the following dose criteria are met in all feasible circumstances:

a) The effective dose expected to be incurred by any member of the public due to the cleared material in addition to the normal background radiation from naturally occurring radionuclides is less than 0.3 mSv per year.

5. Principles for setting and calculating clearance can be found in the following EU-reports:

- *Recommended radiological protection criteria for the recycling of metals from the dismantling of nuclear installations, Radiation Protection 89, European Commission 1998.*
- *Recommended radiological protection criteria for the clearance of buildings and buildings rubble from the dismantling of nuclear installations, Radiation Protection 113, European Commission 2000.*
- *Definition of clearance levels for the release of radioactively contaminated buildings and buildings rubble, Radiation Protection 114, European Commission 2000.*

- *Methodology and models used to calculate individual doses from the recycling of metals from the dismantling of nuclear installations, Radiation Protection 117, European Com-mission 2000.*
- *Practical Use of the Concepts of Clearance and Exemption – Part I, Guidance on General Clearance Levels for Practices, Radiation Protection 122, European Commission 2000.*
- *Practical Use of the Concepts of Clearance and Exemption – Part II, Application of the Concepts of Exemption and Clearance to Natural Radiation Sources, Radiation Protection 122 – Part, European Commission 2001.*

Additional information on clearance in Denmark [Brodén et al, 2000]

Clearance

From nuclear activities
The National Institute of Radiation Hygiene (NIRH), part of the National Board of Health is the national authority that issues the requirements for any clearance of waste containing radioactive substances from a controlled area. Denmark has not by law applied any constraints for such clearances, permission is granted on a case-by-case basis. As a consequence the only nuclear facility in Denmark, Risø, has to submit an application to NIRH for approval before any clearance.

When estimating whether waste may be cleared NIRH follows the basic criteria given in Annex I of the Directive and takes into account any other technical guidance provided by the Commission. The approval of clearance is given on the condition that the recipient is informed that the waste is cleared from a controlled area and additionally there is written approval from the recipient of the waste.

In Brodén et al, 2000 it is stated that NIRH had cleared metal scrap contaminated with small amounts of radioactive material however when the recipient, a Danish steel-melting company, was informed that it was cleared from a controlled area as required by the NIRH it refused to receive the scrap. Conditional clearance within the Risø site have been issued for other materials: sewage sludge and crushed concrete.

From non-nuclear activities
Radioactive waste from non-nuclear activities is regulated by an order issued by the National Board of Health – 'Use of Unsealed Radioactive Sources at Hospitals, Laboratories etc'. It sets the following limits:

- The maximum concentration of solid radioactive waste for municipal dumping - 0.01 MBq kg^{-1} of waste.

- The maximum concentration of liquid radioactive waste for discharge to the public sewer - 0.1 MBq l^{-1}.

- The maximum activity for liquid waste for discharge to the public sewer per month per authorisation is 5 MBq, 50 MBq, and 500 MBq respectively for radionuclides ranked by radiotoxicity.

- For solid waste sent for incineration the maximum activity in every waste bag must not exceed 5 MBq, 50 MBq and 500 MBq respectively for radionuclides ranked by radiotoxicity provided the dose rate on the outer surface of the bag does not exceed 5 $\mu Sv\ h^{-1}$.

Reference:

Brodén K, ØhlenschlæM, Ruokola E, Johnsdottir T, Sekse T and Wiklund Å, *Current Practice for Clearance in the Nordic Countries,* NKS/SOS-3 December 2000.

GERMANY (Deutschland)

Provided by: Dr Lanfermann, Article 31 Expert, Bundesministerium für Umwelt Naturschutz und Reactorsicherheit (BMU) in Germany.

1. Title III, Article 3 paragraph 2 and Title III, Article 5 paragraph 2 of Council Directive 96/29/Euratom define what practices may be exempt and what materials may be cleared. Have these articles been implemented in your country?

   Title III implemented? *Yes*

   Legislative document:

   Verordnung für die Umsetzung von Euratom Richtlinien zum Strahlenschutz, 20 July 2001. Bundesgezetzblatt, Teil I, G5702, Nr. 38, Bonn, July 26, 2001.

   Translated document title:

   Ordinance for the implementation of the European Directive for Radiation Protection (Radiation Protection Ordinance, RPO)

   ***Definition of Exemption**, not provided but described as possession of materials, practices or work activities not requiring prior authorization (Genehmigungsfreie Besitz,Umgang etc.)*

   A definition of Exemption values is however given in point 16 of RPO.

   "Values of activity and specific activity of radioactive substances as specified in Appendix III, Table 1, Columns 2 and 3, the exceeding of which entails that practices involving these radioactive substances are subject to surveillance under this Ordinance."

   ***Definition of Clearance**, provided in point 15 of RPO par. 3, Definitions (Begriffsbestimmungen).*

   Regulatory decision to remove radioactive materials movables, buildings, ground surfaces, installations or parts of installations which are activated or contaminated with radioactive substances and originate from practices as indicated in par. 2, section 1, a, c or d, as non radioactive substances from the regulatory control imposed by:

   a) Nuclear Law and

   b) All legal regulations and governmental decisions on the use, processing, disposal, possession or transfer to third parties based on Nuclear Law.

   For further information on the implementation the concepts of clearance and exemption see answers to question 4.

2. Which organisation(s) is responsible for issuing regulatory documentation, including exemption and clearance levels and overseeing the practical application of the concepts?

Ministry of Environmental Protection

3. What guidance has been issued to ensure compliance with statutory provisions e.g. approved codes of practice? Please include a short description/abstract of what the guidance covers in addition to providing a copy of the document.

The Ordinance itself provides the guidance; no special/additional guidance has been issued. Compliance is ensured through experience and expertise of those involved.

4. Please describe the processes of exemption and clearance for nuclear installations and other practices i.e. hospitals, research establishments etc.

General exemption from scope of RPO

The general exemptions are specified in par 2 (2).
1) The remediation of inheritances of past practices and work activities with exception of the provisions of par. 118. That paragraph deals with provisions regarding area of past uranium mining in the former German Democratic Republic.

2) The closing down and decommissioning of installations and establishments for uranium mining with exception of provisions of par. 118.

3) The establishment and operation of X-ray equipment and jamming stations according to the Röntgen Ordinance. (It is not clear what this is from the legislation)

4) Radiation exposure from radon in houses and associated buildings.

5) Radiation exposure from radionuclides naturally occurring in the human body, cosmic radiation at ground level and radionuclides in the undisturbed earth's crust.

Incorporation of Exemption from Reporting (Title III, Art. 3, par. 2) and prior Authorization (Title III, Art. 4, par. 3) for practices.

Exemption from reporting and authorization of practices with apparatus producing ionising radiation

According to par. 12, section (3), with reference to annex 1, Part C, the operation of the following apparatus is exempted from reporting as well as authorization:

1) Apparatus of the type described in par 25 in connection with Annex V, Part B. Annex V specifies the conditions for type-approval of and other equipment using radioactive substances (Part A) or producing ionising radiation (Part B).

The main provisions of Part A are:

a) According to the Nuclear Law only those radionuclides may be used that are encapsulated and secured from contact.

b) Under normal operating conditions the dose rate may not exceed 1 μSv h^{-1} at 0.1 m of any accessible surface.

c) The activity of the radionuclides incorporated in the instrument must not exceed the tenfold of the levels specified in Annex III, Table 1, column 2 of the exemption levels. These levels correspond with those of Table A of Annex 1 of the CD but have been expanded to include a number of other radionuclides.

The exemptions 4 and 5 from the scope of RPO cover the exemptions from the scope of the CD described in Title II, Article 2, par. 4.

2) Apparatus operating at a maximum potential difference not exceeding 30 kV that under normal operating conditions does not cause a dose rate exceeding 1 μSv h^{-1} at 0.1 m of any accessible surface.

The provision of Part B is:
Under normal operating conditions the dose rate may not exceed 1 μSv h^{-1} at 0.1 m of any accessible surface of the instrument.

Exemption from authorization of establishment and operation of installations producing ionising radiation

The authorization requirement for the establishment and operation of installations producing ionising radiation is laid down in Par 11 section (1) – (3). The installations listed are

a) accelerators or plasma generators which can produce in excess of 10^{12} neutrons per second

b) electron accelerators with an end energy of the electrons exceeding 10 MeV if their radiation output can exceed 1 kW

c) electron accelerators with an end energy of the electrons exceeding 150 MeV

d) ion accelerators with an end energy of the ions exceeding 10 MeV per nucleus if their radiation output can exceed 50 W

e) ion accelerators with the energy of the ions exceeding 150 MeV per nucleus.

Exemption from authorization of operation of installations producing ionising radiation

The exemptions from authorization described in par. 12 of RPO pertain to the operation and changes in installations if they are notified in advance to the responsible authorities. They installations listed are:

1) Plasma generators if the dose rate at 0.1 meter from the walls, which are not accessible for electro technical reasons during operation, does not exceed 10 µSv per hour.

2) Ion accelerators, if the dose rate at 0.1 meter from any accessible surface does not exceed 10 µSv per hour

Authorization of practices involving handling of radioactive substances

Practices requiring authorization
These practices are defined in par. 7 with reference to par. 2 Part 1 of the Nuclear Law (Atomgesetzes) for radioactive substances and to par. 2, Part 3 for nuclear fuel. Exemption from the authorization requirement is laid down in par. 8 (1) and (2) of RPO. In addition, no authorization is required for the exploration, mining, and processing of radioactive mineral resources if they are subject to the requirements of the German Mining Law.

Exemption of practices from authorization
Par. 8, (1) refers to Annex 1, Part A and B for description of the exempt situations. According to Annex I, part A, the administration of radioactive substances to human beings is exempt from authorization when the specific activity of the substances does not exceed 500 µBq per gram.

Annex I, Part B, referring to par. 8 (1), Par. 17 (1) and Par. 21, lists the following exempt conditions:

1) The handling of radioactive substances if their activity does not exceed the exempt levels of Annex III, Table 1, column 2.

2) The handling of radioactive substances if their specific activity does not exceed the exempt levels of Annex III, Table 1, column 3.

3) The use, storage and disposal of medical products that have been made available according to Par 2, Part 1, second sentence and Part 3, second sentence of the Ordinance on radioactive medical products and medical products irradiated with ionizing radiation (AMRadV).

4) The use of installations of the approved type according to Par. 25 in connection with Annex V, Part A, exclusive their assembling, disassembling and maintenance.

5) The storage of installations of the approved type according to Par. 25 in connection with Annex V, Part A as far as the total activity of the radioactive

substances does not exceed a thousand fold of the exempt values of Annex III, Table 1, second column.

6) The production, use and storage of noble gasses by extraction from the air if the isotope ratio's correspond with those in air.

7) The use and storage of consumer goods and medical products defined in the Medicine Act (Arzneimittelgezetz) for which the production is authorized in Par. 106 and their transport in Par. 108 of RPO. This exemption does not pertain to Par. 95 with reference to Annex XI Part B.

The exemption values provided in column 2 and 3 of Annex III, Table 1 of RPO correspond with those of Table A of Annex 1 of the CD but have been expanded to include a number of other radionuclides.

Par. 95 deals with naturally occurring radioactive substances at work places and requires dose estimates to be made at work places listed in Annex XI Part B. The title of Annex XI, Part B reads as follows: Work places with increased exposure to uranium and thorium and their progeny excluding radon.

Clearance, conditions
The conditions for clearance are laid down in Section 9, Article 29 of RPO. Par. 29, (1):

a) ***To whom do they apply?*** *To owners of an authorization according to Par. 6, 7 or 9 of the Nuclear Law (Atomgesetz), of a planning decision (Planfeststellungsbeschluss) according to Par. 9b of the Nuclear Law or an authorization according Par. 7 or Par. 11, (2) of RPO.*

b) ***What is subject to the conditions?*** *Radioactive substances, movables, buildings, ground surfaces, installations or parts of installations that are activated or contaminated and originate from practices indicated in Par. 2, Part 1, No. 1, a, c or d.*

c) ***What is the main condition?*** *The materials indicated may not be used, processed, disposed of or transferred to third parties as non radioactive substances without receipt of a statement of clearance according to Par. 29 (2) from the competent Authority in which the authority declares and that it has established according to Art. 29 (3) that clearance is in agreement with the conditions laid down in the Clearance decision (Freigabebescheid).*

Par. 29 (2)
The competent Authority communicates on request of those indicated in a) above the clearance in writing when the radiation exposure of single members of the public in a calendar year can only be of the order of 10 µSv per year. The competent Authority can assume that this condition is being fulfilled in the following cases:

1) Unconditional clearance of:

a) Solid materials that satisfy the clearance levels provided in Annex III, Table 1, Column 5 and the conditions for clearance laid down in Annex IV, Part A, No 1 and, if solid surfaces are involved, when they satisfy the values for surface contamination of Annex III, Table 1, column 4.

b) Liquids that satisfy the values of Annex III, Table 1, column 5.

c) Building rubble and excavated soil with an expected mass exceeding 1000 tonnes per calendar year that satisfy the clearance levels of Annex III, Table 1, column 6 and the conditions specified in Annex IV, Part A, No 1 and Part F.

d) Surface soil that satisfy the clearance levels of Annex III, Table 1, column 7 and the conditions specified in Annex IV, Part E.

e) Buildings for reuse or further use that satisfy the clearance levels of Annex III, Table 1, column 8 and the conditions specified in Annex IV, Part A, No 1 and Part D.

2) Clearance of:

a) Solid materials to be disposed that satisfy the clearance levels of Annex III, Table 1, column 9 and the conditions specified in Annex IV, Part A, No 1 and Part C and, if solid surfaces are involved, when they satisfy the values for surface contamination of Annex III, Table 1, column 4.

b) Liquids to be disposed of in an incinerator that satisfy the clearance levels of Annex III, Table 1, column 9.

c) Buildings to be pulled down if they satisfy the clearance levels of Annex III, Table 1, column 10 and the conditions specified in Annex IV, Part A, No 1 and Part D.

d) Metal scrap to be recycled if it satisfies the clearance levels of Annex III, Table 1, column 10a and the conditions specified in Annex IV, Part A, Point 1 and Part G and, if solid surfaces are involved, when it satisfies the values for surface contamination of Annex III, Table 1, column 4.

and the competent Authority has no indications that in the cases 2 a and b at the site of disposal facility the radiation exposure of members of the public in a calendar year will exceed an effective dos of 10 µSv. When the conditions specified in 2) with respect to Annex IV Part C to E cannot be met in individual cases. or when for individual radionuclides no clearance levels are established, can compliance with the dose criterion of 10 µSv in a calendar year for members of the public be demonstrated for those materials that do not exceed the clearance levels of Annex III, Table 1, column 3 be shown by other methods taking into account the conditions specified in Annex IV, Part A, No 1.

The conditions for clearance may not be brought on, caused or facilitated by intentional mixing or dilution.

Par. 29 (3)
For each mass of material or part of it that, on the basis of the decision according to Par. 29 (2), will be used, processed, disposed, possessed or transferred to third parties must be established in advance whether it meets the conditions specified in the decision. The clearance measurements necessary for this purpose and their results must be documented.

Par. 29 (4) – (7)
These parts of Art. 29 deal in more detail with procedural aspects of clearance. Table 1 of Annex III plays an important role in how exemption and in particular in clearance is dealt with for practices in RPO. The structure of Table 1 is therefore summarized below.

Structure of Table 1 of Annex III of RPO regarding exemption and clearance

Column No	*Content of the column*
1	*List of radionuclides, "+", "++" or sec. Refer to Table 2 of Annex III*
2	*Exemption level in Bq, summation rules apply*
3	*Exemption level in Bq/g, summation rules apply*
4	*Unrestricted clearance: surface contamination in Bq/cm^2, surface for averaging 300 cm^2, summing rules apply, radionuclides contributing less than 10% to total sum may be disregarded.*
5	*Unrestricted clearance: solids and liquids with exception of column 6, Bq/g, measurements according to Par. 44, averaging over mass M: 3 kg ≥ M ≥ 300. Conditions specified in Annex IV, Part A, No 1. Column 4 also applies.*
6	*Unrestricted clearance: building rubble and excavated soil, more than 1000 tonnes/a, Bq/g. conditions specified in Annex IV, Part A, No 1 and in Part F.*
7	*Unrestricted clearance, surface soil, Bq/g. Conditions specified in Annex IV, Part E*
8	*Unrestricted clearance, buildings for further use or reuse, Bq/cm^2. Conditions specified in Annex IV, Part A, No 1 and in Part D.*
9	*Clearance of solids and liquids for disposal and incineration respectively, column 6 excluded, Bq/g. Conditions specified in Annex IV, Part A, No 1 and in Part C. Column 4 also applies for solids.*
10	*Clearance of buildings to be pulled down, Bq/cm^2. Conditions specified in Annex IV, Part A, No 1 and in Part D.*
10 a	*Metal scrap for recycling, Bq/g. Conditions specified in Annex IV, Part A, No 1 and in Part G. Column 4 also applies.*
11	*Half lives*

Clearance of residues from work activities
Par. 97 specifies the conditions when residues from work activities will require control and Par. 97 describes if and how these residues can be released (entlassen) from control. Note that this release is not indicated as "clearance" (Freigabe)

Par. 97, Residues requiring control
In the following situations the residues from work activities will require control:

1. Those who are responsible for own work activities or work activities carried out by others from which residues arise that require control has to take measures to protect members of the public when the processing or disposal of these residues could result in the reference effective dose (Richtwert) of 1 mSv in a calendar year being exceeded.

2. Control is required for those residues specified in Annex XII, Part A when and if it is made sure that that at their disposal or processing the control levels (Überwachungs-grenze) of Annex XII, Part B and the disposal and processing routes are being satisfied. Arising residues may not before their intended disposal or processing willfully been mixed or diluted with other materials in order to satisfy the control levels of Annex XII, Part B.

3. Section 3 of Par. 97 gives the competent Authority the means to require proof of compliance with Annex XII, Part A and Part B.

4. Section 4 of Art. 97 lays responsibility on those referred to in section 1 above to protect the residues of Annex XII, Part A against getting lost or being handled by unauthorized persons. They may only transferred to other persons for the purpose of disposal or processing.

Annex XII, part A provides a list of residues to be considered in relation to Art. 97:

1) Sludges and scales from oil and gas production.

2) Unpurified phosphogypsum, sludges from the production of phosphogypsum as well as dust and slags from the production of crude phosphate (phosphorite).

3)
a) residual rock, sludge, sand, slag and dust from,

i) the mining and processing of bauxite, columbite, pyrochloor, microlyte, euxenite, copper shale, tin, rare earth's and uranium ores

ii) the processing of concentrates and residues arising from the mining and processing of these raw materials.

4) Dust and sludges from the off gas cleaning of blast furnaces for iron and non-ferro metallurgy.

Residues according to Art. 97 are also:

a) Materials according to 1) and following when their arising has been caused intentionally,

b) Moulds prepared from materials according to 1) and following,

c) Excavated or dug away soil and building rubble from the pulling down of buildings or other build structures if they contain residuals according to 1) and following and are being removed under the provisions of Par. 101 after closing down of the work activity or are being removed from premises according to Par. 118.

The following residues No 1 to 4:above are not being regarded as falling under the provisions of Par. 97

a) When the specific activity of each member of the decay chain of U-238sec and Th-232sec in the residue is lower than 0.2 Bq/g or,

b) When they are brought in those processes as raw materials.

Annex XII, part B provides limits set for the residues described under Part A:

1) For the processing or disposal of residues the representatively determined highest specific activity of any member of the decay chains of U-238sec (U-238 max) and Th-232sec (Th-232max) in Bq/g must satisfy the following condition:
$C_{U\text{-}238max} + C_{Th\text{-}232max} \leq C$,
With the control limit set at C = 1 Bq/g.

2) Contrary to 1) applies C = 0.5 Bq/g
a) when within the area of an exploitable ground water resource more than 5000 tonnes per year is disposed ,

b) when building materials used in the building of houses contain more than 20% or when used in road construction, landscaping or waterworks contain more than 50% of the residues according to Part A.

3) Contrary to 1) applies C = 5 Bq/g for the underground application or disposal of residues.

4) If the specific activity of the radionuclide Pb-210+ a factor A more than 5 higher than the specific activity of the other members of the decay chain of U-238sec the following summation rule applies:
$RC_{U238max} + C_{Th232max} \leq C$

The factor R takes the value of 0.5 for surface application or disposal. For underground processing or disposal the factor R can be derived from the following table.

Factor A	Factor R
$5 > A \leq 10$	0,3
$10\ A \leq 20$	0,2
$20 < A$	0,1

5) Contrary to 1) and 2) apply the conditions:
$C_{U238max} + C_{Th232max} \leq 0{,}2$ *Bq/g and* $C_{Th232max} \leq 0{,}2$ *Bq/g when at the disposal or application in road construction or landscaping including sport and playgrounds*

within the drainage area of a useable aquifer an area of more than 1 hectare is being covered with waste rock. A decay chain can be neglected when the specific activity of all members of the decay chain of U-238sec or Th-232sec lower is than 0.2 Bq/g.

Par. 98 Release of residues from control
The conditions for release of residues of work activities from control are specified in Par. 98 1) to 4).

1) This sections lays down the requirement for formal release of controlled residues by written decision of the competent authorities when it has been established that in the particular circumstances and with the protective measures implemented the protection of the public against radiation exposure is assured. The measure for adequate radiation protection of the public is an effective dose to the public of 1 mSv per calendar year not being exceeded as a result of the disposal or processing.

2) Proof of the conditions in 1) above has to be provided on the basis of the ground rules specified in Annex XII, Part D. People occupationally involved with the application or disposal are being regarded as members of the public. When the residues are disposed together with residues or waste of different origin it can be assumed by the competent authorities that the conditions of point 1) are fulfilled when the requirements of Annex XII, Part C are met.
Annex XII, Part C specifies the conditions for release from control of residues when controlled (überwachungsbedürftigen) residues are disposed of together with other residues or wastes.

3) This section specifies the administrative rules to be observed by the applicant for release and the competent authority with respect to the provisions of the law on the recycling industry and on waste.

Par. 99 Residues remaining under control
This article specifies the obligations for those responsible to report details on residues kept under control including plans to process or dispose those residues that can not be released under the provisions of Par. 98, section 1, first sentence. The competent authority can impose safety measures and ways to dispose these residues.

Par. 100 Reporting obligations, residue concept and residue book keeping
Those responsible for work activities involving annually more than 2000 tonnes of residues as specified in Annex XII, Part A has several reporting obligations to the competent authorities with respect to the preparation of a Residue Concept that provides a internal planning instrument for those residues and residue book keeping. The first Residue Concept has to be prepared before April 1 2003 for the following five years. The first residue book keeping has to be prepared before April 1 2004 and must cover the previous year.

Par. 101 Removal of radioactive contamination from soil

This article specifies the obligation to remove soil contamination with residues requiring control within five years after a work activity has been put to an end. The criterion for adequate removal is that further use of the area by third parties is in no

way limited. The measure for unlimited further use is a guidance value of 1 mSv effective dose per calendar year from the residues remaining in or on the soil.

5. Was Annex 1 (of BSS Euratom) used for defining exemption levels? If not, what are these other levels. Please describe the reasoning/methodology in their derivation.

From Annex III, Table 1, the first three columns providing exemption limits are based on Annex 1 Table A from CD. Annex III, table 1 has been expanded with a number of radionuclides not occurring in Annex 1 Table A from CD. In addition, Annex III contains the provision that if now exemption limits for specific radionuclides are provided in Table 1 those exemption limits have to be calculated or assumed to take the values of

a) 1 Bq/g and 10^3 Bq for alpha emitters or spontaneous fission nuclides and

b) 10^2 Bq/g and 10^5 Bq for beta and gamma emitters as far as not included under c)

c) 10^5 Bq/g and 10^8 Bq for electron capture nuclides and beta emitters with maximum beta energy of less than 200 kV.

6. Was EC guidance used in the derivation of clearance levels? Please indicate which guidance and for which materials and practices. In situations where EC guidance was not used please describe the reasoning/methodology and the dose criteria applied in the derivation of the clearance levels and provide details on these clearance levels.

Clearance levels have been derived for unconditional clearance of different types of material and for (conditional) clearance for disposal of solids and liquids, buildings to be pulled down and metal scrap to be recycled. The methods used to derive the clearance levels are based on or consistent with the guidance provided by the European Commission and the recommendations of the German Commission on Radiological Protection (Strahlenschutzkommission). With respect to guidance from the European Commission the following documents have been taken into account:

Radiation Protection 89, on recommended radiological protection criteria for recycling of metals from the dismantling of nuclear installations.

Radiation Protection 101, on the Basis for definition of surface contamination clearance levels for recycling or reuse of metals from the dismantling of nuclear installations (1999).

Radiation Protection 113, Article 31 of Euratom Treaty Group of Experts Recommended radiological protection criteria for clearance of buildings and building rubble from the dismantling of nuclear installations (2000).

Radiation Protection 114, on the Definition of Clearance Levels for the Release of Radioactively contaminated Buildings and Building Rubble (1999).
Radiation Protection 117, on the Methodology and models used to calculate individual and collective doses from the recycling of metals from the dismantling of nuclear installations (2000).

Radiation Protection 122, on the Practical use of the concepts of clearance and exemption – Part I: Guidance on general clearance levels for practices (2000).

7. Please give specific situations, sources, waste streams to which exemption and clearance have been applied. Please list exempt practices. Have both general and specific clearance levels been applied in your country (i.e. after clearance, is material cleared for all uses or are restrictions imposed)? Please give examples.

   Germany is decommissioning its NPPs. There is therefore a lot of experience of applying clearance under the old RPO. It is important to note that the application of clearance levels is not open to everyone; before they can be used the operator must hold a 'Decision' from the licensing authority.

   There is provision for both conditional and unconditional clearance however conditional clearance levels are rarely used.

8. Has clearance been a useful concept or have cleared materials still been rejected as radioactive? Please give details.

   Yes, success in achieving clearance can be attributed to long experience. For many years the formula of Exemption values X 10^{-4} has been applied in cases of clearance before actual clearance levels were ever incorporated into legislation.

9. Please identify needs for improvement (legal, practical application, additional guidance) in this area

   No.

Benchmark Example

In order to fairly and simply compare the approaches of different EU Member States it is our hope to analyse the responses Authorities would take to a sample situation. Thus could you consider the following and justify the appropriate proposed course of action:

- Operator of a nuclear installation in your country hopes to clear about 5,000 t steel in the course of decommissioning the site.

- Half the material has surface contamination while the other half is activated.

- The typical surface contamination and activity is given below:

Radionuclide	Surface Contamination (Bq/cm^2)
Cs-137	80
Ce-144	50
Sr-90	15

Radionuclide	Specific Activity (Bq/g)
Co-60	1
Zn-65	0.5
Mn-54	1.2

The suggested answers are based on the text of the German legislation however because of the possibilities for application of general as well as specific clearance levels there remains a certain uncertainty.

Benchmark example 5000 t surface contaminated steel for recycling

Radionuclide	Surface contamination (Bq/cm^2)	Clearance level surface contamination Annex III, Table 1, column 4, (Bq/cm^2)	Sum of ratios
Cs-137	80	10	8
Ce-144	50	100	0.5
Sr-90	15	1	15
Sum			**23.5 (> 1)**

Is the steel likely to be cleared? What conditions may be applied? Will it be: -

a Given unconditional clearance? *No*
b Cleared for recycling? *No*
c Cleared for reuse? *No*
d Refused clearance, sent for disposal? *Yes/No??*
e Refused clearance further decontamination required? *Yes*
f Other (please give details)? *Specific clearance??*

Conclusion: no clearance for recycling possible

Benchmark example 5000 t activated steel for recycling

Radionuclide	Specific activity (Bq/g)	Clearance level specific, Annex III, Table 1, column 10a, (Bq/g)	Ratios column 2/column 3
Co-60	1	0.6	1.7
Zn-65	0.5	0.5	1
Mn-54	1.2	2	0.6
Sum			**3.3 (> 1)**

Is the steel likely to be cleared? What conditions may be applied? Will it be: -

a Given unconditional clearance? *No, levels of Annex III, Table 1, column 5 being exceeded*

b Cleared for recycling? *No, see table above*

c Cleared for reuse? *No*

d Refused clearance, sent for disposal? *Yes, on the basis of Annex III, Table 1, column 9??/No??*

e Refused clearance further decontamination required? *No, decontamination is not possible.*

f Other (please give details)? *Specific clearance??*

Conclusion: no clearance for recycling possible

June 2002 (additional clarification April 2003)

GREECE (Elláda)

Provided by: Dr Panagiotis Dimitriou, Article 31 Expert, Greek Atomic Energy Commission (GAEC)

1. Title III, Article 3 paragraph 2 and Title III, Article 5 paragraph 2 of Council Directive 96/29/Euratom define what practices may be exempt and what materials may be cleared. Have these articles been implemented in your country?

   These articles have been implemented in the Greek legislation through the harmonized with the BSS Directive, Radiation Protection Regulations (RPR) enforced in the form of a Joint Ministerial Order (No 1014 (ΦΟΡ) 94, Official Gazette No 216B, 06/03/01).

   The concept of exemption has been incorporated into the Greek RPR, in the part "exemptions" (paragraph 1.1.6), the same wording as in Title III, Article 3 paragraph 2 of the BBS Directive was used.

   Title III, Article 5 paragraph 2 of Council Directive 96/29/Euratom concerning the concept of clearance levels, was incorporated in part 6 of the RPR.

   The definitions of clearance, clearance levels and exemption levels are included in the part "Definitions" of the RPR, paragraph 1.9.

2. Which organisation(s) is responsible for issuing regulatory documentation, including exemption and clearance levels and overseeing the practical application of the concepts?

   The Greek Atomic Energy Commission

3. What guidance has been issued to ensure compliance with statutory provisions e.g. approved codes of practice?

   Only a guidance concerning exemption and clearance for steel beams has been finalised and submitted for approval to the GEAC's Board.

4. Please describe the processes of exemption and clearance for nuclear installations and other practices i.e. hospitals, research establishments etc.

   Since there is no nuclear industry in Greece, the exemption process has been applied only to the scrap metals processing. General clearance levels (RPR, Table 6.1 and 6.2) are applied to discharges of waste arising from hospitals and research applications. Specific clearance levels, approved by the GAEC, can also be used taking into account the exposure pathways and the dose constraint criterion of 10μSv/y for the general public.

5. Was Annex 1 (of BSS Euratom) used for defining exemption levels? If not, what are these other levels. Please describe the reasoning/methodology in their derivation.

Annex 1 (of BSS Euratom) is used for defining exemption levels and is incorporated in part 12, paragraph 12.1 of the RPR.

6. Was EC guidance used in the derivation of clearance levels? Please indicate which guidance and for which materials and practices.

The following EC Radiation Protection publications were used in the derivation of clearance levels:

RP publication 122, part I: general clearance levels (RPR, Table 6.2).

RP publications 117, 114, and 89 for scrap metals (steel beams).

7. Please give specific situations, sources, waste streams to which exemption and clearance have been applied. Please list exempt practices. Have both general and specific clearance levels been applied in your country (i.e. after clearance, is material cleared for all uses or are restrictions imposed)? Please give examples.

For steel beams see answer to question 3. As mentioned above, general clearance levels have been already applied to all discharges of wastes arising from medical, research and industrial applications. According to the present situation in Greece, there is no need so far to exempt practices according to the exception values provided by the RPRs.

8. Has clearance been a useful concept or have cleared materials still been rejected as radioactive?

Yes for unconditional clearance.

9. Please identify needs for improvement (legal, practical application, additional guidance) in this area

No answer.

Benchmark Example:

In order to fairly and simply compare the approaches of different EU Member States it is our hope to analyse the responses Authorities would take to a sample situation. Thus could you consider the following and justify the appropriate proposed course of action:

- Operator of a nuclear installation in your country hopes to clear about 5,000 t steel in the course of decommissioning the site.

- Half the material has surface contamination while the other half is activated.

- The typical surface contamination and activity is given below:

Radionuclide	Surface Contamination (Bq/cm^2)
Cs-137	80
Ce-144	50
Sr-90	15

Radionuclide	Specific Activity (Bq/g)
Co-60	1
Zn-65	0.5
Mn-54	1.2

Is the steel likely to be cleared? What conditions may be applied?

This hypothetical situation does not apply to Greece with no nuclear power reactors. This may be the case of imported scrap metal.

1. The 2,500 t of surface contaminated steel with the above said contamination will be considered for disposal, as Ce-144 contamination is above clearance levels for recycling. Decontamination of steel will not be considered. Scrap metal with the above contamination will not be accepted for import.

2. The 2,500 t of activated steel with the activity given above, will be stored for about three months, allowing the activity of Mn-54 to fall below the corresponding clearance levels for recycling (1 Bq/g, RP 89). The activities of Co-56 and Zn-65 are below clearance levels for recycling. Therefore the activated steel will be sent for recycling after three months.

May 2002

SPAIN (España)

Provided by: Ignacio Lequerica, Technical Director for Radiation Protection, Consejo de Seguridad Nuclear (CSN) (initially); subsequent clarification given by Juan Carlos Lentijo, Deputy Director for Environmental Radiation Protection (CSN).

1. Title III, Article 3 paragraph 2 and Title III, Article 5 paragraph 2 of Council Directive 96/29/Euratom define what practices may be exempt and what materials may be cleared. Have these articles been implemented in your country?

   Yes

   Exemption:
   This concept is presently set in Art. 35 and Annex I of the Nuclear and Radioactive Installation Royal Decree (RD 1836/1999). It is applied to Radioactive Installations with the same radiological criteria as the Council directive states.

   Clearance:
   The definition of radioactive waste established by Nuclear Energy Act modified by Electric Sector Law 54/1997 and the Royal Decree 1836/1999 on nuclear and radioactive installations provides the necessary legal framework for implementing Clearance. This definition made possible the conventional management of some residuals materials with very low levels of activity arising from the operation and dismantling of nuclear and radioactive installations.

   This definition, which is merely conceptual rather than numerical, as well as the Art. 76 of the Nuclear and Radioactive Installation Royal Decree (RD 1836/1999), allowed however the Regulatory Authority to establish the numerical criteria.

   The CSN uses an extensive interpretation of the Exemption concept and its basic radiological criteria for clearance, so in fact these last are the same in practice as those established by the Directive, but in a case by case basis through specific licenses.

2. Which organisation(s) is responsible for issuing regulatory documentation, including exemption and clearance levels and overseeing the practical application of the concepts?

   The Ministry of Economy is responsible for issuing all kind of permits, including the authorisation for clearance, following a mandatory and binding report by the CSN.

   The Nuclear Safety Council is in charge of performing the necessary inspections and assessments of nuclear and radioactive installation.

3. What guidance has been issued to ensure compliance with statutory provisions e.g. approved codes of practice?

   The Common Projects for waste stream clearance in NPP, referred below, were the subject of plant specific Technical Instructions by the CSN (1999).

Regarding the clearance of residuals materials generated by radioactive installations (hospitals, small research practices, industrial applications), recently the CSN has issued a Safety Guide (CSN SG 9.02) that endorses the recommendations of IAEA TECDOC-1000.

See below.

Further clarification received in April 2003:

Does the Safety Guide CSN SG9.2 that endorses IAEA TECDOC-1000 also specify numerical values for clearance of materials from non-nuclear practices and if so, what values, are they identical to the representative levels from IAEA TECDOC?

The CSN Guide 9.2 specifies numerical values for the clearance of materials from category 2 and 3 radioactive facilities using unsealed sources. This corresponds to small industries and users of radionuclides such as universities and hospitals.

CSN Guide 9.2 would not be applicable to the clearance of residual materials from nuclear installations.

4. Please describe the processes of exemption and clearance for nuclear installations and other practices i.e. hospitals, research establishments etc.

The basic principles governing the Spanish clearance system are as follows:

- *Responsibility of waste producer.*
- *Traceability of the process.*
- *Intrinsic safety.*

The clearance system adopted for nuclear installations (nuclear power plants) is based on the collaboration by the producers on a Common Project (see Annex I) for each potentially clearable waste stream. The Common Project should consider the peculiarities and the national legal framework for the conventional management of wastes, in order to derive the appropriate set of clearance levels. The Common Project also includes a methodology for the radiological characterisation of the residual materials with the required levels of confidence.

The clearance system adopted for the residuals materials generated in radioactive installations (hospitals, small research practices, industrial applications) endorses the recommendations of IAEA TECDOC-1000 (1998): Clearance of materials resulting from the use of radionuclides in medicine, industry and research".

5. Was Annex 1 (of BSS Euratom) used for defining exemption levels? If not, what are these other levels. Please describe the reasoning/methodology in their derivation.

Yes. Annex 1 of BSS Euratom was fully adopted in the definition of exemption levels for practices with low quantities of materials (below 3 tonnes/year).

Further clarification received November 2002:

I understand that the use of Table A from Real Decreto 1836/1999 is restricted to quantities below 3 tonnes/year. Where is this restriction stated?

The restriction of 3 tonnes/year is not stated in any legal/regulatory document.

Is it correctly understood that the levels in Table A are only used for exemption of practices not for clearance of materials from regulatory control?

Yes.

6. Was EC guidance used in the derivation of clearance levels? Please indicate which guidance and for which materials and practices. In situations where EC guidance was not used please describe the reasoning/methodology and the dose criteria applied in the derivation of the clearance levels and provide details on these clearance levels.

EC guidance is used in terms of radiological criteria for the derivation of clearance levels of very low activity residual materials generated in controlled practices.

Specific clearance levels for the recycling of metals, reuse of metallic components and building rubble are also implemented in Spain considering EC specific recommendations (RP-89 and RP-113).

When EC guidance is not developed (. i.e. other hazardous wastes like used oils, used active charcoal, low activity ion exchange resins), specific clearance levels have been derived in Spain taking into account the peculiarities and the national legal framework for the conventional management of this kind of wastes.

The methodology and administrative process is based on a Common project for each waste stream. (See attached diagram).

Further clarification received November 2002:

Has the Common Project already resulted in clearance levels set for specific materials and routes? Your answer to question 7 mentioned clearance of scrap metals, buildings and oil.

Yes. Common Projects accepted by CSN have already resulted in clearance levels being set for:

a. *Low activity used oils (regeneration and thermal treatment)*

b. *Low activity used active charcoal.*

c. *Low activity spent ion exchange resins.*

Common Projects referred to the clearance of scrap metals and building rubble include the set of levels recommended in RP-89 and RP-113.

Regarding specific clearance levels for recycling of metals, reuse of metallic components and building rubble how have these been incorporated into the regulatory system? Are these part of the Common Project procedure and so part of site specific waste management manuals?

The specific clearance levels for recycling of metals, re-use of metallic components and building rubble have been incorporated into the specific waste stream clearance authorisation after the application made by the licensee.

With regard to the Common Project procedure is this a collaboration between nuclear operators to define clearance levels for various waste streams which are then approved by CSN and then these agreed clearance levels are then used in site specific clearance authorisations? Have I understood correctly?

Yes

Further clarification received April 2003:

Before the publication of CSN Guide 9.2, a review of radiation exposure scenarios and quantities of residual materials involved in second and third categories of radioactive installations (small industries and users of radionuclides such as universities and hospitals) was conducted to ensure that the trivial dose criteria are met. The rationale for CSN's recommendation of TECDOC-1000 clearance levels was that no specific European Commission guidance exists for small users of radionuclides, such as universities and hospitals with a very low quantity of residual materials production. It appeared to us more consistent to join an international approach specific for the clearance of materials resulting from the use of radionuclides in medicine, industry and research.

7. Please give specific situations, sources, waste streams to which exemption and clearance have been applied. Please list exempt practices. Have both general and specific clearance levels been applied in your country (i.e. after clearance, is material cleared for all uses or are restrictions imposed)? Please give examples.

Exemption have been applied to any justified practice with low quantities of radioactive materials (small-scale usage of radioactivity), considering the total activity and activity concentration values given in Annex 1 of BSS Euratom.

Clearance has been applied to residual materials arisen from previously regulated/controlled practices. Licensees conduct the process of clearance with a previous authorisation by the competent authorities.

Both general and specific clearance levels have been applied to very low activity residual materials. General clearance levels means that any possible disposal route after clearance is permitted without any radiological restriction. In this case the restrictions are mainly connected with the nature of the waste, i.e. urban solid wastes, hazardous wastes, recyclable waste and the final fate. General clearance levels are the most restrictive and usually are not very interesting for the waste producer, considering the resources that need to be implemented in order to demonstrate that

materials are bellow general clearance levels. (Further comment received in April 2003 stated that only specific clearance levels are in use.)

Specific clearance levels have been used for the clearance of scrap metals with the restriction of recycling, buildings for further use or demolition and used oils for thermal treatment.

For both, general and specific approaches, radiological regulatory control ceases after the clearance of the residual material, but other regulatory controls, different than radiological remain applicable to the cleared materials.

8. Has clearance been a useful concept or have cleared materials still been rejected as radioactive? Please give details.

There are several examples of waste streams in which clearance has been applied in a very successful way, such as steel scrap, concrete debris in a decommissioning NPP, or oil coming form NPP in operation. These examples have demonstrated the benefit of using clearance, as far as this concept provides a conventional management of wastes without any negative response. Clearance has been *as well a useful concept in terms of the definition of a "controlled" management option for very low activity wastes.*

There are also some examples in which the implementation of clearance has got a sort of political and social reaction, such as the very low radioactive waste coming from the Acerinox accident.

9. Please identify needs for improvement (legal, practical application, additional guidance) in this area

The CSN is preparing a plan for developing a more coherent set of rules, regulations and safety guides on waste management, including these issues. Regarding clearance, the intention is to standardize what has been established through a case-by-case approach. The inclusion of IAEA-TECDOC-1000 clearance levels in Spanish legislation is presently under consideration, but a decision has not yet been made.

Additional guidance for the clearance of hazardous waste streams, considering that regulations in this matter are common in the EU, would be very useful. It would be also very convenient some EC guidance in the definition of standard requirements for the radiological characterisation of materials before clearance i.e. methodology, required level of confidence, etc.

European Commission clearance guidance for small users such as universities and hospitals would be helpful and welcomed following the objective of harmonisation.

Benchmark Example:

In order to fairly and simply compare the approaches of different EU Member States it is our hope to analyse the responses Authorities would take to a sample situation. Thus could you consider the following and justify the appropriate proposed course of action:

- Operator of a nuclear installation in your country hopes to clear about 5,000 t steel in the course of decommissioning the site.

- Half the material has surface contamination while the other half is activated.

- The typical surface contamination and activity is given below:

Radionuclide	Surface Contamination (Bq/cm^2)
Cs-137	80
Ce-144	50
Sr-90	15

Radionuclide	Specific Activity (Bq/g)
Co-60	1
Zn-65	0.5
Mn-54	1.2

In view of the typical surface contamination and specific activity of the steel, in Spain:

- *The steel is not likely to be cleared for recycling.*

- *The steel is not likely to be cleared for reuse.*

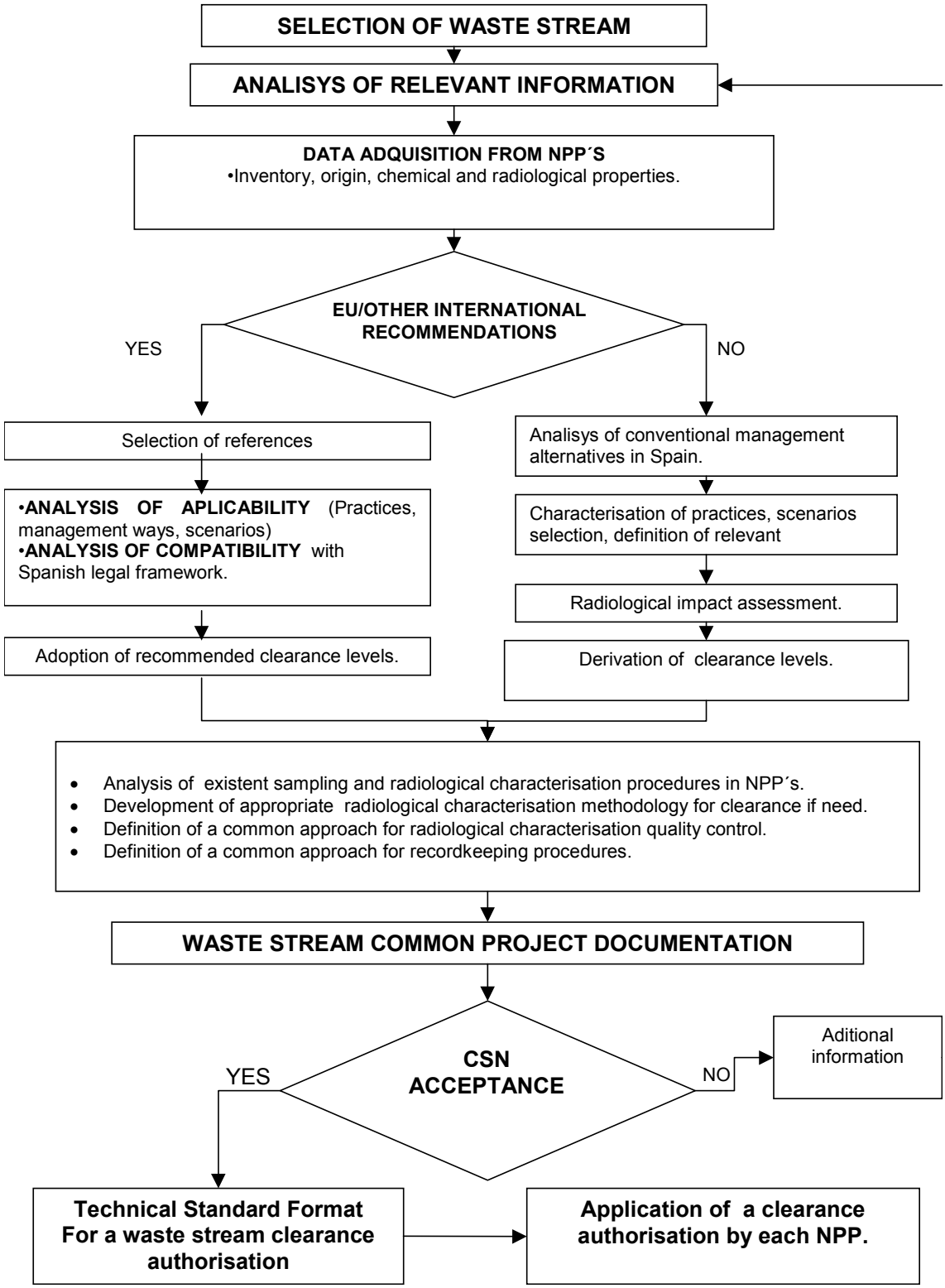
The producer should decide if the fraction of material with surface contamination could be decontaminated.

The fraction of activated material would be sent for disposal.

March 2002 (with added clarification in November 2002 and April 2003)

ANNEX I

METHODOLOGY FOR THE DEVELOPPMENT OF CLEARANCE COMMON PROJECTS IN NNP´s



FRANCE

Provided by: Mr. Jean-Luc Godet at DGSNR (former chief of the "Radioprotection Bureau" at DGS), regarding the questionnaire "Evaluation of the Application of the Concepts of Exemption and Clearance for Practices According to Title III of Council Directive 96/29/Euratom".

In response to this questionnaire, I attach an article which I had published in 2001; the article summarizes the French position on the concept of "clearance".

Rules of waste disposal resulting from the use of unsealed sources - Concept of "threshold of release"

According to Euratom Directive 96/29, disposal, recycling or the re-use of the radioactive substances or materials resulting from an activity using radioactive sources is subjected to prior authorisation, if this activity is a practice i.e. subject to authorisation. However, this same Directive specifies that the Member States can be exempted from this obligation if the cleared substances or radioactive materials respect thresholds of release fixed at the national level.

For the definition of these thresholds, the Directive introduces basic criteria to be taken into account. In the case of waste produced by nuclear installations or installations classified for environmental protection (ICPE), it is not envisaged to set up such thresholds. Thus, the decree of the secretariat to the industry of December 31, 1999 introduced a mode of approval (by the Director of Nuclear Safety) of the plans of management of the waste produced inside the basic nuclear installations, without resorting to thresholds of release. This step makes it possible to maintain monitoring on the radioactive waste and the routes retained for their removal, whatever their level of radioactivity. In the case of the ICPE, the necessary prefectoral authorization also requires to control of future waste produced as well as the waste occasionally caused by the use of sources (unsealed in particular).

Case of waste and effluents produced by the hospitals.

In the particular case of the hospitals, the publication of Directive Euratom 96/29 will be accompanied by an update of the rules of management by the effluents and waste produced and likely to have a low radioactivity. The presence of these substances in waste and effluents result mainly from the use of the radioactive sources, in the form of unsealed sources, in the services of nuclear medicine but also in the biomedical research laboratories. While waiting, the opinion of the ministry for the Public health and the Social security of June 6, 1970 was repealed (cf circular DGS/DHOS/E4/323 of 9 July 2001 relating to the management of the effluents and waste contaminated by radionuclides).

This update offered the occasion to remind each establishment is it responsible for disposal of the effluents and waste which it generates, in accordance with the amended law n°75-633 of July 15, 1975 relating to the waste disposal and the recovery of materials. The exercise of this responsibility must result in management aiming to reduce the exposure of the people, with the emphasis on optimization of the exposures below the lawful limits. For that, the methods of management of waste and effluents will have to be defined by considering the following four principles: waste must be sorted and conditioned as far upstream as possible in each unit which produces them, while taking into account in particular the radioactive

half-life of the radioelements present i.e. waste and effluents coming from the use of radioelements with half-life lower than 100 days will be distinguished from other waste (containing radioelements with longer half-lives).

The effluents and waste are then stored in such a way in order to allow:

- *local treatment by radioactive decay of the effluents and waste coming from the use of radioelements of half-life less than 100 days,*

- *the national Agency for the management of the radioactive waste (ANDRA) to take responsibility for the other waste.·*

    - *The radioactivity of the effluents and waste is controlled before their removal,*

    - *the effluents and waste is sent towards an identified routes: routes of domestic waste in the absence of infectious and chemical risks, or routes of hazardous waste (infectious), or routes adapted from hazardous wastes (chemical),*

- *release to the public sewer network, ·*

- *control by ANDRA for waste with a half-life greater than 100 days.*

August 2002

The following answers were subsequently developed by NNC Ltd and later sent to Mr Godet for comment, however no further response was received within the period of the project.

1. Title III, Article 3 paragraph 2 and Title III, Article 5 paragraph 2 of Council Directive 96/29/Euratom define what practices may be exempt and what materials may be cleared. Have these articles been implemented in your country?

   The transposition of the directive into French Law is not complete. It will include four texts:

   1. Ordinance No 2001-270 of the 28th March 2001 relating to the transposition of community directives in the area of protection from ionising radiation. JO No. 77 of 31st March 2001. (General Principles of radiation protection).

   2. Decree No 2002-460 of the 4th April 2002 relating to protection of the public from ionising radiation.

   3. 2 Decrees relating to the protection of workers and interventions are still outstanding.

   Transposition of the Directive appeared to require a rewriting of the French legislative system for control of radiation thus accounting for the delays.

   Exemption and Clearance concepts are implemented by Ordinance No. 2001-270, Public Health Code (cf art L1333-11 with L1333-20) and the Fair Labour Standards Act (cf act L231-7-1) [Godet, 2001]

   The relevant legislation may be found from the 'Le JournalOfficiel' at http://www.legifrance.gouv.fr/html/plan/plan_site.htm.

2. Which organisation(s) is responsible for issuing regulatory documentation, including exemption and clearance levels and overseeing the practical application of the concepts?

   France has recently undergone institutional reform in the field of radiation protection. The Directorate-General of Nuclear Safety and Radiation (DGSNR) is now responsible for regulatory documents. This body along with the Office for the Control of Nuclear Reactors (BCCN) and the eight divisions of Nuclear Installations make up the Safety Authority which is advised by the Institute of Radiation Protection and Nuclear Safety (IRSN).

3. What guidance has been issued to ensure compliance with statutory provisions e.g. approved codes of practice?

   No answer.

4. Please describe the processes of exemption and clearance for nuclear installations and other practices i.e. hospitals, research establishments etc.

Exemption

In the field of medicine, human biology and biomedical research authorisation will continue to be necessary for manufacture of radionuclides, products or devices containing such and for their distribution, import and export. Use of radioactive sources sealed or unsealed in hospitals, biomedicine and medical laboratories will remain subject to authorisation although the Directive permits exemption.

For all other fields in the area of industry and research laboratories authorisation is only necessary when exemption levels are exceeded as fixed in the Directive in Annex I Table A.

[Godet, 2001]

Clearance

In France the view is that the process of clearance should remain under the control of the national authorities. The authorities licence the clearance practices and subsequently check compliance with the clearance criteria through inspections. France has decided not to issue unconditional clearance levels.

Nuclear Installations [Brigaud, 1999]

In general equal attention must be paid to all waste (non-radioactive and radioactive) from nuclear installations. Though management will be commensurate with the characteristics and toxicity of the waste. Waste must be traceable and the impact on workers, the public and the environment be considered.

For very low level waste the radiological risks are low however the precaution and optimisation principles still apply. A strategy of management through known and justified treatment methods are used as opposed to unconditional clearance strategies. Unconditional clearance was rejected as it was seen by the public as a way to enable the waste producers to bypass adequate controls and also as an encouragement to dilute.

The French system relies on a case-by-case approach corresponding to the different categories of waste or the different categories of waste treatment methods. Clearance from regulatory control may be involved at the treatment facility stage however the process must be fully described in specific procedures. These procedures and their use must be covered by a quality assurance system including record keeping.

In order to implement these principles and procedures each nuclear site or facility is required to produce a waste management plan. The waste management plan will consist of:

- *a zoning map identifying the parts of the plant giving rise to conventional waste or to radioactive waste; this geographical approach, completely different*

from the approach based on measurements, is the basis of distinguishing potentially radioactive and non-radioactive waste

- *a description of how waste is generated*
- *the principles and organisation adopted by the operating organisation for monitoring waste of all categories,*
- *a description of management practices and procedures,*
- *a description of management of the interim storage facilities.*

Before defining the waste management strategy the facility must under take what could be described as a Best Practical Environmental Options Study (BPEO) and a Best Practical Means Study (BPM) i.e. identify techniques for removal of each category of waste accounting for the physical and chemical nature of the waste. For each treatment/removal method the waste is identified, feasibility both economic and technical considered, how it affects the objective to reduce secondary waste and impacts on health are discussed.

The waste management plan has to be approved by the Nuclear Safety Authority. The Authority will review the proposed pathways and ensure an adequate quality assurance system is in place and that every pathway is legally authorised.

The public is involved in the assessment of treatment plants. The assessment verifies the lack of impact and the complete control of the operator over the process.

Non-nuclear installations [Carlier, 2001]

Waste must be sorted and conditioned as early as possible at the point of production and categorised into those radionuclides with a half-life less than 100 days and those with half-lives greater than 100 days.

Waste with a half-life less than 100 days:

i Remove infectious and pathogenic risks

ii The waste is stored long enough so that through radioactive decay the activity is reduced to that of background.

iii After this the waste can follow conventional waste disposal routes i.e. domestic waste, sewers or conventional hazardous waste paths.

Waste with a half-life of greater than 100 days:

i Classified according to physiochemical nature, the national Agency for the management of radioactive waste (ANDRA) will advise on packaging and management

ii ANDRA accepts and processes the waste.

5. Was Annex 1 (of BSS Euratom) used for defining exemption levels? If not, what are these other levels. Please describe the reasoning/methodology in their derivation.

   Yes, see Annex II Table A of Decree 2002-460 of the 4th April 2002

6. Was EC guidance used in the derivation of clearance levels? Please indicate which guidance and for which materials and practices.

   No see question 4, the derivation of any levels in the framework of the treatment method involves an impact assessment to workers, the public and the environment. Cleared waste must enter a known pathway meeting precise requirements.

7. Please give specific situations, sources, waste streams to which exemption and clearance have been applied. Please list exempt practices. Have both general and specific clearance levels been applied in your country (i.e. after clearance, is material cleared for all uses or are restrictions imposed)? Please give examples.

   A conventional melting plant has been authorised to receive metal scrap from dismantling operations conducted in a nuclear facility.

8. Has clearance been a useful concept or have cleared materials still been rejected as radioactive? Please give details.

   No answer.

9. Please identify needs for improvement (legal, practical application, additional guidance) in this area

   No answer.

Benchmark Example:

In order to fairly and simply compare the approaches of different EU Member States it is our hope to analyse the responses Authorities would take to a sample situation. Thus could you consider the following and justify the appropriate proposed course of action:

- Operator of a nuclear installation in your country hopes to clear about 5,000 t steel in the course of decommissioning the site.

- Half the material has surface contamination while the other half is activated.

- The typical surface contamination and activity is given below:

Radionuclide	Surface Contamination (Bq/cm^2)
Cs-137	80
Ce-144	50
Sr-90	15

Radionuclide	Specific Activity (Bq/g)
Co-60	1
Zn-65	0.5
Mn-54	1.2

Is the steel likely to be cleared? What conditions may be applied? Will it be: -

a. Given unconditional clearance
b. Cleared for recycling
c. Cleared for reuse
d. Refused clearance, sent for disposal
e. Refused clearance further decontamination required
f. Other (please give details)

Answer: National clearance levels not defined.

References:

Brigaud Oliver, 'Management of Very Low Level Waste from Nuclear Installations: A Comprehensive Approach Developed in France for Authorizing the Release of Radioactive Waste from Regulatory Control', *Proceedings from the 2nd International Symposium Release of Radioactive Material from Regulatory Control,* Hamburg 8th –10th November 1999.

Carlier Vincent, 'Les petits producteurs: la gestion des déchets radioactifs, de la collecte au stockage'**,** *Le contrôle de l'utilisation des rayonnements ionisants,* No 143, November 2001.

Godet Jean-Luc, 'Les règles d'utilisation des rayonnements ionisants: Evolution du cadre réglementaire et du contrôle'**,** *Le contrôle de l'utilisation des rayonnements ionisants,* No 143, November 2001.

IRELAND

Provided by: Dr Ann McGarry, Chief Executive of the Radiation Protection Institute of Ireland; with additional comment provided by Christopher Hone, Principal Scientific Officer, RPII.

1. Title III, Article 3 paragraph 2 and Title III, Article 5 paragraph 2 of Council Directive 96/29/Euratom define what practices may be exempt and what materials may be cleared. Have these articles been implemented in your country?

   Yes. Council Directive 96/29/Euratom has been transposed into Irish Law. The relevant legislation is The Radiological Protection Act, 1991 (Ionising Radiation) Order, 2000 (S.I. No. 125 of 2000). Articles 4 and 5 of the Order covering Licensing of Practices and Exemptions are given in full below.

   Regarding Exemption, the legislation requires all practices (defined as "means 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, other than an activity that results in an emergency exposure") to be licensed (Article 4(1)) except where the quantities are below the exemption values. The Radiological Protection Institute (RPII) is the licensing authority.

   Regarding Clearance, this concept is deliberately excluded from the legislation. The Institute must license the disposal, recycling or reuse of radioactive substances or radioactive materials arising from any licensed practice. In drafting the legislation, recognising that Ireland does not have a nuclear industry, it was not immediately apparent that there was any need/demand for clearance levels and it was decided not to include this concept in the legislation.

2. Which organisation(s) is responsible for issuing regulatory documentation, including exemption and clearance levels and overseeing the practical application of the concepts?

   The Radiological Protection Institute of Ireland is the competent authority for all matters relating to ionising radiation.

3. What guidance has been issued to ensure compliance with statutory provisions e.g. approved codes of practice?

   No specific guidance document on either exemption or clearance has been issued.

4. Please describe the processes of exemption and clearance for nuclear installations and other practices i.e. hospitals, research establishments etc.

   There are no nuclear installations in Ireland. In the case of all other practices; these must be carried out under a licence issued by the RPII (see Question 1 above).

5. Was Annex 1 (of BSS Euratom) used for defining exemption levels? If not, what are these other levels. Please describe the reasoning/methodology in their derivation.

Yes, the exemption values used are those given in Annex 1 of the BSS Euratom.

6. Was EC guidance used in the derivation of clearance levels? Please indicate which guidance and for which materials and practices.

No clearance levels have been set. See Question 1 above. It is expected that values will be determined on a case-by-case basis.

7. Please give specific situations, sources, waste streams to which exemption and clearance have been applied. Please list exempt practices. Have both general and specific clearance levels been applied in your country (i.e. after clearance, is material cleared for all uses or are restrictions imposed)? Please give examples.

Exemption has been applied in the case of very small sources with activities below the exemption levels, e.g. some small check sources are exempted.

The legislation (The Radiological Protection Act, 1991 (Ionising Radiation) Order, 2000 (S.I. No. 125 of 2000) also provides a mechanism whereby certain practices can be exempted (Article 5). However, this mechanism is not generally used and most practices are included in the licensing framework.

8. Has clearance been a useful concept or have cleared materials still been rejected as radioactive? Please give details.

See Question 1.

9. Please identify needs for improvement (legal, practical application, additional guidance) in this area

As already stated, it is not exactly clear how clearance would work in practice and further guidance in this area would be useful. It should be noted, however, that at present the lack of clearance levels has not posed any particular difficulties in the Irish context.

Further comment by Christopher Hone, April 2003:

Ireland would support calls made to harmonise both exemption and clearance levels. While the issue of clearance is obviously of less direct relevance to non-nuclear countries, there is still a need for harmonisation, particularly in relation to trans-border movement of decayed sources which were previously used in hospitals or in industry.

Furthermore, in a round-about-way, the introduction of the High Activity Sealed Sources Directive will also increase the need for harmonisation of exemption and clearance values. The portal monitors, which, under this Directive, Member States will be obliged to install at nodal points such as ports and airports and in scrap yards, will inevitably result in the detection of more contaminated material and

weakly radioactive objects and hence the need to determine whether or not such material and objects should be subject to regulatory control.

Benchmark Example

In order to fairly and simply compare the approaches of different EU Member States it is our hope to analyse the responses Authorities would take to a sample situation. Thus could you consider the following and justify the appropriate proposed course of action:

- Operator of a nuclear installation in your country hopes to clear about 5,000 t steel in the course of decommissioning the site.

- Half the material has surface contamination while the other half is activated.

- The typical surface contamination and activity is given below:

Radionuclide	Surface Contamination (Bq/cm^2)
Cs-137	80
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Radionuclide	Specific Activity (Bq/g)
Co-60	1
Zn-65	0.5
Mn-54	1.2

Is the steel likely to be cleared? What conditions may be applied? Will it be: -

a. Given unconditional clearance
b. Cleared for recycling
c. Cleared for reuse
d. Refused clearance, sent for disposal
e. Refused clearance further decontamination required
f. Other (please give details)

As already stated, there are no previously agreed clearance values that could be used. As there are no nuclear facilities in Ireland, it is unlikely that a large volume of contaminated material would arise. However, a situation did occur some years ago where a source was inadvertently melted down in a steel recycling facility resulting in a large volume of material with a low level of contamination. In this case, the material was returned to the country from which the scrap had originated. For smaller volumes of contaminated material, the licensee is usually required to store the material under licence. In this context, it is worth noting that there is no facility for the disposal of radioactive waste in Ireland.

Section from The Radiological Protection Act, 1991 (Ionising Radiation) Order, 2000 (S.I. No. 125 of 2000)

Licensing of Practices

4. *(1) Subject to Article 5, a practice to which this Order applies shall not be carried on save under and in accordance with a licence issued by the Institute.*

(2) Such a licence shall not be granted in respect of the deliberate addition of radioactive substances in the production of foodstuffs, toys, personal ornaments and cosmetics and the import and export of such goods.

Exemptions

5. *(1) Subject to paragraph (2), Article 4 does not apply to practices involving -*

(a) radioactive substances where the quantities involved do not exceed in total the exemption values set out in column 2 of Table A to Annex I or in exceptional circumstances, different values authorised by the Institute that satisfy the criteria in Annex I,

(b) radioactive substances where the concentrations of radioactivity per unit mass do not exceed the exemption values set out in column 3 of Table A to Annex I or, in exceptional circumstances, different values authorised by the Institute that satisfy the criteria set out in Annex I,

(c) apparatus containing radioactive substances exceeding the quantities or concentration values specified in paragraph (a) or (b), provided that -

(i) it is of a type approved by the Institute,

(ii) it is constructed in the form of a sealed source,

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

(iv) conditions for disposal have been specified by the Institute,

(d) the use of any electrical apparatus to which this Order applies, other than that referred to in subparagraph (e), provided that -

(i) it is of a type approved by the Institute, and

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

or

(e) the use of any cathode ray tube intended for the display of visual images, or other electrical apparatus operating at a potential difference not exceeding

30 kV, provided that this operation does not cause, in normal operating conditions, a dose rate exceeding 1 μSv h^{-1} at a distance of 0.1 m from any accessible surface of the apparatus;

(2) Nothing in paragraph (1) shall affect the application of this Order to -

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

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

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

(d) the disposal, recycling or reuse of radioactive substances or radioactive materials arising from any licensed practice.

May 2002 (with additional comment given in April 2003)

ITALY (Italia)

Provided by: Giorgio Cesari, Director General of Agenzia per la Protezione dell'Ambiente e per i Servizi Tecnici (APAT)

Preliminary note
Radiation protection legislation in Italy is embodied in Legislative Decree no. 230 of 17th March 1995, published in Italy's Official Journal no. 136 of 13th June 1995 (ordinary supplement 74); as a result of the transposal of Directive 96/29/Euratom into Italian legislation, Legislative Decree no. 230 of 1995 was modified, inter alia, by Legislative Decree no. 241 of 26th May 2000, published in Italy's Official Journal no. 136 of 31st August 2000 (ordinary supplement 140/L).

Unless explicitly stated otherwise, relevant provisions of Legislative Decree no. 230 of 1995 that are made reference to from now on are meant as amended by Legislative Decree no. 241 of 2000.

1. Title III, Article 3 paragraph 2 and Title III, Article 5 paragraph 2 of Council Directive 96/29/Euratom define what practices may be exempt and what materials may be cleared. Have these articles been implemented in your country?

   It must be pointed out beforehand that Italian legislation introduces a distinction between exemption of practices, pursuant to Article 2, paragraph 1, of Directive 96/29/Euratom, and exemption from prior reporting of practices, pursuant to Article 3, paragraph 2, of the same Directive.

   In particular, threshold levels for exemption of practices do not coincide in Italian legislation with those for exemption from reporting since the former are either less than, or equal to, those established for the latter (see for this under paragraphs 1.1 and 1.2).

   According to Italian legislation, if a practice is exempt no radiation protection requirements apply; if a practice is not exempt but complies with requirements for exemption from prior reporting, nonetheless ordinary provisions for radiation protection of workers and the public apply, pursuant to Articles 1, 59 and 97 of Legislative Decree no. 230 of 17th March 1995, although in this case neither reporting nor, for that matter, authorisation requirements apply.

   A special case are the practices addressed in 1.1.c), where prior authorisation is always mandatory whatever the radioactivity levels involved, even below the exemption levels for practices addressed in 1.1.

   1.1. Threshold levels for exemption of practices

   1.1.a). Italian requirements for exemption of practices with radioactive substances are currently laid down in Annexe I, paragraphs 0.1 to 5, to Legislative Decree no. 230 of 17th March 1995, pursuant to Article 1, paragraph 2-bis, of the said Decree no. 230 of 1995 and to Article 36 of Legislative Decree no. 241 of 2000.

   1.1.b). In accordance with the provisions mentioned in 1.1.a), a practice is subject to

radiation protection requirements, i.e. is not exempt, if certain thresholds of activity and concentration are both exceeded. Notably, the scope of radiation protection legislation is determined by overall thresholds of:

- mass activity concentration for all radionuclides >= 1 Bq/g, and

- activity >= values either from Directives 84/467/Euratom or 96/29/Euratom, whichever the smaller.

1.1.c). Special practices

For some practices such as use of radiation for medical purposes, deliberately adding radioactivity to consumer goods, importing and exporting such goods and releases of radioactive materials from installations, i.e. discharges of effluents, clearance, reuse or recycle, the Decree's radiation protection requirements apply even below thresholds in 1.1 above, pursuant to paragraph 6 of the above mentioned Annexe I to Legislative Decree no. 230 of 1995.

The practices referred to above are per se subject to authorisation, i.e. whatever the levels of radioactivity involved. Further characteristics of the Italian system as regards releases are addressed in 1.4 and 1.5.

1.2. Threshold levels for exemption from prior reporting of practices

For practices to be exempt from prior reporting radionuclide-specific exemption levels are laid down in Legislative Decree no. 230, pursuant to Article 22, to Annexe VII, paragraph 4, and Tables VII-1 and VII-2. Notably, exemption levels from reporting laid down in Italian legislation coincide with activity and concentration values tabled in Annex I to Directive 96/29/Euratom. It must also be pointed out that no reporting is required when a practice is subject to prior authorisation, pursuant to Article 22, paragraph 1, of Legislative Decree no. 230 of 1995.

1.3. The 'Below Regulatory Concern' criterion

The 'Below Regulatory Concern' criterion for practices to be exempt, with its implications on unrestricted release of radioactive materials from practices, was also formally introduced into Italian legislation (Article 2, paragraph 6, and paragraph 0.1 of Annexe I), in accordance with the following basic rule for individual and collective doses, both conditions of which must be met:

- effective dose <= 10 μSv/year, and

- either collective effective dose committed in one year of performance of the practice not greater than about 1 man-Sv/year or the relevant analysis demonstrates that exemption is the optimum option.

Obviously, the criterion above arises from Annex I to Directive 96/29/Euratom.

1.4. General rule for unrestricted release

A general rule is laid down for unrestricted release, pursuant to Article 154, paragraph 2, of Legislative Decree no. 230 of 1995. Thus, radioactive materials can be unconditionally released (i.e. discharged, cleared, recycled or reused) from regulatory control if all radionuclides concerned comply with two conditions regarding both activity concentration and radioactive half-life:

- *mass activity concentration <= 1 Bq/g, and*

- *radioactive half-life < 75 days.*

1.5. Prior authorisation of releases

If both conditions in 1.4 above are not complied with an authorisation is always required for release (discharge of effluents, clearance, reuse or recycle) of radioactive materials from a practice and relevant technical specifications are established in the licence, pursuant to Articles 30, paragraph 1, and Article 154, paragraph 3-bis, of Legislative Decree no. 230 of 1995.

1.6. Definitions of the concepts of practice and clearance

The definition of practice is addressed in Article 4, paragraph 3.e), in the same terms used in Article 1 of Directive 96/29/Euratom. The definition of release is addressed in Article 30, paragraph 1, and in Article 154, paragraph 3-bis, as being any act of discharge, clearance, disposal, recycle or reuse of radioactive materials meant for activities or places not subject to radiation protection requirements. Article 4, paragraph 2.q), addresses the definition of release levels from practices as concentration or activity values of radioactive substances that can be exempted from the requirements laid down in Legislative Decree no. 230 of 1995.

2. Which organisation(s) is responsible for issuing regulatory documentation, including exemption and clearance levels and overseeing the practical application of the concepts?

In the Italian legislative framework exemption and clearance levels are laid down by regulatory acts (Legislative Decrees and/or Government Regulations) of general application, such as the ones mentioned above in 1.

Inspection powers are also addressed in legislation. Under Article 10 of Legislative Decree 230 of 1995, there is a general remit for APAT Inspectors (APAT, formerly ANPA, is Italy's Agency for Protection of the Environment and for Technical Services) for all aspects concerning nuclear safety and radiation protection; inspection powers as regards requirements for protection of workers and the public respectively are the remit of Labour Inspectorates, according to article 59 of Legislative Decree 230 of 1995, and of the Ministry of Health as well as of local Health Bodies, pursuant to Article 97 of the same Decree.

3. What guidance has been issued to ensure compliance with statutory provisions e.g. approved codes of practice?

A comprehensive review of radiological criteria for the release of materials with low level radioactive contamination from decommissioning of nuclear installation was issued in 1999 by the Technical Commission for Nuclear Safety and Health Protection, for which Body please see in 4.b). In the review reference is obviously made, inter alia, to the then available European Commission's Radiation Protection Publication no. 89 for metals.

In addition, the Italian National Standards Body (UNI) has been issuing over the years technical guidance on various aspects of decommissioning, such as:

- UNI 9498 Part 1 Decommissioning of nuclear plants – General Criteria;

- UNI 9498 Part 2 Decommissioning of nuclear plants – Decontamination techniques;

- UNI 9498 Part 5 Decommissioning of nuclear plants – Radioactivity inventory;

- 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 or site.

APAT is currently revising previous guidance ("Technical Guide no. 26") addressing categorisation and management of radioactive waste. Moreover, a draft of a further UNI standard (UNICEN 189 U54.02.189.0) is at an advanced stage of approval, the draft concerns "Solid material from nuclear plants – Radiological methods and procedures for clearance".

4. Please describe the processes of exemption and clearance for nuclear installations and other practices i.e. hospitals, research establishments etc.

From an administrative viewpoint, practices can be subject to the mutually exclusive requirements either of notification or of authorisation.

a) The Decree no. 230's provisions state (Article 22, paragraph 1) that a practice is subject to notification insofar as requirements for authorisation do not apply; besides, in accordance with the provisions of Legislative Decree no. 230 of 1995, as resulting from modifications introduced, inter alia, by Legislative Decree no. 241 of 2000, a practice is subject to notification requirements starting from the thresholds in activity and activity concentration mentioned in paragraph 1.2.

Thus, any physical or legal person who is not subject to prior authorisation is required to notify local authorities of his intention to carry out a practice at least 30 days in advance, pursuant to Article 22 of Legislative Decree no. 230. Besides, provisions for detailed technical information to be submitted to local authorities by

the prospective user, which closely mirror those provided for in cases of authorisation, are laid down for reporting in Annex VII, paragraph 3.1 to 3.4, of the Decree.

b) As regards authorisation requirements, nuclear installations, which are minutely defined in Article 7 of Legislative Decree no. 230 of 1995, are not subject to notification requirements since such installations are per se subject to the complex authorisation requirements laid down in Articles 36 to 58, ad hoc provisions for decommissioning being included. In the course of the authorisation process the technical advice of APAT is sought under law, as well as the advice of the Technical Commission for Nuclear Safety and Health Protection, also in order to state technical specifications in the relevant licensing acts. The latter Body, established pursuant to Article 9 of Legislative Decree no. 230 of 1995, sits at APAT and includes representatives, inter alia, of all Ministries concerned.

For other installations using ionising radiation for medical, industrial and research purposes the Italian authorisation system is based, as in the past, on a two tiered structure: according to Article 28 authorisation of the more important installations is the remit of the Ministry of Production that issues authorisations acting in accordance with other relevant Ministries (Environment, Health, Labour, Home Affairs) and the Region concerned; the advice of APAT is sought under law also in order to determine technical specifications applicable to the installation.

Pursuant to Article 27, paragraph 2, of Legislative Decree no. 230 of 1995, thresholds were laid down in Annexe IX, paragraphs 1.2 to 3.4 and Tables IX-1 and IX-2, with a view to determining installations where prior authorisation is required respectively by local authorities or by the Ministry of Production. Radionuclide specific authorisation thresholds are set in terms of values of activity, activity concentration and neutron yield for radioactive sources as well as of energy and neutron yield for accelerators. Mass activity concentration thresholds are those established for exemption from reporting in Annex I of Directive 96/29/Euratom and in Italian legislation; activity thresholds were chosen as multiples of the exemption values for reporting laid down in Annex I of the said Directive as well as in Italian legislation.

For industrial and research installations of a less complex nature, i.e. below the relevant thresholds laid down in Annexe IX, the Prefect of the province has administrative competence under Article 29 to issue authorisations after seeking the advice of regional technical bodies and of the Fire Corps; authorisations required for installations where ionising radiation is used for medical purposes are under Article 29, paragraph 2, the remit of Regions or local Health Bodies; the advice of technical bodies is also sought under law.

The same Annexe IX, paragraphs 4.1 to 4.4, specifies the information to be submitted by the applicant, notably requiring detailed technical features of the radiation sources and of the installation to be specified, inter alia, in applications; detailed analyses concerning doses to be received by workers and the public, waste management, requests for releases (discharges, clearance, reuse or recycle) and for decommissioning of the installation must be specified as well.

Pursuant to Article 27, paragraph 4-quater, and to Annex IX, paragraphs 5.3.b) and 5.3.c), of Legislative Decree no. 230 of 1995 the licence must state technical specifications bearing on doses to reference groups of the public and release of radioactive materials; as concerns the latter aspect explicit reference is made in Annexe IX, paragraph 5.3.c), to compliance with criteria and thresholds mentioned above in 1.1.b) and 1.4.

Authorisations for release from a practice are obviously granted on the basis of a case-by-case review of the analysis submitted by the operator with a view to demonstrating compliance with the requirements in 1.1.b), with the basic 'below regulatory concern' criterion stated above in 1.4 and with European Union's directives, technical recommendations and guidance, pursuant to Article 154, paragraph 3-bis. In the case where the practice is not subject per se to authorisation requirements, as for instance in the case where only notification requirements apply, an ad hoc authorisation for release is mandatory, pursuant to Article 30, paragraph 1, of the said Legislative Decree.

c) Special requirements in Annexe VII, paragraphs 3.5 and 3.6, for practices subject to reporting and in Annexe IX, paragraphs, 5.10 to 5.13, for practices subject to authorisation cover cases of closing practices down; users are required to submit in advance a report on close-down operations as well as the meant-for destination of radioactive sources and waste to competent authorities. After closing a practice down a report must be submitted to the same authorities stating the lack of constraints of a radiation protection nature for the installations where the practice was carried out.

Like all cases of infringement of Italian radiation protection legislation, it must be emphasised that non compliance with technical specifications in a licensing act is a punishable offence, pursuant to Article 137, paragraphs 1 to 3, for non nuclear installations, and to Article 138, paragraph 3, for nuclear installations; as such, non compliance must be reported by Inspectors to the Office of Public Prosecution.

5. Was Annex 1 (of BSS Euratom) used for defining exemption levels? If not, what are these other levels. Please describe the reasoning/methodology in their derivation.

As mentioned in paragraphs 1.1 and 1.2, pursuant to Article 22 and Annexe VII, paragraph 4 and Tables VII-1 and VII-2, of Legislative Decree no. 230 of 1995, exemption levels from reporting are the same in Italian legislation as those laid down in Annex I of Directive 96/29/Euratom.

To define activity and activity concentration thresholds for practices to be exempt, it was mentioned in 1.1.b) above that activity values for each radionuclide were chosen as the lesser from Euratom directives 84/467 and 96/29; as concerns activity concentration, an overall threshold of 1 Bq/g for all radionuclides already existed in Legislative Decree no. 230 of 1995 before modifications were introduced by Legislative Decree no. 241 of 2000 in order to transpose Directive 96/29/Euratom; thus, the already existing concentration threshold of 1 Bq/g was maintained in the legislation revised as a consequence of transposal for reasons of conservatism and of stability of the legislative framework.

6. Was EC guidance used in the derivation of clearance levels? Please indicate which guidance and for which materials and practices.

Articles 30, paragraph 1, and 154, paragraph 3-bis, of Legislative Decree no. 230 of 1995 explicitly state that reference has to be made when defining technical specifications in authorising releases, inter alia, to the European Union's relevant directives, technical recommendations and reports.

7. Please give specific situations, sources, waste streams to which exemption and clearance have been applied. Please list exempt practices. Have both general and specific clearance levels been applied in your country (i.e. after clearance, is material cleared for all uses or are restrictions imposed)? Please give examples.

As an instance of application both of the general criteria in 1.1.b) and 1.4, as well as of European Union technical recommendations mentioned in 6, technical specifications concerning clearance in the first regulatory licence issued in the decommissioning process of the Caorso former nuclear power station are worth mentioning, for which please see the Table below.

In determining clearance values allowance had to be made for three constraining factors: the request submitted by the applicant, which was lower for some radionuclides than values recommended in the European Union's technical guidance on clearance; the strict specific requirements of the legislation concerning the scope that were mentioned in 1.1.b), i.e. the overall threshold of 1 Bq/g, and the European Union technical guidance.

Thresholds for authorised releases from the Caorso NPP are shown in the following table.

Nuclide	**Metal materials**		**Building materials**		**Other materials**
	Bq/g	***Bq/cm^2***	***Bq/g***	***Bq/cm^2***	***Bq/g***
^{3}H	1	10000	1	10000	0.1
^{14}C	1	1000	1	1000	0.1
^{54}Mn	1	10	0.1	1	0.1
^{55}Fe	1	1000	1	10000	0.1
^{60}Co	1	1	0.1	1	0.1
^{59}Ni	1	1000	1	10000	0.1
^{63}Ni	1	1000	1	10000	0.1
^{90}Sr	1	1	1	100	0.1
^{125}Sb	1	10	1	1	0.1
^{134}Cs	0.1	1	0.1	1	0.1
^{137}Cs	1	10	1	1	0.1
^{152}Eu	1	1	0.1	1	0.1
^{154}Eu	1	1	0.1	1	0.1
α emitters	0.1	0.1	0.1	0.1	0.01
^{241}Pu	1	1	1	10	0.1

In the authorisation for the initial phase of the Caorso nuclear power plant

decommissioning, ad hoc technical specifications for metal scrap were provided for with a view to controlling the final destination of metal meant for the foundry; for instance the NPP operator is required to arrange for contractual agreements with the foundry in order to mix metal scrap arising from Caorso NPP decommissioning with uncontaminated scrap in a 1/10 ratio.

8. Has clearance been a useful concept or have cleared materials still been rejected as radioactive? Please give details.

While the concept of clearance is certainly being made use of both in Italian legislation and practice, it can equally well be argued that clearance is just a case of exemption applied to releases of material from an installation at low levels of radioactivity, though with some additional constraints. Till now the Caorso NPP case has been the sole example of application of the clearance rules laid down in current Italian legislation.

This having been said, it must be borne in mind that exemption levels laid down in Italian legislation (see in 1.1.b) must be complied with in all cases of release in order to avoid that radioactive materials re-enter the regulatory regime after being released under the clearance concept, also because radiometric surveillance on incoming scrap metal materials is in operation at foundry installations.

9. Please identify needs for improvement (legal, practical application, additional guidance) in this area

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.

Benchmark example:

In order to fairly and simply compare the approaches of different EU Member States it is our hope to analyse the responses Authorities would take to a sample situation. Thus could you consider the following and justify the appropriate proposed course of action:

- Operator of a nuclear installation in your country hopes to clear about 5,000 t steel in the course of decommissioning the site.
- Half the material has surface contamination while the other half is activated.
- The typical surface contamination and activity is given below:

Radionuclide	Surface Contamination (Bq/cm^2)
Cs-137	80
Ce-144	50
Sr-90	15

Radionuclide	Specific Activity (Bq/g)
Co-60	1
Zn-65	0.5
Mn-54	1.2

Is the steel likely to be cleared? What conditions may be applied? Will it be: -

a. Given unconditional clearance
b. Cleared for recycling
c. Cleared for reuse
d. Refused clearance, sent for disposal
e. Refused clearance further decontamination required
f. Other (please give details)

Pursuant to current rules in Italian legislation (paragraphs 1.1.c), 1.4 and 1.5 above), an operator of a nuclear installation with 2,500 tons of steel with the following levels of mass activity concentration Co^{60} = 1 Bq/g; Zn^{65} = 0.5 Bq/g; Mn^{54} = 1.2 Bq/g, would not be given unconditional clearance or clearance for recycling or clearance for reuse out of regulatory control. Disposal would be subject to authorisation, even though a national long term storage facility is not available at the moment in Italy. A possible way of reusing the steel would be to utilise it within the nuclear industry, like casks for spent fuel, or anyway in regulated installations or purposes.

On the other hand, considering 2,500 tons of contaminated steel with the following levels of surface contamination (in Bq/cm^2) Cs^{137} = 80; Ce^{144} = 50; Sr^{90} = 15, such levels would not have complied with technical specifications for the Caorso case, for which see in 7. On a more general level, the surface contamination values given above do not comply with nuclide specific clearance levels recommended in Tables 3-1 and 3-2 of the European Commission's Radiation Protection 89. Therefore, pursuant to Article 154, paragraph 3-bis, of Legislative Decree no. 230 of 1995, the steel in question could not be candidate either for unrestricted release or, clearance in particular, and the considerations made above for mass contamination apply.

November 2002

LUXEMBOURG

Provided by: Dr M Feider, Article 31 Expert, Ministry of Health in Luxembourg

1. Title III, Article 3 paragraph 2 and Title III, Article 5 paragraph 2 of Council Directive 96/29/Euratom define what practices may be exempt and what materials may be cleared. Have these articles been implemented in your country?

Title III implemented: *Yes*

Legislative document:

Règlement grand-ducal du 14 décembre 2000 concernant la protection de la population contre les dangers résultant des rayonnements ionisants.

Definition of Exemption:
No specific definition of exemption is given in annex 1. In Art. 2.7.5 a description applicable to exclusion is given: a practice or work activity excluded from authorisation or reporting. The exemption levels given in Council Directive 96/29/Euratom Table A are basically used for the classification of industries in three classes II – IV. The classification system of industries is given in Art.2.

Exemption values for ***practices*** *are given in Table A for total activity (quantity) as well as activity per unit of mass (Bq/g).*

- *Industries using materials with a radioactivity level below 1/100 of the exemption level are excluded from the requirement of reporting or authorisation.*

- *Industries using materials with a radioactivity level < the exemption level and > 1/100 of the exemption level require prior reporting.*

- *Industries using materials with a radioactivity level > the exemption level require prior authorisation.*

Work activities
The use of materials containing natural radionuclides, and which have not been processed in view of their radioactive properties, requires prior authorisation if the total mass activity of the long lived mother radionuclides > 100 Bq/g.

Definition of Clearance:
No specific definition of clearance is given in annex 1. In Art. 2.12.2 a description applicable to clearance is given: disposal or reuse of materials released from prior authorisation.

In the national legislation limits are fixed for unconditional clearance for disposal, recycling and reuse of substances arising from practices subject to the requirement of reporting or authorisation. The limits are those recommended by the German Commission on Radiological Protection: Clearance of Materials, Buildings and Sites with Negligible Radioactivity from Practices subject to Reporting or Authorisation.

These clearance levels are based on dose scenarios. Clearance levels in Bq/g (Table A) as well as Bq/cm^2 are given (Table B).

In the National legislation of Luxembourg the activity concentrations for exemption and unconditional clearance differ.

Material is exempted from the requirements of authorisation as well as reporting if the activity concentration < 1/100 Xe (f.e. for Ra-226 < 0,1 Bq/g).

The same materials will be unconditional cleared when the concentration of Ra-226 < 0,03 Bq/g). The values for unconditional clearance are those recommended by the German Commission on Radiological Protection (SSK). It should be stressed that these values are applicable for the unconditional clearance where you might suppose cautious scenarios. On the other hand Luxembourg might apply for the conditional release, higher values for Ra-226, but these would be case by case decisions.

2. Which organisation(s) is responsible for issuing regulatory documentation, including exemption and clearance levels and overseeing the practical application of the concepts?

   The Ministry of Health.

3. What guidance has been issued to ensure compliance with statutory provisions e.g. approved codes of practice?

   Except for the national regulation, no written official code of practice exists in our country. Compliance with statutory provisions is normally assured by the control and supervision of the competent authorities.

   Potential users of radioactive sources have to submit a demand for licensing. A first check of the compliance with statutory provisions is made on the basis of the written demand. Instructions how to comply with statutory provisions are generally included in the written licence. At its first use, every source has to be submitted to an acceptance test performed by the competent authorities: this acceptance test has to be considered as the second check of the compliance with statutory provisions. For bigger industries or high acivity level sources an annual control is foreseen by the competent authorities. In case of non-compliance with statutory provisions the source holder is informed by letter and remedial actions are again controlled by authorities. This system is only possible in a small country with a limited amount of radioactive sources.

4. Please describe the processes of exemption and clearance for nuclear installations and other practices i.e. hospitals, research establishments etc.

   For sealed sources: *the exemption levels given in Table A of our national regulation apply to each individual sealed source. For the licensing procedure the activity of each individual source is considered. So a user may hold different sources ranging in different licensing classes, but from the point of view of radiation protection, the*

owner is ranged in the highest class. Generally clearance levels do not apply to sealed sources except for sources with very short half-life.

For hospitals or laboratories using unsealed sources: *the total amount of activity held at any time by the user is considered for the exemption level (Art. 2.7, point 2). Holders using activities above the exemption level need a license, whereas activities below the exemption level need only to be notified.*

Users holding activities below the exclusion level have no legal obligation for notification.

The user is responsible for the control and the clearance of radioactive substances to be eliminated, reused or recycled. The owner may have three possibilities with radioactive substances to be cleared:

- *the specific activity concentration or the contamination level are above the clearance level: the user may store the substances on its own premises until decrease below clearance level (if the radionuclides used have a short half-life),*

- *the specific activity concentration or the contamination level are above the clearance level: the user must transfer the substances or devices to an foreign agreed installation,*

- *the specific activity concentration or the contamination level are below the clearance level: unconditional clearance levels apply.*

Conditions associated with the unconditional clearance levels: they only do apply to quantities below 1000kg; dilution is not allowed.

For substances or contamination exceeding the clearance levels or for substances above 1000 kg: a conditional clearance is possible with an authorisation of the competent authorities on a case by case decision.

5. Was Annex 1 (of BSS Euratom) used for defining exemption levels? If not, what are these other levels. Please describe the reasoning/methodology in their derivation.

The exemption levels given in Council Directive 96/29/Euratom Table A are basically used for the classification of industries in three classes II – IV (see also question 1). Exclusion of materials is obtained if the activity concentration is < 1/100 the exemption value in Table A.

In the Luxembourg legislation the exemption level is used to set a limit between licensing and notification, the exclusion level is used to fix a limit between notification and "free from any reporting". In that view exemption means: exempted from licensing but not free from any reporting.

In the Luxembourg legislation three levels are foreseen:

For activities above the exemption levels (the actual values of annex 1 of BSS Euratom) a prior licensing is required. This licensing permits authorities to:

- *keep records of all users and sources held in the country,*

- *to establish a system for the adequate control and inspection of sources and working conditions.*

For activities below the exemption but above exclusion level a prior written notification is required. Although these sources do not generally give rise to a radiation protection problem, this notification permits competent authorities a certain control of the stream of the disused sources.

Activities below the exclusion level are generally of no concern at all and do not need any kind of reporting.

We used this methodology because it fits more or less with our old radiation protection regulation, which turned out to be suitable.

6. Was EC guidance used in the derivation of clearance levels? Please indicate which guidance and for which materials and practices.

The clearance levels are those recommended by the German Commission on Radiological Protection: Clearance of Materials, Buildings and Sites with Negligible Radioactivity from Practices subject to Reporting or Authorisation.

The clearance levels apply in principle to all practices and work activities underlying licensing or notification. The EC scenarios for clearance apply to "work place scenarios" or "landfill scenarios" or are linked to the dismantling of nuclear installations. All these scenarios are, to our opinion, not suitable for the unconditional clearance of radioactive materials. For this reason Luxembourg applies the clearance levels recommended by the German Commission on Radiological Protection. The methodology and the dose criteria applied in the derivation of the clearance levels are described in the publication "Clearance of Materials, Buildings and Sites with Negligible Radioactivity from Practices subject to Reporting or Authorisation".

7. Please give specific situations, sources, waste streams to which exemption and clearance have been applied. Please list exempt practices. Have both general and specific clearance levels been applied in your country (i.e. after clearance, is material cleared for all uses or are restrictions imposed)? Please give examples.

As a non-nuclear country the number of users of radioactive materials is limited to:

- *conventional industries using sealed sources*

- *use of non-sealed sources in medicine and labs (research, biomedical..)*

- *use of smaller sources e.g. anti-static devices or other consumer goods, small calibration sources, sources used in school, etc..*

For industries using sealed sources problems with the exemption levels do not occur: all sealed sources used in industries exceed the exemption level and are not exempt from licensing. Luxembourg industries using sealed sources do not give rise to questions on clearance, except for short-lived radionuclides (Ir-192) and no problems actually arose from the dismantling of industrial facilities. Very high activity sealed sources, e.g. irradiators, are not in use in Luxembourg.

For unsealed sources in medicine and labs the decision on exemption is rather simple. Depending on the quantities used, they need either a license if they exceed the exemption levels or they are subject to prior notification if the activities used are below the exemption level. Exemption levels refer in this case to the total amount of activity present at the same time in the lab. The quantities used in medicine or labs always exceed the exclusion levels.

Clearance of materials from medicine or labs are under the responsibility of the users (see also point 4). There exists currently no code of practice for medicine and labs to evaluate the specific activity of materials to be cleared.

The dismantling of medical facilities or labs also is not likely to give rise to problems as they use either short-lived radionuclides (Tc-99m, I-131, Co-58, Tl-201, I-125,...) or low level activities (C-14, H-3...). Dismantling problems will certainly arise in the future, e.g. accelerator facilities in radiotherapy.

Less evident for exemption is the use of smaller sources e.g. anti-static devices or other consumer goods, small calibration sources, sources used in school, etc.. No sources of that kind are manufactured in Luxembourg. Because of the common market a systematic control of goods containing radioactive substances is rather difficult within the country because of the free movement of such goods within EU member states. Direct imports of such goods from third countries are difficult to control as the exemption (exclusion) levels in the producing countries may differ from those fixed in the national regulation. In practice, exemption levels or clearance levels are difficult to apply for those low-level activity sources if they are not produced within the own country. For that reason, but also for reason of justification, the use of some goods is prohibited in Luxembourg: ionisation chamber smoke detectors, thoriated incandescent gas mantles, irradiated gemstones, radioactive lightning preventors, toys and novelties containing radioactive substances.

Problems arise with radioactive sources or NORM contained in imported scrap materials. Industries importing and using scrap (steel- and aluminium industries) are not subject to licensing or notification, as their initial aim is not to use radioactive materials. These industries may identify in the imported scrap radioactive material and may not be able to identify the supplier of the scrap. From the legal point of view, exemption and clearance levels apply in principle to all practices and work activities underlying licensing or notification. The involuntary import of radioactive sources or NORM in scrap is not considered as a practice or work activity. However we generally apply clearance levels also in such cases.

For substances or contamination exceeding the unconditional clearance level, a conditional clearance is possible with a prior authorisation of the competent authorities on a case by case decision. In the last 20 years only one authorisation has been delivered by the competent authorities. This was the case for the dismantling of an industry processing natural ores with a high content of natural radioactivity. The dismantled facility as well as some tens of thousand of tons of slag resulting from the ore processing and largely exceeding the unconditional clearance levels were put in agreed special waste disposal.

From a legal point of view, no difference is made between practice and work activity.

8. Has clearance been a useful concept or have cleared materials still been rejected as radioactive? Please give details.

As mentioned at point 7, our experience in this field is rather limited. But since clearance levels have been introduced in our legislation a general tendency may be observed. Industries have problems to accept the concept of clearance for reuse or recycling. They:

are anxious to "contaminate" their own products, generally "free" of radioactivity with radioactive substances (mainly steel-and aluminium industries),

avoid to trigger any public discussion on that matter in relation with their company name,

avoid triggering any discussion with their personal, the unions or ecological organisations.

Luxembourg has no agreed installation for radioactive waste and no "disposers".

9. Please identify needs for improvement (legal, practical application, additional guidance) in this area

A code of practice to give guidance to determine or evaluate the specific activity of materials to be cleared resulting from the use of unsealed sources is needed in our country.

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.

Benchmark Example

In order to fairly and simply compare the approaches of different EU Member States it is our hope to analyse the responses Authorities would take to a sample situation. Thus could you consider the following and justify the appropriate proposed course of action:

- Operator of a nuclear installation in your country hopes to clear about 5,000 t steel in the course of decommissioning the site.

- Half the material has surface contamination while the other half is activated.

- The typical surface contamination and activity is given below:

Radionuclide	Surface Contamination (Bq/cm^2)
Cs-137	80
Ce-144	50
Sr-90	15

Surface contamination
Is the steel likely to be cleared? What conditions may be applied? Will it be: -

a. Given unconditional clearance?
b. Cleared for recycling?
c. Cleared for reuse?
d. Refused clearance, sent for disposal?
e. Refused clearance further decontamination required?
f. Other (please give details)

Radionuclide	*Specific Activity (Bq/g)*	*Total activity kBq*	*Clearance level, Bq/g*	*Contribution to weighted sum*
Co-60	*1*	*5,000,000*	*0,1*	*10*
Zn-65	*0.5*	*250,000*	*0,5*	*1*
Mn-54	*1.2*	*6,000,000*	*0,4*	*3*
Weighted sum				*14 (>1)*

Activated steel
Is the steel likely to be cleared? What conditions may be applied? Will it be: -

a. Given unconditional clearance?
b. Cleared for recycling?
c. Cleared for reuse?
d. Refused clearance, sent for disposal?
e. Refused clearance further decontamination required?
f. Other (please give details)?

Remark No 1: Luxembourg is not operating a nuclear installation, the example is hypothetical.

Remark No 2: The total weight of about 5,000 tons does not meet the requirements for an unconditional clearance (limited to 1000kg). Only a conditional clearance with prior authorisation of the competent authorities is possible.

Surface contamination

- *Unconditional clearance is not possible from a legal point of view,*
- *Recycling: we would not find a Luxembourg steel company accepting the recycling of those 5000 tons, so recycling can be excluded,*
- *Cleared for reuse: not possible as the contamination is exceeding the clearance level for contaminated materials,*
- *Refused clearance, sent for disposal: would be an option if further decontamination not possible,*
- *Refused clearance further decontamination required: is an option but depends on the costs of the decontamination.*

Activated steel

Is the steel likely to be cleared: no, see remark No 2

Given unconditional clearance?

- *Cleared for recycling: in theory an option but we would not find a Luxembourg company accepting the recycling of those 5000 tons, so in practice recycling within the country can be excluded,*
- *Cleared for reuse: could be in theory an option if the steel is reused in a specific context (e.g. nuclear industry). As Luxembourg has no nuclear industry, this option is hypothetical,*
- *Refused clearance, sent for disposal: would be an option to consider seriously.*
- *Refused clearance further decontamination required: how can you decontaminate activated steel?*
- *Other: looking for recycling or reuse in a neighbouring country.*

September 2002

NETHERLANDS (Nederland)

Provided by: Dr Ciska Zuur, Radiation Protection Expert and Co-ordinator of Models, NORMS and International Aspects with the Ministry of the Housing, Spatial planning and the Environment (VROM) in the Netherlands.

1. Title III, Article 3 paragraph 2 and Title III, Article 5 paragraph 2 of Council Directive 96/29/Euratom define what practices may be exempt and what materials may be cleared. Have these articles been implemented in your country?

   Title III implemented? ***Yes***

   Legislative document:

   Koninklijk Besluit van 16 juli 2001, houdende vaststelling van het Besluit stralingsbescherming, Staatsblad 2001, 397.

   Translated document title:

   Royal Decision of 16 July 2001 holding the establishment of the Radiation Protection Decree. Referred to as BS in this questionnaire.

   ***Definition of Exemption**, provided in par. 4.4 of Explanatory Notes:*
   A practice or work activity not subject to reporting or authorization but still subject to other obligations following from BS

   ***Definition of Clearance**, provided in par. 4.4 of Explanatory Notes*
   The disposal of material originating from a practice subject to reporting or authorization that is no longer regarded as subject to reporting or authorization. 'To dispose of' covers here reuse as well as discharge or disposal as non-radioactive waste.

   Is the definition of clearance only applicable to material from practices?
   The whole BS is written for practices, but almost all articles are declared to be applicable for work activities, including the articles about Exemption/Clearance.

   Exclusions from the scope of BS:

   a) The discharge or disposal of radioactive substances which do not fall under the prohibitions specified in Article 35, 37 and 108 of BS.

   b) The transport and the transfer radioactive substances into or out of the Dutch territory of radioactive substances.

   c) The transport of apparatus not being used during transport

   d) Practices involving an apparatus with a maximum potential difference of 5 kV.

   e) Exposure to radon and radon progeny originating from the undisturbed earth's crust or from building materials used in buildings.

f) Aboveground exposure to radionuclides in the undisturbed earth's crust or in building materials used in buildings.

g) Radiation from radionuclides naturally contained in the human body

h) Cosmic radiation prevailing at ground level

i) Cosmic radiation in air planes for members of the public and for workers not belonging to the aircrew.

j) Exposure to radon and progeny originating from the burning or blow-of of natural gas.

The exclusions d – h from the scope of BS cover the exclusions from the scope of the CD described in Title II, Article 2, par. 1(b) and Article 4.

Exemption b), c) and j) can be regarded as added exemptions.

The articles 35, 37 and 108 referred to in exemption a) pertain to:

***Article 35** Requirement for authorization for discharges into air, surface water and ground and cleared discharges from practices,*

***Article 37** Requirement for authorization to dispose of radioactive materials for product or material reuse or waste disposal and cleared disposals from practices,*

***Article 108** Requirement for authorization to discharge natural sources, or to undertake work activities that lead to such discharges, and cleared discharges of natural sources.*

Reporting practices with apparatus

The reporting requirement for practices with apparatus is laid down in Article 21, par. 1. Exemptions from reporting requirements are provided in par. 2 of Article 21.

Exempted apparatus are:

a) Apparatus that requires authorization

b) Cathode ray tubes used for display of visual images

c) Other apparatus than referred to under a) and b) with a maximum potential difference not exceeding 30 kV that under normal operating conditions does not cause a dose rate exceeding 1 μSv h^{-1} at 0.1 m of any accessible surface

d) Any other apparatus than referred to under a), b) or c) that under normal operating conditions does not cause a dose rate exceeding 1 μSv h^{-1} at 0.1 m of any accessible surface and is of a type that has been approved by Our Ministers on the basis of rules laid down in a Ministerial Regulation.

These exemptions cover the provisions of Title III, Article 3, par. 2, (d) and (e) of the CD.

Authorization of practices with apparatus

The authorization requirement for practices with apparatus is laid down in Article 23, par. 1. These practices cover the following apparatus specified in Article 23, par. 1:

a) For: industrial radiography, treatment of products, educational purposes and exposure of persons and animals for therapeutic purposes

b) Any other apparatus than referred to under a) with a maximum potential difference of 100 kV or more

c) Particle accelerators that can emit ionising radiation with an energy exceeding 1 MeV

Part 2 of Article requires prior authorization for research on and development of apparatus.

Exemptions from authorization requirements are provided in par. 3 of Article 23. These exemptions are:

a) Practices with electron microscopes

b) The storage of apparatus for the sole purpose of trade

e) Apparatus used for educational purposes that under normal operating conditions does not cause a dose rate exceeding 1 $\mu Sv\ h^{-1}$ at 0.1 m of any accessible surface and is of a type that has been approved by Our Ministers on the basis of rules laid down in a Ministerial Regulation.

The exemption provisions of Article 23 fall in the category of additional exemptions decided upon by Member States as defined in Article 4 par. 3 of Title III of the CD.

Authorization of practices involving radioactive substances

Practices requiring authorization

These practices are defined in Article 24 and Article 37 as far as they do not involve discharges.

***Article 24** defines the following practices as requiring authorization:*

a) The administration of radioactive substances to persons, and so far as radiation protection of human beings is concerned, to animals for the purpose of:

- *Medical or veterinary diagnosis*

- *Therapy or (bio)medical research*

b) Addition of radioactive substances to products intended for use on or in the immediate vicinity of human beings

c) To carry out practices with radioactive substances for:

- *Industrial radiography*
- *The treatment of products*
- *Educational purposes or scientific research.*

***Article 37** pertains to the disposal of radioactive substances for reuse or recycling or as radioactive waste. The paragraph 1 of article 37 read as follows:*

Article 37
1) Without prior authorization it is prohibited to dispose of radioactive substances for product or material reuse or as radioactive waste.

Exemptions from Article 24

The exemptions from the authorization requirements of practices involving radioactive substances are specified in Article 25. The paragraphs of Article 25 read as follows:

1) It is prohibited to carry out without prior authorization any other practice, *not being a discharge, than indicated in Article 24 (or 37) with a radioactive substance.*

2) The prohibitions, provided in par. 1 above and in par. 24 c) do not apply when within an establishment:

a) The activity of the radionuclides in the radioactive substance lower is than the value given in Annex 1, Table 1, or

b) The activity concentration of the substance lower is than the value given in Annex 1 Table 1.

3) When the radioactive substance contains a mixture of radionuclides, then the activity concentration of the radionuclides must be calculated as a weighted sum as indicated in Annex 3. The requirement of par. 2.b is fulfilled when the result of the summation is smaller than or equal to 1.

4) When within an establishment at any moment several practices are carried out then the activities of the radionuclides involved must be calculated as a weighted sum as indicated in Annex 3. The requirement of par. 2.a is fulfilled when the result of the summation is smaller than or equal to 1.

Par. 5 – 8 of Article 25 provide the Ministers with legal options to deviate from the provisions of the Article.

Exemptions from Article 37

Exemptions from the authorization requirement laid down in par. 1 of Article 37 are specified in par. 2 – 8 of Article 37.

Article 37
1) Without prior authorization it is prohibited to dispose of radioactive substances for product or material reuse or as radioactive waste.

2) Par. 1 does not apply when:

a) The total activity of the radioactive substances in a calendar year is lower than the value given in Annex 1, Table 1,

b) The activity concentration of the substance is lower than the value given in Annex 1, Table 1.

3) Par. 3 and 4 of Article 25 (summation rules) are equally applicable as are par. 6 and 7 of art 25.

4) The authorization requirement does not apply to encapsulated sources that are taken back by the producer or provider of the sources

5) Par. 1 does also not apply when radioactive substances are delivered by direct transfer to a third party for the purpose of:

a) use and product or material reuse of radioactive substances

b) collection of radioactive wastes

6) *Par 1 does not apply to the transfer of confiscated radioactive substances as referred to in article 33 par. 4* of the Nuclear Law *to an institution appointed by Our* Ministers. *Par. 1 does not apply to the disposal of radioactive wastes by transfer to the institution appointed by Our Ministers as collecting service for radioactive wastes.*

8) *Par. 1 does not apply to transfer to the institutions appointed by Our Ministers to receive radioactive wastes.*
9) Paragraph 4 up to 8 do only apply if the entrepreneur knows for sure that the receiver has a proper authorization for the practice or otherwise is allowed officially to receive the materials. ***[This is important in view of the forthcoming European Council Directive on High Activity Sealed radioactive Sources (HASS)]***

Conclusion: art 24 and 37 are in line with the requirements of the BSS

Annex 1 of BS

The exemption provisions specified in Article 25 and 37 of BS refer to Annex 1 of BS. With respect the to numerical values in Table 1 this annex is largely identical to Annex 1, Table A of the CD. However, there are principle differences pointed out below.

1) The numerical values in BS apply to both exemption and clearance.

2) They apply to artificial and natural sources, thus to practices and work activities.

3) Numerical concentration values are different from the CD for three naturally occurring radionuclides:

a) Ra-226: 1 kBq/kg in BS and 10 kBq/kg in CD

b) Ra-228: 1 kBq/kg in BS and 10 kBq/kg in CD

c) Pb-210+ and Po-210: 100 kBq/kg in BS and 10 kBq/kg in CD

In addition, the exemption/clearance level for Co-60 is set at 1 Bq/g in BS and is 10 Bq/g in CD.

4) Practices with radioactive substances exceeding the levels specified in Annex 1 Table 1 in principle will require prior authorization (as in CD) but work activities will require reporting.

5) If the weighted sum of the activity concentrations within a work activity is equal to or higher than 10 and the weighted sum of the total activity within a work activity is equal to or higher than 1, that work activity will require authorization.

The summation rules to be applied in calculating weighted total activities and total activity concentrations are provided in Annex 3 of BS. For natural radionuclides Our Ministers have decided that the following radionuclides can be omitted from the summation and, accordingly, from analysis: Th-234, U-234, U-235, Ra-223, Ra-224, Th-227 and Pa-231.

<u>Explanation</u>

Because of the usually fixed relation in raw materials of the activities or activity concentrations between the radionuclides within the decay chain of U-238 and between the decay chains of U-238 and U-235 respectively it is not meaningful to include the radionuclides mentioned above in the analysis and summation requirements. For example, Th-234 is short lived and attains radioactive equilibrium with U-238 in a rather short time regardless of the initial activity ratio between the two radionuclides. So it can be neglected. U-234 occurs in a fixed activity ratio with U-238 of about 1 in almost all cases except depleted or enriched uranium. So it can be regarded as included in the levels set for U-238+ and it is already included in U-238sec. The radionuclides of the decay chain of U-235 occur in natural raw materials at a level of a factor of about 20 lower than the U-238 chain nuclides. Ra-224 and Ra-227 have short half-lives and their exemption levels are higher than

for Ra-226 + from the U-238 decay chain. The exemption level for Th-227 is higher than for Th-230 included in U-238sec. so it can also been neglected. Finally, strong and specific enrichment of Pa-231 in products or residues from work activities is unlikely to be a phenomenon of radiological and regulatory concern.

Authorization of discharges from practices and exemptions
Authorization requirements for disposal of radioactive substances by discharges and conditions for exemption from this requirement are laid down in Article 35. The paragraphs of this article read as follows.

Article 35
1) Without prior authorization it is prohibited to dispose of radioactive substances into the air, a public sewer or in surface water.

2) These discharges are exempted from the authorization requirement when:

a) For discharges in the air the total activity discharged within one calendar year at the point of discharge is less than one radiotoxicity equivalent for inhalation as specified in Annex 2,

b) For discharge into a public sewer the total activity discharged within one calendar year at the point of discharge is less than 10 radiotoxicity equivalents for ingestion as specified in Annex 2,

c) For discharges into surface water the total activity leaving the premises at a point of discharge in one calendar year is less than 0.1 radiotoxicity equivalents for ingestion as specified in Annex 2.

3) Without prior authorization it is prohibited to dispose of radioactive substances by discharge into the ground.

4) Discharges into the ground are exempted from authorization requirement of par. 3 when the total activity discharged within one calendar year at the point of discharge is less than 10^{-6} radiotoxicity equivalents for ingestion as specified in Annex 2,

5) Discharges of produced water from mining operations are exempted from the authorization requirement of par. 3 when the discharge involves re-injection into a geological formation comparable to and at the same depth as the formation from which the produced water originated and is carried out under such conditions that the produced water does not enter other aquifers.

6) The discharged activities, expressed in radiotoxicity equivalents, are corrected for physical half-life by means of correction factors as specified in Annex 2.

Annex 2 defines the radiotoxicity equivalent (Re) for inhalation or ingestion as the inverse effective dose coefficient for the age of > 17 years for inhalation and ingestion respectively. The Re's are corrected with correction factors (CR) for physical half-life. These factors are multiplication factors to be applied to the Re's in case of discharge into the air, public sewer or surface water:

Half life	*Discharge into the air, CR_a*	*Discharge into surface water and sewer, CR_w*
≤ 5 days	*1*	*0.001*
5 days< $T_{1/2}$ ≤ 7.5 days	*1*	*0.01*
7.5 days< $T_{1/2}$ ≤ 15 days	*1*	*0.1*
15 days< $T_{1/2}$ ≤ 25 years	*1*	*1*
25 years< $T_{1/2}$ ≤ 250 years	*10*	*10*
250 years < $T_{1/2}$	*100*	*100*

The effective dose coefficients to be used are listed in Table 4.1 and Table 4.2 of Annex 4 of BS. They are identical to the dose coefficients listed in Table A and B of Annex III of the CD.

Identification of work activities

In Article 102 of BS, the Ministers are obliged to announce a list of identified work activities in the Staatscourant. This list is already ready and will be published in very short time (before the end of 2002).

Reporting of work activities and exemptions

Reporting requirements for work activities not being discharges are dealt with in Article 103 of BS. This article reads as follows:

1) Prior to the start of a work activity, not being a discharge, the employer (entrepreneur) must report the work activity in accordance with Article 40.

2) Par. 1 does not apply when within the establishment

a) it involves a work activity in which:

i) the activity of the radionuclides in the natural sources involved is at any time *lower is than the values provided in Annex 1, Table 1 of BS, or*

ii) the activity concentration of the radionuclides in the natural sources involved lower is than the values provided in Annex 1, Table 1 of BS

b) for which on the basis of Article 107 authorization is required.

3) Article 25, par. 3 and 4 (summation rules) as well as par. 6, 7 and 8 apply equally.

4) By Ministerial regulation it can be ruled that in view of radiation protection par. 2 of Article 103 does not apply.

Article 105 specifies what should be reported and states in par. 2 that specific rules regarding reporting of work activities can be laid down in Ministerial regulations.

Authorization requirements for work activities and exemptions

The requirement for authorization of work activities, not being discharges, and exemption conditions are laid down in Article 107 of BS. This article reads as follows.

1) It is prohibited to carry out a work activity, not being a discharge, without authorization.

2) Art 1 does not apply within an establishment when:

a) The activity of the radionuclides in the natural sources involved in the work activity lower is than the values provided in Annex 1, Table 1 of BS, or

b) The activity concentration of the natural sources involved in the work activity are lower than 10 times the values provided in Annex 1, Table 1 of BS.

3) Article 25, par. 3 and 4 (summation rules) as well as par. 6, 7 and 8 apply equally.

4) By Ministerial regulation it can be ruled that in view of radiation protection par. 2 of Article 107 does not apply.

Authorization requirements and exemptions for discharge of natural sources

The requirement for authorization of discharges of natural sources and exemption conditions are laid down in Article 108 of BS. This article reads as follows.

1) Without authorization it is prohibited to discharge natural sources or to carry out a practice involving the discharge of natural sources.

2) Par. 1 does not apply when the activity to be discharged from the premises in a calendar year lower is than the values provided in Annex 1, Table 2 of BS.

3) Article 25, par. 3 and 4 (summation rules) as well as par. 6, 7 and 8 apply equally.
4) By Ministerial regulation it can be ruled that in view of radiation protection par. 2 of Article 108 does not apply.

The content of Table 2 of Annex 1 of BS is reproduced below.

Clearance levels for annual discharges in water and air of radionuclides from work activities

Radionuclide	*Liquid discharge GBq/a*	*Aerial discharge GBq/a*
Pb-210	*10*	*10*
Po-210	*10*	*10*
Rn-222	*---*	*10000*
Ra-223	*1000*	*---*

Ra-224	*1000*	*---*
Ra-226	*10*	*10*
Ra-228	*100*	*10*
Ac-227	*100*	*1*
Th-227	*1000*	*---*
Th-228	*1000*	*1*
Th-230	*100*	*1*
Th-232	*100*	*1*
Th-234	*10000*	*---*
Pa-231	*10000*	*0.1*
U-234	*1000*	*10*
U-235	*1000*	*10*
U-238	*1000*	*10*

These clearance levels pertain to total activities per installation *discharged annually into sewers and various types of receiving surface water and into air. They were derived on the basis of a reference dose level of 10 μSv/a and with respect to liquid discharges, on dose assessments for discharges into a large river, lake, sewer, estuary or sea. Cleared levels for aerial discharge were based on a source with moderate effective stack height.*

2. Which organisation(s) is responsible for issuing regulatory documentation, including exemption and clearance levels and overseeing the practical application of the concepts?

The establishment of the regulatory system laid down in the Radiation Protection Decree (BS) is the joint responsibility of several ministers indicated as "Our Ministers". They comprise:

1) State Secretary of the Ministry of Social Affairs and Employment (principle establisher of the regulations) also on behalf of:

2) The Minister of Housing, Spatial Planning and the Environment

If appropriate in consent with:

The Minister of Public Health, Welfare and Sport (for matters dealing with public health) or The Minister of Economic Affairs.

In Chapter 6 (medical exposures) 'Our Minister' means The Minister of Public Health, Welfare and Sport.

The policy departments of the ministries of these Ministers are responsible for the issuing of the regulatory documentation each on their own territory or combined. The same counts for overseeing the practical applications.

Control or enforcement of the practical implications is the primary responsibility of the:

- *Inspectorate for the Environment of the Ministry of Housing, Spatial Planning and the Environment,*

- *State Inspectorate of Mining of the Ministry of Economic Affairs,*

- *Labour Inspectorate of the Ministry of Social Affairs and Employment.*

3. What guidance has been issued to ensure compliance with statutory provisions e.g. approved codes of practice?

Guidance as referred to in this question is provided by:

1) The articles of BS.

2) General explanatory notes and specific notes with each article.

3) Ministerial regulations on specific topics, some of them are still being developed. These regulations give more detailed requirements and extensive explanations.

4) General information to all the licensees and to the public is given in 2002.

Examples of topics dealt with in Ministerial regulations are Assessment methods of the consequences of ionising radiation in the environment (MR AGIS, April 2002), Specification of reporting requirements for work activities, Criteria for exemption and clearance of objects contaminated on the surface with NORM. A ministerial regulation containing two lists of justified and non-justified practices or work activities will be published early October. In the list of non-justified practices the practices mentioned in Article 6, par. 5 of CD 96/29 are included and thereby forbidden.

MR Consumer goods is published

MR Alarm signals (of zoiets) also

4. Please describe the processes of exemption and clearance for nuclear installations and other practices i.e. hospitals, research establishments etc.

See information provided in answers to question 1.

Special attention needs to be given to the fact that for all practices and work activities, both for clearance and exemption, for on-site and off-site the same levels are used (given in Annex I, BS)

5. Was Annex 1 (of BSS Euratom) used for defining exemption levels? If not, what are these other levels. Please describe the reasoning/methodology in their derivation.

As explained in answers to question 1 the principles of Annex 1 and Table A of the CD have been used to set the exemption (and clearance) *levels of Annex 1, Table 1 of BS. For some radionuclides the levels set in BS are different from the CD, Ra-226, Ra-228 and Co-60 have been set at a ten times lower concentration level and Pb-210*

and Po-210 at a ten times higher level. These deviations from the CD are motivated in explanatory note 3 to Table 1 of Annex 1 of BS. These arguments can be summarised as follows.

- *Co-60 is being encountered as activation product in steel scrap from the dismantling of nuclear installations. Because of the relatively high energy of the gamma radiation emitted by Co-60 a clearance level that would allow recycling into consumer goods, like cars, is to high.*

- *Ra-226 and Ra-228 occur in many residues from work activities. Their decay products emit gammas with high energies. Reuse and disposal as waste of such materials could give rise to unacceptably high exposures to external radiation of workers and members of the public.*

- *Pb-210 and Po-210 occur in particular in residues from the process industry. Do not contribute significantly to radiation exposure in scenarios dominated by exposures to external radiation from waste dumping grounds. An exemption level of 10 Bq/g as in the CD would impose unnecessarily strict conditions on the process industry.*

The arguments reproduced above for the different exemption for Ra-226, Ra-228, Pb-210 and Po-210 are directly related to the fact that in BS Annex 1, Table 1 pertains to practices as well as work activities.

6. Was EC guidance used in the derivation of clearance levels? Please indicate which guidance and for which materials and practices.

No, for the assessment of the clearance levels for natural sources different scenario's were used. These scenario's were based on the scenario's as used for calculating the Exemption Levels by the Cie – EU as the points in Annex 1 BSS asks for.

7. Please give specific situations, sources, waste streams to which exemption and clearance have been applied. Please list exempt practices. Have both general and specific clearance levels been applied in your country (i.e. after clearance, is material cleared for all uses or are restrictions imposed)? Please give examples.

Exemptions and Clearance applies in principle to all situations, sources and waste streams. Only the situations specified in answer 1 are excluded from the BS and so from exemption and clearance.

If a material is really cleared, this counts for all uses. However, we have an escape specially for reuse or recycling: if it happens to be that a certain– specially – work activity give a too high dose (> 1 mSv ambient dose) Ministries can require special care or apply extra requirements. E.g. natural sources used as building material in roads, parking places or dikes. An extra top layer could be requested.

8. Has clearance been a useful concept or have cleared materials still been rejected as radioactive? Please give details.

We don't know yet. To avoid problems (we hope) we mentioned specifically in the BS that waste containing radionuclides below the clearance levels, is not supposed to be 'radioactive waste' anymore but just 'waste' (Article 38, para 2).

9. Please identify needs for improvement (legal, practical application, additional guidance) in this area

We don't know yet, we have to evaluate the system set up in a few years.
In the past the clearance (also called then exemption) never gave problems. The values were also then the same as for exemption (500 Bq/g and 100 Bq/g for activity concentration and the toxicity classes for activity).

Benchmark Example:

In order to fairly and simply compare the approaches of different EU Member States it is our hope to analyse the responses Authorities would take to a sample situation. Thus could you consider the following and justify the appropriate proposed course of action:

- Operator of a nuclear installation in your country hopes to clear about 5,000 t steel in the course of decommissioning the site.

- Half the material has surface contamination while the other half is activated.

- The typical surface contamination and activity is given below:

Radionuclide	Surface Contamination (Bq/cm^2)
Cs-137	80
Ce-144	50
Sr-90	15

Answer: *no generic clearance levels based on surface contamination with artificial radionuclides have been included in BS yet or in previous legislation. A Ministerial Regulation (NARS) will set a level of 1 Bq/cm^2 for natural sources in due time.*
On the basis of experience with operational experience with clearance of contaminated scrap at a level of 4 Bq/cm^2 beta emitters the answers would be as follows:

Surface contamination

Is the steel likely to be cleared? What conditions may be applied? Will it be: -

a. Given unconditional clearance? *No*
b. Cleared for recycling? *No*
c. Cleared for reuse? *No*
d. Refused clearance, sent for disposal? *Yes, if decontamination is proven to be practically impossible*
e. Refused clearance further decontamination required? *Yes*
f. Other (please give details)

Radionuclide	Specific Activity (Bq/g)	Total activity kBq	Relevant exemption level, Bq/g	Contribution to weighted sum
Co-60	1	5,000,000	1	1
Zn-65	0.5	250,000	10	0.05
Mn-54	1.2	6,000,000	10	0.12
Weighted sum				1.17 (>1)

Activated steel

Is the steel likely to be cleared? What conditions may be applied? Will it be: -

a. Given unconditional clearance? *No*
b. Cleared for recycling? *Could be. For the purpose of recycling mixing with other – clean – materials are allowed. Moreover the normal recycling process should result in a product with a dose of < 10 μSv in a year for members of the public or workers.*
c. Cleared for reuse? *Not likely*
d. Refused clearance, sent for disposal? *Yes, national radioactive waste depository*
e. Refused clearance further decontamination required? *Not applicable*
f. Other (please give details)?

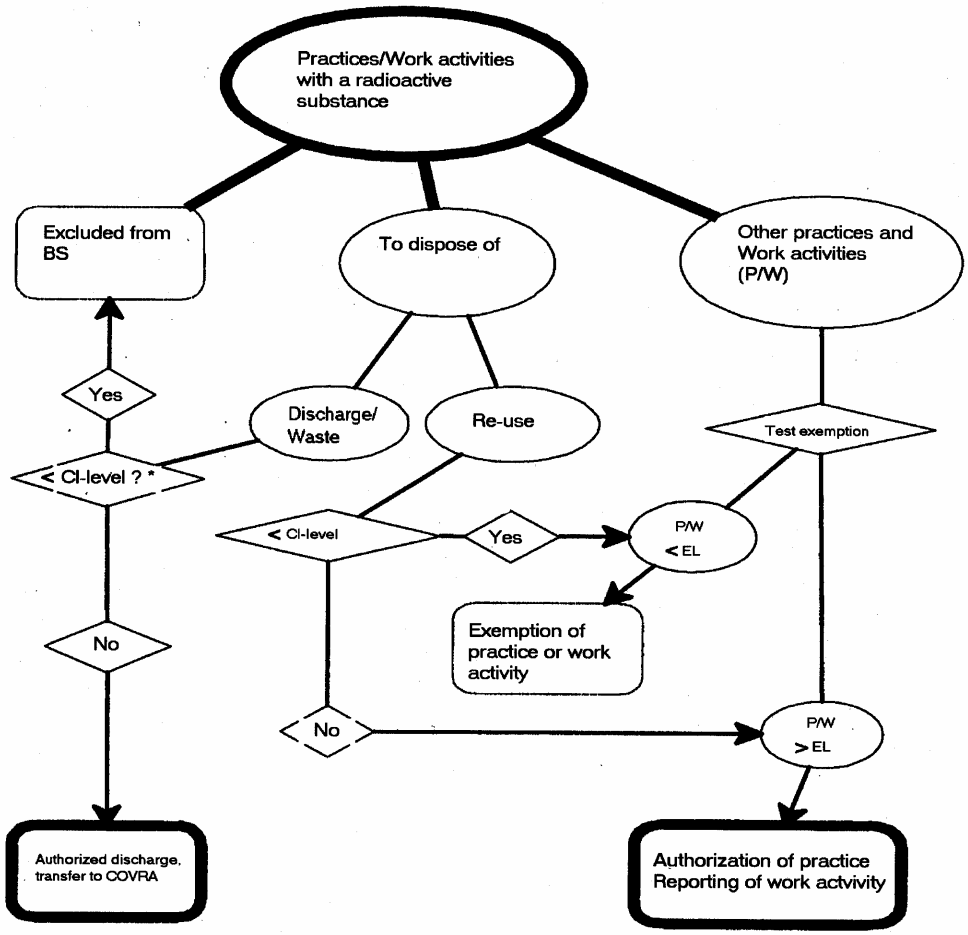
NB: the Dutch steel industry doesn't accept (yet) steel contaminated with radionuclides even not below the EL/CL

September 2002

Overview of reporting, authorization exemption and clearance in the Dutch regulatory system.

The figure below, adapted from BS Figure 1 explains the decision-making system with respect to reporting the requirements for an authorization for radioactive substances and natural sources.

BS system for establishing authorization and reporting requirements for radioactive substances and natural sources



* The clearance levels for waste are equal to exemption and clearance levels for re-use; other clearance levels are established for discharges

AUSTRIA (Österreich)

Provided by: Mr Johann-Klaus Hohenberg, Head of Division V/7, Radiation Protection, Federal Ministry for Agriculture, Forestry, Environment and Water Management (BMLFUW).

1. Title III, Article 3 paragraph 2 and Title III, Article 5 paragraph 2 of Council Directive 96/29/Euratom define what practices may be exempt and what materials may be cleared. Have these articles been implemented in your country?

   These two articles have been implemented into the draft of the Radiation Protection Law. The limits will have to be set in the Radiation Protection Ordinance. There is no doubt, that the exemption levels given in Annex I of the Directive will be implemented into the Ordinance. However the limits for clearance still have to be considered carefully. Unfortunately "Radiation Protection 122: Practical Use of the Concepts of Clearance and Exemption – Part II, Application of the Concepts of Exemption and Clearance to Natural Radiation Sources" has become available only recently. The recommendations contained in RP 122 will have to be considered carefully, but it has not yet been decided whether to follow them in every respect.

2. Which organisation(s) is responsible for issuing regulatory documentation, including exemption and clearance levels and overseeing the practical application of the concepts?

   The Federal Ministry for Agriculture, Forestry, Environment and Water Management.

3. What guidance has been issued to ensure compliance with statutory provisions e.g. approved codes of practice?

   Usually no official Guidance Documents are issued by authorities in Austria. Very often Austrian Standards, which are recommendations only provide guidance and are applied in practice. Since the Ordinance has not yet been finished there have not been any attempts until now, to work on Standards for exemption and clearance processes.

4. Please describe the processes of exemption and clearance for nuclear installations and other practices i.e. hospitals, research establishments etc.

   Until the new legislation will come into force each nuclear installation, hospital or research establishment has an individual permit, defining exemption and clearance.

5. Was Annex 1 (of BSS Euratom) used for defining exemption levels? If not, what are these other levels. Please describe the reasoning/methodology in their derivation.

   Exemption levels will be defined in the Ordinance. As mentioned above, it is very likely that the limits will be those of Annex I of the Directive. The levels in Annex 1 are in most cases (almost) identical with the ones from the old Austrian Ordinance.

6. Was EC guidance used in the derivation of clearance levels? Please indicate which guidance and for which materials and practices.

   See #1.

7. Please give specific situations, sources, waste streams to which exemption and clearance have been applied. Please list exempt practices. Have both general and specific clearance levels been applied in your country (i.e. after clearance, is material cleared for all uses or are restrictions imposed)? Please give examples.

   Exemption criteria are always applied – until now, using the exemption values from the old Ordinance. Clearance has been applied, but exclusively on an individual case by case basis for clearance of for instance waste after decay of short-lived radionuclides from hospitals and research establishments. The individual clearance levels are prescribed by the authorities. No clearance with respect to NORM is known.

8. Has clearance been a useful concept or have cleared materials still been rejected as radioactive? Please give details.

   In the above mentioned cases it was and is useful. No rejection occurred.

9. Please identify needs for improvement (legal, practical application, additional guidance) in this area.

   Since no levels have been set yet, no needs for improvement can be identified.

Benchmark Example:

In order to fairly and simply compare the approaches of different EU Member States it is our hope to analyse the responses Authorities would take to a sample situation. Thus could you consider the following and justify the appropriate proposed course of action:

- Operator of a nuclear installation in your country hopes to clear about 5,000 t steel in the course of decommissioning the site.

- Half the material has surface contamination while the other half is activated.

- The typical surface contamination and activity is given below:

Radionuclide	Surface Contamination (Bq/cm^2)
Cs-137	80
Ce-144	50
Sr-90	15

Radionuclide	Specific Activity (Bq/g)
Co-60	1
Zn-65	0.5
Mn-54	1.2

Is the steel likely to be cleared? What conditions may be applied?

Austria has no nuclear power plant. Furthermore no clearance limits are implemented yet. So even for similar contamination cases, not involving a nuclear power plant, no answer can be given.

May 2002

Further Developments:

The Radiation Protection Act (146 Strahlenschutz-EU-Anpassungsgesetz 2002) comes into force on the 1st January 2003. The Radiation Protection Ordinance is in its last development stage and it is hoped that it will also come into force in January or February 2003.

November 2002

PORTUGAL

Provided by: Dr Fernando P Carvalho, Article 31 Expert, (in a personal capacity), Department of Radiological Protection and Nuclear Safety (DPRSN)

Approaches were made on several occasions to the General Directorate for Health which is the public service with responsibility for preparing legislation to transpose the Directive into national legislation however no response was elicited.

1. Title III, Article 3 paragraph 2 and Title III, Article 5 paragraph 2 of Council Directive 96/29/Euratom define what practices may be exempt and what materials may be cleared. Have these articles been implemented in your country?

   No practices have been declared exempt and no materials have been given clearance. The Articles mentioned have not been implemented as yet.

2. Which organisation(s) is responsible for issuing regulatory documentation, including exemption and clearance levels and overseeing the practical application of the concepts?

   Organisation(s) with such a task are not properly identified. However, it may be considered part of the competencies of the Directorate General of Health (DGS), Ministry of Health. So far no action has been taken by this body on these issues.

3. What guidance has been issued to ensure compliance with statutory provisions e.g. approved codes of practice?

   I am not aware of any guidance issued for such purpose in Portugal.

4. Please describe the processes of exemption and clearance for nuclear installations and other practices i.e. hospitals, research establishments etc.

   Processes of exemption and clearance for nuclear installations and other practices are not established as yet.

5. Was Annex 1 (of BSS Euratom) used for defining exemption levels? If not, what are these other levels. Please describe the reasoning/methodology in their derivation.

   See Qu 1.

6. Was EC guidance used in the derivation of clearance levels? Please indicate which guidance and for which materials and practices.

   See Qu 1.

7. Please give specific situations, sources, waste streams to which exemption and clearance have been applied. Please list exempt practices. Have both general and specific clearance levels been applied in your country (i.e. after clearance, is material cleared for all uses or are restrictions imposed)? Please give examples.

   See Qu 1.

8. Has clearance been a useful concept or have cleared materials still been rejected as radioactive?

   See Qu 1.

9. Please identify needs for improvement (legal, practical application, additional guidance) in this area

   There is a need to improve the national legislation, as recognised, for example, in the Decree-Law 311/98

Benchmark Example:

In order to fairly and simply compare the approaches of different EU Member States it is our hope to analyse the responses Authorities would take to a sample situation. Thus could you consider the following and justify the appropriate proposed course of action:

- Operator of a nuclear installation in your country hopes to clear about 5,000 t steel in the course of decommissioning the site.

- Half the material has surface contamination while the other half is activated.

- The typical surface contamination and activity is given below:

Radionuclide	Surface Contamination (Bq/cm^2)
Cs-137	80
Ce-144	50
Sr-90	15

Radionuclide	Specific Activity (Bq/g)
Co-60	1
Zn-65	0.5
Mn-54	1.2

Is the steel likely to be cleared? What conditions may be applied?

See Qu 1.

May 2002

FINLAND (Suomi)

Provided by: Mika Markkanen**,** Department of Radiation Safety, Radiation and Nuclear Safety Authority (STUK)

1. Title III, Article 3 paragraph 2 and Title III, Article 5 paragraph 2 of Council Directive 96/29/Euratom define what practices may be exempt and what materials may be cleared. Have these articles been implemented in your country?

   The primary legislation in Finland is the nuclear law (990/87) and the nuclear decree (161/88). These are detailed and define fundamental issues relating to licensing and safety. The Decision of the Council of State (VNP 395/91) gives secondary regulatory requirements. Furthermore YVL-guides form the actual regulatory system, although they in principle are on a lower level than the decisions of STUK. [Wahlström et al, 2001]

   The nuclear law and decree apply to the construction and operation of nuclear facilities and define the principles for possession, use and transport of nuclear materials. [Wahlström et al, 2001]

   The Radiation Act (592/1991) and the Radiation Decree (1512/1991) apply to applications in which radiation or nuclear reactions are not used as a source of energy. [Wahlström et al, 2001]

   Yes. Radiation Act (592/1991)

   <u>Exemption</u>

   The primary means of controlling the use of radiation is the safety licence procedure. In section 17 of the Act certain practices are exempt from the licence. In addition STUK may (on the basis of the same legal clause) exempt other practices if it is possible to ascertain with sufficient certainty that the use of the radiation will not cause damage or danger to health. In connection with the exemption from the safety licence, it may be ruled that the use of the radiation in question be subject to a reporting obligation.

   Section 17 (of Radiation Act)

   *According to Section 16 the use of radiation is subject to licence unless otherwise stipulated. Section 17 outlines those activities which are licence-free operations (i.e. are **exempt practices**). No safety licence is required for:*

   1. *the use of non-ionising radiation,*
   2. *the use of a radiation appliance used as a consumer product*
   3. *the use of a radiation appliance that has been exempted from safety licensing owing to its safety properties,*

4. *the use of a radiation source requiring no special supervision in order to ensure radiation safety, because the radiation exposure caused thereby is so minor.*

5. *the manufacture of or trade in radiation appliances producing radiation electrically and used as consumer products, and for any operations pertaining to the said manufacture or trade.*

6. *the export of radiation sources not containing radioactive material, and*

7. *the transport of radioactive materials.*

In addition to points 3 and 4 STUK may exempt other uses of radiation if it can be shown with sufficient confidence that the use will cause no detriment or danger to health. Licence-free use of radiation can be made notifiable to STUK by order.

Further requirements and instructions concerning exemption are given in Guide ST 1.5 issued by STUK under Section 70, paragraph 2 of the Radiation Act (592/1991). The Guide presents exemption criteria and values in accordance with the Annex I of the BSS. The Guide is available in English at: http://www.stuk.fi/saannosto/ST1-5e.html

The Guide ST 5.4 dealing with Trade in Radiation Sources lists the following practices exempted from safety licence by STUK in accordance with Section 17 of the Radiation Act:

- Trade in radioactive substances and equipment containing such substances, whose imported, exported or momentary activity does not exceed the exemption limit laid down in ST Guide 1.5, or whose activity concentration does not exceed the exemption limit[*)].

- Trade in watches, clocks, compasses and similar products, provided the tritium (^{3}H) activity is below 400 MBq or the promethium (^{147}Pm) activity is below 8 MBq.

- Trade in compasses and similar products containing gaseous tritium light ampoules if the activity of the tritium is below 10 GBq.

- Trade in navigation equipment and instrument panels used in waterborne transport, aviation or the like, provided the said equipment or panels are ready-installed in the vessels or aircraft, and provided their radiation source is luminous paint containing tritium (^{3}H) or promethium (^{147}Pm), or gaseous tritium light ampoules.

- Trade in X-ray equipment not involving installation, maintenance, repair or test running.

- Trade in cathode-ray tubes which meets the requirements laid down in the IEC 65 Standard (1985) or similar radiation safety requirements.

Trade in other equipment that produces radiation by electricity whose operating voltage does not exceed 30 kV and which, under normal operating conditions, does not cause a dose rate higher than 10 μSv/h at any point at a distance of 10 cm from the accessible surfaces of the equipment.

**)* *The exemption limits shall not be applied to the trade in radioactive pharmaceuticals or to the import or export of consumer goods containing radioactive material. For these operations, irrespective of the activity involved, a safety license is required unless separately exempted from a safety license by a decision of STUK.*

Smoke detectors are classified as consumer goods and therefore their use, possession and resale are exempted from safety licenses. However, a safety license is required for their import, export and wholesale trade. Smoke detectors based on ionisation shall be approved by STUK, and shall be furnished with radiation safety signs (Ministry of the Interior Order SM-1999-00256/Tu-33). If a ^{241}Am radiation source is used in the smoke detectors, its activity shall not exceed 40 kBq.

The Guide ST 5.4 is available at the moment only in Finnish (http://www.stuk.fi/saannosto/ST5-4.html)

Use of nuclear energy exempted from a licence

Exemption of the use of nuclear energy is prescribed in Nuclear Energy Decree, Chapter III (Sections 11 - 22). The Decree is available in English at: http://www.stuk.fi/saannosto/19880161e.html

Clearance

1. Non-nuclear radioactive waste

According to section 24 of the Radiation Decree (1512/1991), the STUK shall lay down the principles and limits applying to concentration and activity needed for determining whether a given waste shall be defined as a radioactive waste or not. Section 23 of the Decree authorizes the STUK to issue limits for quantities of radioactive substances discharged into the air, sewage system or otherwise into the environment.

Guide ST 1.5 states that:

"Exemption values will not apply in the case of the final disposal, recycling or reuse of radioactive materials that originate from activity subject to a reporting obligation or the safety licence procedure. These activities must have the approval of STUK, by means of which the substances or materials in question will be exempted from the requirements of the radiation legislation. In this case the basic criteria presented in Appendix C (= the criteria established in Annex I of the BSS) must be met, and the activity concentrations of the materials to be exempted (= should read "cleared", the use of "exempted" in this context is a mistake in translation) must not exceed the guide values set out in the technical instructions issued by the European Community (clearance levels). These guide values can be significantly lower than the exemption values for the safety licence and reporting obligation set out in Appendix A of the

BSS. Exemption values will not, furthermore, apply when the exploitation of materials containing natural radionuclides is in question. "

Guide ST 1.5 is available in English at: http://www.stuk.fi/saannosto/st6_2e.pdf

2. Radioactive waste arising from the use of nuclear energy

The general requirements of Nuclear Energy Decree (161/1988), Section 10, are also applicable to clearance of waste arising from the use of nuclear energy. The Decree is available in English at: http://www.stuk.fi/saannosto/19880161e.html

Thus clearance of wastes from regulatory control is prescribed in Section 10 of the Nuclear Energy Decree and in Guide YVL 8.2 Exemption from Regulatory Control of Nuclear Wastes.

Clearance can be conditional or unconditional.

***Unconditional clearance** is applicable to waste that, due to its low activity, shall not be regarded as nuclear waste as referred to in Section 3 of the Nuclear Energy Act. Fixed activity constraints for the waste are applied and the disposal or recycling method is not defined.*

*In the case of **conditional clearance**, the transferee and the disposal or recycling method for the waste is defined and activity constraints set on a case-by-case basis. By virtue of Section 10 of the Nuclear Energy Decree, the provisions of the Nuclear Energy Act are not applicable to the cleared waste.*

Section 10 (of the Nuclear Energy Decree)

The provisions of the Nuclear Energy Act are not applied to the possession, re-transfer, handling, use, storage or transport of nuclear waste which has been transferred by virtue of a transfer licence, if:

1. Average specific activity of the waste is less than 10 kBq/kg

2. The total activity in possession of the transferee is less than 1 GBq and the alpha activity less than 10 MBq

3. It is estimated that the annual effective dose caused by the transferred nuclear waste to any individual cannot exceed 0.01 mSv; and

4. The radiation exposure caused by the transferred waste is also otherwise as low as reasonably achievable.

Section 10a

The provisions of the Nuclear Energy Act are not applied to the possession, transfer, handling, use, storage or transport, export and import of special fissile material if: The material is part of an instrument for medical purposes and has been placed inside the human body.

Section 10b

The provisions of the Nuclear Energy Act are not applied to the possession, re-transfer, handling, use, storage or transport, export and import of a source material if:

1. Material is part of fabricated device, component or utility article.

2. The amount of source material inside the product is less than 4 g; and

3. The material is not subject to any particular safeguards obligation.

Detailed instructions are given in Guide YVL 8.2 (at the moment available only in Finnish, see http://www.stuk.fi/saannosto/YVL8-2.html). The general clearance levels (destination of the waste not defined) established in the Guide are:

Nuclide	***Activity concentration***	***Surface contamination***
Alpha emitters	*0,1 Bq/g*	*0,4 Bq/cm²*
Significant gamma and beta emitters[a]	*1 Bq/g*	*4 Bq/cm²*
Weak gamma and beta emitters[b]	*10 Bq/g*	*40 Bq/cm²*

a For example ^{54}Mn, ^{58}Co, ^{60}Co, ^{65}Zn, ^{106}Ru, ^{110m}Ag, ^{124}Sb, ^{125}Sb, ^{134}Cs, ^{137}Cs, ^{144}Ce, ^{90}Sr other nuclides emitting corresponding gamma or beta radiation.
b For example ^{3}H, ^{14}C, ^{51}Cr, ^{55}Fe, ^{63}Ni and other nuclides emitting corresponding gamma or beta radiation.

The values are applicable for waste streams of 100 ton/year for one installation, at the maximum. In case where several radionuclides are present, the following rule is applied:

$$\sum_{i=1}^{n} \frac{a_i}{a_{vi}} \leq 1$$

where a_i is the activity concentration or surface contamination of nuclide i (Bq/g or Bq/cm²)
a_{vi} is the general clearance level for nuclide i(Bq/g tai Bq/cm²)

STUK may also issue specific clearance levels (destination of the waste specified) for an individual lot of waste or a specified continuous waste stream. However, specific clearance levels may not exceed the values given in the Nuclear Energy Degree, Section 10.

2. Which organisation(s) is responsible for issuing regulatory documentation, including exemption and clearance levels and overseeing the practical application of the concepts?

The Radiation and Nuclear Safety Authority (STUK) which is an independent government organisation for the regulatory control of radiation and nuclear safety. STUK's role includes:

- *issuing regulations and proposals for general requirements concerning radiation and nuclear safety*

- *controlling the fulfilment of licence conditions and setting detailed requirements concerning plant operation as referred to in the plant licence.*

- *regulatory control of the use of radiation and other radiation practices.*

- *regulatory control of safety of the use of nuclear energy, emergency preparedness, physical security and nuclear materials.*

[Wahlström et al, 2001; STUK, 2001]

In Finland setting and supervision of the safety requirements of nuclear installations is done through the regulatory system and not individual plant licensing conditions.
[Wahlström et al, 2001]

3. What guidance has been issued to ensure compliance with statutory provisions e.g. approved codes of practice?

ST 1.5 Exemption of the Use of Radiation from the Safety Licence and Reporting Obligation, 1 July 1999 –
(http://www.stuk.fi/saannosto/ST1-5e.html)

This guide presents the conditions applying to exemption from the safety licence for the use of radiation and the reporting obligation, and also the exemption values for radioactive substances which if exceeded, will entail the application of the safety licence and notification procedure of the use of the radiation in question. The guide also presents exceptions in the use of exemption values, and requirements associated with the exemption of radiation appliances. This guide does not apply to the use of nuclear energy, nor to natural radiation sources. ***Note:*** *This guide does not apply to nuclear power. Licences concerning nuclear materials and nuclear waste, the use of nuclear energy which is exempted from subjection to licence, and the notifications required, are regulated in the Nuclear Energy Act (990/1987) and the Nuclear Energy Decree (161/1988, amendment 473/1996)*

ST 5.4 Trade in Radiation Sources
(http://www.stuk.fi/saannosto/ST5-4.html , only in Finnish)

The Guide lays down the obligations pertaining to the trade in radiation sources, specifies the related safety licenses and license exemptions, as well as the requirements for shipments of radioactive materials between EU member states as laid down in EU Council Regulation (Euratom) No. 1493/93. It also specifies obligations and procedures relating to the trans-border movement of radioactive waste in accordance with EU Council Directive 92/3/Euratom.

ST 6.2 Radioactive Wastes and Discharges 1 July 1999 -
(http://www.stuk.fi/saannosto/st6_2e.pdf)

This guide sets out the radiation safety requirements and limits for the treatment of radioactive waste. These should be observed when discharging without a separate waste treatment plan, operations which may be exempt from the requirement to produce a treatment plan are also given in this guide. These are namely ordinary laboratory waste meeting the criteria in section 3.1 of the guide or if the operations are such that the activity limits specified in sections 3.2- 3.4 are not exceeded. The guide does not apply to radioactive waste from nuclear power or exploitation of natural resources.

Guide YVL 8.2 Exemption from regulatory control of nuclear wastes
(http://www.stuk.fi/saannosto/YVL8-2.html)

The Guide prescribes the general principles to be applied in prospective planning and in clearing waste containing very low concentrations of radioactive substances and the disposal or recycling of such waste as well as activity monitoring and recoding thereof. The Guide is applicable to clearing waste arising from the use of nuclear energy. It is also applicable to imported waste where it is known or assumed to originate from a nuclear installation.

The YVL-guides are not legally binding, deviations from the requirements of the YVL-guides are permitted provided the safety level given in the guides are attained by solution presented by the licence holder.

4. Please describe the processes of exemption and clearance for nuclear installations and other practices i.e. hospitals, research establishments etc.

Exemption (not nuclear power)

Provided the activity or activity concentration of the radioactive substance associated with the practice is smaller than or equal to the exemption value set for that radionuclide or the summing ratio for the mixture is less than 1 neither a safety licence nor a report is required.

The exemption values presented in Appendix A of ST 1.5 apply to all radioactive substances held at any one time by a person or enterprise. For large organisations such as hospitals or universities a sub-unit such as a department is considered the holder. However exemption values will not apply to the following practices which must always have a safety licence:

- *The medical use of radiation as referred to in section 38 of the Radiation Act*
- *The manufacture, trading and import and export of radiopharmaceuticals*
- *The manufacture and import and export of consumer goods which include radioactive substances (unless exempted by decision of STUK)*

- *The administration of radioactive substances to animals for purposes of diagnosis, treatment or research.*

Clearance [Brodén et al, 2000]

*For **unconditional (or general) clearance** of waste from regulatory control, an application shall be submitted to STUK, in which the origin and characteristics of the waste and the methods to be used for the determination of the activity of the waste are described. After the approval of the application, the waste can be removed from the facility as soon as it arises. Unconditional clearance is not applicable to waste which is highly volatile or flammable, of significant practical value or can otherwise easily cause radiation exposure.*

*For **conditional (or specific) clearance,** an application shall be submitted to STUK for approval as for general clearance. The application shall include the information required in Section 48 of the Nuclear Energy Decree, and identification and approval by the recipient of waste. In addition, a description of*

i) the origin and characteristics of the waste

ii) the methods used to determine the activity of the waste

iii) the method to be used for disposing of or recycling the waste and

iv) the radiation exposure arising from the clearance of the waste are required.

Waste is removed from the controlled area occasionally, a fairly large amount at a time. The clearance approval may either apply to a single batch of waste or be constantly valid in case waste arises repeatedly and its disposal or recycling method remains unchanged.

Once started, STUK may inspect the operations in order to ensure that that they are conducted in accordance with the application and conditions set in the authorization. A summary of all cleared waste is annually required by STUK.

Clearance From non-nuclear power activities [STUK, 1999b]

Hospitals, research installations, etc.

ST Guide 6.2 sets out the radiation safety requirements and limits for the treatment of radioactive waste. The limits applied separately to gaseous and liquid discharges and to solid radioactive waste are:

- *The effective dose for an individual in the critical group is not to exceed 10μSv in a year.*

- *The collective effective dose commitment resulting from one year's operation is not to exceed 1 manSv.*

The responsible party wishing to release radioactive material to sewer, atmosphere, landfill or incineration plant must prepare and submit for approval a waste treatment plan to STUK. The conditions and special regulations to be followed are specified in the approval notice. However should the waste meet the clearance conditions and levels set out in ST Guide 6.2, and summarised below, the waste can be disposed of without submitting a waste treatment plan but even in such situations STUK may order monitoring and reporting of the exhaust gases.

The activity limits are given below however in addition to these there are some guiding principles:

- *The amount of radioactive substances released to the environment shall be kept as low as reasonably possible.*

- *Low-activity solid waste must be packaged so as to prevent leakage during transportation.*

Ordinary Laboratory Waste

SOLID WASTE
It is not considered radioactive waste (i.e. it is cleared) if:

- *Activity of radionuclides emitting beta or gamma radiation is not more than 10 kBq/kg*

- *Activity of radionuclides emitting alpha radiation is not more than 1 kBq/kg.*

Activity may be averaged over no more than 10 kg of waste.

Such waste can be treated as ordinary laboratory waste. Radiation warnings should be removed or cancelled, the waste packaged to prevent contamination and if necessary the activity checked by measurement.

LIQUID SCINTILLATION SOLUTIONS
Liquid scintillation solutions or similar waste containing organic solvents are not considered radioactive waste if:

- *The activity concentration does not exceed 10 Bq/ml, and there are no alpha-active radionuclides*

- *The activity concentration does not exceed 100 Bq/ml, and there are no radionuclides other than ^{3}H or ^{14}C.*

Discharge to the Sewers

The maximum activity permitted for radioactive discharge to the sewers are:

- *2.5 ALI_{min} of the radionuclide on any one occasion, but not more than 100 MBq*

- *25 ALI_{min} from one source in any one month but not more than 100 GBq in any one year.*

- *If there is more than one radionuclide the sum of the ratios of activity over ALI_{min} for each must not exceed 2.5 for one discharge or 25 for one month's discharge.*

Where ALI_{min} refers to the smallest annual limit on intake of the radionuclide in question. The ALI_{min} of the most commonly used radionuclides are set out in Appendix A of ST Guide 6.2 these values are in terms of Bq and these 'clearance' figures differ from the 'exemption' quantities given for radionuclides in Table A of Annex I of the BSS Euratom and are generally higher. The annual limit on intake (ALI) is defined, and the method for its calculation is set out in ST Guide 7.2. These discharge limits do not apply to excreta from patients receiving treatment.

Emissions to the Atmosphere

The maximum activity concentration (MAC) in the immediate vicinity of the stack (i.e. within a few metres) must not be more than 1/100 of the derived air concentration (DAC) of a radiation worker. With the following provisos:

- *Activity concentration may be for a specific period but not exceeding one year. DAC values are calculated according to the methodology given in ST Guide 7.2 using conversion coefficients given in ST Guide 7.3.*

- *Where more than one radionuclide is emitted the sum of the ratios of concentration over limit must not exceed 1.*

- *Activity concentration limits are set out in Appendix B and C of ST Guide 6.2.*

Disposal of Solid Low-activity Waste

Solid low activity waste may be sent to landfill or incineration if the maximum activity doesn't exceed:

- *2.5 ALI_{min} in any one package and the dose rate on the surface of the package must not exceed 5μSv/h*

- *25 ALI_{min} from one source in any one month but not more than 100 GBq in any one year.*

As for the liquid discharge where there are more than one radionuclide present the sum of the ratios of different radionuclides must not exceed the 2.5 for one package or 25 for discharges over one month.

Waste must not contain sealed sources with an activity greater than 100kBq.

Exemption of radiation equipment

In accordance with section 17 of the Radiation Act, STUK can exempt certain types of radiation equipment from safety licences. The exemption can be granted upon application, based on an inspection made by STUK, but it can also be granted without an inspection if the documents, inspection of similar equipment performed elsewhere, and other data make it clear that the equipment is entitled to a safety licence exemption, the requirements for which are specified in ST Guide 1.5. The exemption may concern a certain type of equipment or an equipment group (such as teaching equipment, gas-chromatographic EC detectors and electron microscopes). In the case of a group of equipment, any new types of equipment introduced in the group in question are subject to approval by STUK.

If necessary, the exemption decision will be accompanied by instructions to ensure the safe use of the equipment. It can also be ordered that the equipment be reported for inclusion in the appropriate STUK Register. An exemption decision will be accompanied by instructions about whether the equipment containing radioactive material taken out of use shall be managed as radioactive waste, and about whether safety licences are required for its installation, maintenance and repair. The exemption decision and the related approval can be accompanied by other instructions on radiation safety, as well.

5. Was Annex 1 (of BSS Euratom) used for defining exemption levels? If not, what are these other levels. Please describe the reasoning/methodology in their derivation.

Yes. See Guide ST 1.5 at http://www.stuk.fi/saannosto/ST1-5e.html. The values given in Appendix A of ST 1.5 are the same as Annex I of BSS.

6. Was EC guidance used in the derivation of clearance levels? Please indicate which guidance and for which materials and practices.

Initially no however it is stated that where EC guidance exists the activity concentrations of the materials to be cleared must not exceed the guide values set out in the technical instructions issued by the European Community (clearance levels). The publication "Radiation Protection No 122" was one of the reference documents used in establishing the clearance levels of Guide YVL 8.2.

Apart from values established for the discharges and releases in Guide ST 6.2, there has not yet been any practical need to establish clearance levels for non-nuclear radioactive waste. The possible need in the future has, however been anticipated in Guide ST 1.5 which states that in establishing clearance levels (either general or specific) these values "shall not exceed the guidance values set out in the technical instructions issued by the European Community (clearance levels). These guidance values can be significantly lower than the exemption values for the safety licence and reporting obligation." In this way, clearance level possibly issued in the future (once needed…) will most likely be consistent with e.g. the publication "Radiation Protection 122".

7. Please give specific situations, sources, waste streams to which exemption and clearance have been applied. Please list exempt practices. Have both general and

specific clearance levels been applied in your country (i.e. after clearance, is material cleared for all uses or are restrictions imposed)? Please give examples.

Use of nuclear energy:
Limited amounts of scrap metal from the NPPs (up to 10 tons/NPP/year) have been cleared unconditionally. Specific clearance permits have been granted e.g. for trash waste, waste oil and larger quantities of scrap metal from the NPPs.

Non-nuclear practices:
See question 1.

8. Has clearance been a useful concept or have cleared materials still been rejected as radioactive? Please give details.

The cleared nuclear waste originates mainly from the repair and maintenance works of the NPPs. There are two nuclear power stations and annually, tens of tonnes of very low level waste is cleared from regulatory control.

The amount of very low level metal scrap cleared for recycling varies from some tons to a few tens of tons per year and per NPP. This is mainly iron-based material. Occasionally the amount can be considerably higher when large components are dismantled and cleared. For example, about 300 tons of brass was cleared after dismantling of the condensers of the Olkiluoto NPP.

The cleared metal scrap has been transferred to Finnish foundries to be used as raw material. There has been fairly little public concern about clearance of nuclear wastes. [Brodén et al, 2000]

The metal recycling industry tends to apply a policy according to which no radioactive substances are accepted. It has happened that a batch of scrap metal which has been cleared from a NPP has caused an alarm at foundry's gate detector and has been returned to the consigner.

9. Please identify needs for improvement (legal, practical application, additional guidance) in this area

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.

Benchmark Example:

In order to fairly and simply compare the approaches of different EU Member States it is our hope to analyse the responses Authorities would take to a sample situation. Thus could you consider the following and justify the appropriate proposed course of action:

- Operator of a nuclear installation in your country hopes to clear about 5,000 t steel in the course of decommissioning the site.

- Half the material has surface contamination while the other half is activated.

- The typical surface contamination and activity is given below:

Radionuclide	Surface Contamination (Bq/cm^2)
Cs-137	80
Ce-144	50
Sr-90	15

Radionuclide	Specific Activity (Bq/g)
Co-60	1
Zn-65	0.5
Mn-54	1.2

Is the steel likely to be cleared? What conditions may be applied? Will it be: -

a. Given unconditional clearance
NO, because the concentrations exceed the values given in Guide YVL 8.2.

b. Cleared for recycling
NO, for the same reason as above and because the total activity exceeds the limit of Section 11 of the Nuclear Energy Decree (1 GBq). A smaller batch might be cleared to specific use provided that it is demonstrated that the steel does not cause doses exceeding 10 μSv/a. In Finland, there is no option for recycling inside the nuclear industry.

c. Cleared for reuse
NO, for the same reason as above.

d. Refused clearance, sent for disposal
Yes, disposal is a viable option.

e. Refused clearance further decontamination required
Yes, if decontamination of the contaminated portion below the levels given in guide YVL 8.2 is practicable.

f. Other (please give details)

References:

Brodén K, Øhlenschlæ M, Ruokola E, Johnsdottir T, Sekse T and Wiklund Å, *Current Practice for Clearance in the Nordic Countries,* NKS/SOS-3 December 2000.

STUK, *Compliance with the obligations of the Convention on Nuclear Safety,* 12th October 2001.

STUK, *ST Guide 1.5, Exemption of the Use of Radiation from the Safety Licence and Reporting Obligation* 1st July 1999.

STUK, ST Guide 6.2, *Radioactive Wastes and Discharges,* 1st July 1999b.

Wahlström B and Sairanen R, *Views of the Finnish Nuclear Regulatory Guides,* STUK, 12th October 2001.

September 2002

SWEDEN (Sverige)

Provided by: Lars Mjönes, Gunilla Hellström and Henrik Efraimsson, Swedish Radiation Protection Authority (SSI)

1. Title III, Article 3 paragraph 2 and Title III, Article 5 paragraph 2 of Council Directive 96/29/Euratom define what practices may be exempt and what materials may be cleared. Have these articles been implemented in your country? If yes, how have the concepts of Exemption and Clearance been incorporated into the national legislation/regulatory documentation? Please give a summary of the legislation, including the definitions of the concepts and reference to the location of these definitions in national legislation.

   Yes, exemption has been implemented in the Swedish Ordinance on Radiation Protection issued by the government. In 2 § in the ordinance it is stated that exemption from licensing is valid for practices where activity levels lower than the values from the BSS is handled and also that SSI is allowed to exempt devices from licensing if they fulfil the demands of the BSS.

   Two regulations from SSI exempt consumer goods from licensing, the use of smoke detectors and the use of compasses and binoculars containing tritium. Import and manufacturing of these products are not exempted from licensing.

   Clearance is mainly regulated by general regulations on clearance, issued by SSI in accordance with the Ordinance on Radiation Protection, 7-8 §§. The regulations should thereby be regarded as specifications of general obligations for those engaged in practices.

   Clearance is also regulated by case-by case decisions by SSI in accordance with the Ordinance on Radiation Protection, 4 §. The material is thereby exempted from the application of the Act on Radiation Protection, i.e. no license is needed for the handling of the material.

   Clearance is not defined specifically.

2. Which organisation(s) is responsible for issuing regulatory documentation, including exemption and clearance levels and overseeing the practical application of the concepts?

   The Swedish Government has issued the Radiation Protection Ordinance, where the BSS exemption levels are included. The Swedish Radiation Protection Authority (SSI) has issued general regulations on clearance levels for material from nuclear installations (SSI FS 1996:2) and from laboratories (SSI FS 1983:7). The SSI has also taken several case-by-case decisions on clearance. The SSI is responsible for supervision of the practical application of the ordinance and the regulations.

3. What guidance has been issued to ensure compliance with statutory provisions e.g. approved codes of practice? Please include a short description/abstract of what the guidance covers in addition to providing a copy of the document.

Some guidance is given in SSI FS 1996:2. For example, surface contamination shall be calculated as a mean for 0.03 m^2. Measurements of alpha contamination is not necessary if it can be assured that no alpha contamination can be expected. For waste that is deposited on ordinary dump sites, nuclide specific measurements shall be made.

4. Please describe the processes of exemption and clearance for nuclear installations and other practices i.e. hospitals, research establishments etc.

For nuclear installations, clearance is mainly performed according to SSI FS 1996:2. Surface contamination is measured by representative smear samples. Mass specific activity content is measured gamma spectrometrically. The holder of the license for the nuclear facility is responsible for compliance with the regulations and no review or approval of measurements is needed before clearance. All clearance for deposition or incineration is reported yearly to the SSI.

Hospitals and research establishments have clearance levels for fluids and solid materials stated in SSI FS 1983:7, based on the concept of ALI. It is also for these practices the responsibility of the holder of the license to comply with the regulations.

5. Was Annex 1 (of BSS Euratom) used for defining exemption levels? If not, what are these other levels. Please describe the reasoning/methodology in their derivation.

Yes.

6. Was EC guidance used in the derivation of clearance levels? Please indicate which guidance and for which materials and practices. In situations where EC guidance was not used please describe the reasoning/methodology and the dose criteria applied in the derivation of the clearance levels and provide details on these clearance levels.

EC guidance was not used. The clearance levels in SSI FS 1996:2 were based on IAEA-TECDOC-855 and on Swedish studies on management of conventional waste (deposition of different materials and incineration of oil). The individual dose criterion was 10 microsieverts per year. Details on the clearance levels are given in the table below.

	Activity concentration		*Total activity*
	gamma/beta	*alpha*	*per nuclear site*
Unrestricted use	*40 kBq/m^2*	*4 kBq/m^2*	*No limit*
	0.5 kBq/kg	*0.1 kBq/kg*	*No limit*
Deposition	*5 kBq/kg*	*0.5 kBq/kg*	*1 GBq/year*
Incineration of oil	*5 kBq/kg*	*0.1 kBq/kg*	*0.5 GBq/year*

7. Please give specific situations, sources, waste streams to which exemption and clearance have been applied. Please list exempt practices. Have both general and specific clearance levels been applied in your country (i.e. after clearance, is material cleared for all uses or are restrictions imposed)? Please give examples.

As indicated in the table above, there are both general and specific clearance levels. Operational waste from nuclear facilities is regularly released from regulatory control for unrestricted use, deposition at municipal dump sites or incineration, according to SSI FS 1996:2 or special permits. Ingots from a nuclear melting facility are released from regulatory control for unrestricted use according to SSI FS 1996:2 or for re-smelting with other material according to special permits.
Clearance has also been applied to buildings and small areas of land according to special permits.

Exempt practices: No specific exempt practices have been introduced other than consumer goods (smoke detectors and compasses containing tritium) and those below the activity levels (and activity concentration level) according to the ordinance (and based on the BSS).

General estimate of the quantities of materials involved in recycling, reuse or unconditional clearance in Sweden:

<u>From nuclear power plants in Sweden</u>, about 200 tons per year with an activity content of in the order of 0.1 GBq are deposited on municipal dump sites. About 60 tons per year of oil and hazardous waste are incinerated in conventional facilities (activity content in the order of 20 MBq). About 500 tons per year are released for free reuse or recycling, mainly as scrap metal or ingots from melting in a licensed facility.

<u>From nuclear fuel fabrication</u>, about 500 tons per year with a total uranium content of in the order of 50 kg are deposited on municipal dump sites.

<u>From non-nuclear practices</u> (mainly laboratories and hospitals), about 20 TBq (mainly short-lived, half-life less than a month) per year is released as liquid or solid waste.

8. Has clearance been a useful concept or have cleared materials still been rejected as radioactive? Please give details.

Clearance has been a useful concept in Sweden. 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.

9. Please identify needs for improvement (legal, practical application, additional guidance) in this area.

The SSI has identified the need for regulations on clearance of materials from non-nuclear activities and clearance of large amounts of material arising from decommissioning of nuclear facilities. The SSI has also identified the need for review of the existing regulations in the light of the EC recommendations on clearance.

One deficiency of our regulations for NPPs is that they are not intended for clearance in connection with decommissioning. We are planning to develop the regulations, and as a first step we examine the applicability of existing EC recommendations in 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).

Benchmark Example

In order to fairly and simply compare the approaches of different EU Member States it is our hope to analyse the responses Authorities would take to a sample situation. Thus could you consider the following and justify the appropriate proposed course of action:

- Operator of a nuclear installation in your country hopes to clear about 5,000 t steel in the course of decommissioning the site.
- Half the material has surface contamination while the other half is activated.
- The typical surface contamination and activity is given below:

Radionuclide	Surface Contamination (Bq/cm^2)
Cs-137	80
Ce-144	50
Sr-90	15

Radionuclide	Specific Activity (Bq/g)
Co-60	1
Zn-65	0.5
Mn-54	1.2

Is the steel likely to be cleared? What conditions may be applied? Will it be: -

a. Given unconditional clearance
b. Cleared for recycling
c. Cleared for reuse
d. Refused clearance, sent for disposal
e. Refused clearance further decontamination required
f. Other (please give details)

The surface contaminated steel is not likely to be cleared without decontamination and/or controlled melting, since the surface contamination exceeds the clearance levels in SSI FS 1996:2.

The activated steel is not likely to be cleared directly, since the specific activity exceeds the clearance levels in SSI FS 1996:2. The steel would possibly be cleared after controlled melting and some years decay storage.

March 2002 (with additional clarification given September 2002)

UNITED KINGDOM

Provided by: Shelly Mobbs (NRPB), Kathy Hillis and Bob Major (NNC).

The completed report including this questionnaire was reviewed by Chris Wilson, Head of Technical Policy Branch, Radioactive Substances (RAS), Department for Environment, Food and Rural Affairs (DEFRA), Mr McHugh, Strategic Policy Manager at the Environment Agency for England and Wales and Mr Larmour of the Industrial Pollution & Radiochemical Inspectorate (IPRI) of the Environment & Heritage Service in Northern Ireland in the UK and their comments are included.

Representatives from the Scottish Environmental Protection Agency (SEPA) were also contacted.

1. Title III, Article 3 paragraph 2 and Title III, Article 5 paragraph 2 of Council Directive 96/29/Euratom define what practices may be exempt and what materials may be cleared. Have these articles been implemented in your country?

   Title III implemented? *Yes*

   Legislative documents:

   The Ionising Radiation Regulations 1999 (IRR99) relating to the basic safety standards for the protection of the general public and workers against the dangers of ionising radiation as a consequence of work. In Northern Ireland these are the Ionising Radiation Regulations 2000 (IRR2000).

   The Radioactive Substances Act 1993 (RSA93) relating to the holding, storage, use and disposal of radioactive materials.

   In addition there are the following supplementary legislation:

   Radioactive Substances (Basic Safety Standards) (England and Wales) Direction 2000, 9th May 2000. This Direction was given by the Secretary of State for the Environment, Transport and the Regions to the Environment Agency for England and Wales for the purposes of implementing the obligations of the Council Directive 96/29/Euratom. Similar provisions applying to Northern Ireland is to be found in the Radioactive Substances (Basic Safety Standards) (Northern Ireland) Regulations 2003 SR 2003 No 208.

   An additional piece of legislation amending the RSA93 regarding the exemption of clocks and watches has also been issued ***for England and Wales, the*** *Radioactive Substances (Clocks and Watches) (England and Wales) Regulations 2001 SI 2001 No 4005 and for Scotland in the Radioactive Substances (Basic Safety Standards) (Scotland) Regulations 2000 SI 2000 No 100, in the case of Northern Ireland these provisions are in SR 2003 No 208.*

   Definition of Exemption? *Not provided in IRR99 Reg. 2 Interpretation*

Definition of Clearance? *Not provided in RSA93 Reg. 1 Preliminary, term not recognised in UK legislation.*

General exemption from the scope of IRR99

The application of IRR99 is defined in Reg. 3. It is given in the form of what it applies to as opposed to what is exempt. Subject to Reg. 3 and Reg. 6(1) [Schedule 8 practices exempt from notification] the Regulations apply to:

- *Any practice*

- *Any work (other than a practice) conducted in an atmosphere with Rn-222 concentration exceeding 400 Bqm^{-3}*

- *Any work (other than above) with any radioactive substance containing naturally occurring radionuclides.*

<u>Incorporation of Exemption from Reporting (Title III, Art. 3, par. 2) for practices.</u>

The work with ionising radiation not requiring to be notified under Reg. 6 is given in Schedule 1 of IRR99. Where the only such work being carried out is in one or more of the following categories it may be exempt from reporting:

1. Where the specific activity (Bq/g) of a radioactive substance does not exceed that specified in column 2 of Part I of Schedule 8

2. Where the quantity (Bq) of radioactive material involved does not exceed that specified in column 3 of Part I of Schedule 8.

Part I of Schedule 8 of IRR99 gives numerical values of specific activities to be used in connection with Reg. 6. The Schedule is more extensive than Annex 1 of the CD. The Basic Criteria stated in Annex 1 of CD are not stated. However in Reg. 2(4) it states that:

- *Where only one radionuclide is involved it shall exceed to exemption limit if the quantity is exceeded; or*

- *Where there is more than one radionuclide the quantity is exceeded if quantity ratio given in Part II of Schedule exceeds 1.*

Note that the schedule contains the BSS Annex 1 values plus values for other nuclides derived using the same models and dose criteria.

3. Where apparatus is used which contains radioactive substances in a quantity exceeding the values specified in points 1 and 2 provided that:

- *The apparatus is of a type approved by the Executive*

- *The apparatus is constructed in the form of a sealed source*

- *The apparatus does not under normal operating conditions cause a dose rate of more than 1μSv h^{-1} at a distance of 0.1m from any accessible surface;* ***and***

- *Conditions for the disposal of the apparatus have been specified by the appropriate Agency (Environment Agency in E&W).*

4. The operation of any electrical apparatus to which the regulations apply (i.e. that emitting ionising radiation and containing components operating at a potential difference of more than 5kV), other than that covered by point 5, provided that:

- *The apparatus is of a type approved by the Executive;* ***and***

- *The apparatus does not under normal operating conditions cause a dose rate of more than 1μSv h^{-1} at a distance of 0.1m from any accessible surface*

5. The operation of any cathode ray tube for displaying visual images or any other electrical equipment operating at a potential difference (pd) not exceeding 30kV provided the operation of the tube or apparatus does not under normal operating conditions cause a dose rate of more than 1μSv h^{-1} at a distance of 0.1m from any accessible surface

6. Where the work involves material contaminated with radioactive substances resulting from authorised releases which the appropriate Agency (EA in E &W) has declared not to be subject to further control. Material which has been cleared.

These points 1-6 from Schedule 1 follow closely the provisions set out in Title III Article 3 par 2.

Additionally work carried on at a site licensed under section 1 of the Nuclear Installations Act 1965 are also exempted from Regulation 6 to notify the Executive of work with ionising radiation.

Incorporation of Clearance for disposal, recycling or reuse (Title III, Art 5, par 2)

Title III Article 5 par 1 requires that 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 to be subject to prior authorisation.

In the UK disposal of radioactive waste is controlled and regulated under the Radioactive Substances Act 1993 (RSA93). It requires prior registration of the keeping and use of radioactive materials (Reg. 6) and the prior authorisation of the accumulation and disposal of radioactive waste, by the appropriate regulatory authority, unless exempted or excluded (Reg. 13 & 14).

Under Reg. 13 the disposal of any radioactive waste on or from any premises requires authorisation from the appropriate agency (EA in E&W). This is subject to the following exceptions as given in Reg. 15:

- *Radioactive waste arising from clocks and watches but not in the case of premises where the luminous watches and clocks are manufactured or repaired. [This has been amended, see Statutory Instrument 2001 No 4005 for details].*

- *Exemption from provisions as stated in Exemption Orders*

Exemption Orders

Exemption Orders allow for exemption from the specified provisions of the Radioactive Substances Act 1993 (RSA93). There are currently 18 such Orders. Northern Ireland has an equivalent set of Exemption Orders which can be used to provide a level of control below that of site specific authorisations issued under RSA-93.

Natural Radioactivity

- *Phosphate Substances, Rare Earths*

- *Precipitated Phosphate*

- *Uranium and Thorium*

- *Uranium and Thorium Compounds*

- *Geological Specimens*

- *Lead*

- *Natural Gas*

Products Containing Radioactivity

- *Luminous Articles*

- *Testing Instruments*

- *Smoke Detectors*

- *Gaseous Tritium Light Devices*

- *Electronic Valves*

Specific Types of Undertaking

- *Hospitals*
- *Schools*
- *Exhibitions*

Transit of Radioactivity

- *Waste Closed Sources*
- *Storage in Transit*

Clearance Level

- *Substances of Low Activity (SoLA)*

The SoLA is nearest to clearance, but others allow disposal of waste without regulation and can be used by regulated industries/undertakings so they are also clearance. Solid insoluble radioactive material with an activity less than 0.4 Bq/g is exempt from regulation. Organic liquid that is solely radioactive because of the presence of C-14, H-3 or both with an activity less than 4 Bq/ml is exempt. Gases containing one or more radionuclide with a half-life of less than 100s are exempt.

There are gaps in the coverage of the Exemption Orders:

Solid wastes-

All solid wastes that contain radioactive material above the levels in Schedule 1 of RSA93 and that cannot be shown to be 'substantially insoluble' must be disposed of under specific authorisations regardless of the quantities involved.

Liquid wastes-

All liquid wastes containing radionuclides wholly or partly in solution at concentrations above the Schedule 1 of RSA93 must be disposed of under specific authorisations regardless of their volume and even though the radiological impact may be very low.

Gases and Vapours

All gases and vapours other than isotopes of uranium and thorium in compounds at concentrations above Schedule 1 levels must be discharged under specific authorisations however small their radiological impact.

Title III Article 5 par 2 allows for the release from the requirements of the Directive, those materials complying with the clearance levels established by national competent authorities which should follow the basic criteria used in Annex I.

Clearance levels don't appear explicitly in UK legislation but Schedule 1 of the RSA93 and the Exemption Order for Substances of Low Activity contain levels that could be used for unconditional clearance of large volumes of materials on agreement with the appropriate Agency. Currently, the legal criterion for clearance is an average activity concentration of less than 400kBq/t. Such material is not defined as radioactive waste in the Radioactive Substances Act [RSA93] and the legal criterion for clearance was not changed when the RSA was reviewed to assess compliance with the Euratom Basic Safety Standards.

The review was commissioned by Department of the Environment, Transport and the Regions (DETR) (now DEFRA) and concluded that all the Exemption Orders considered in the review are in need of extensive revision and updating however it also concluded that for those Orders covering 'premises' and 'products' the assessments show that the radiological impacts on members of the public of disposals permitted under the Orders are consistent with Annex 1 criteria of the Directive (Martin, 1999). The report further concluded that the Exemption Orders satisfy the requirements of Article 5 of the Directive and that, in most cases, the Orders can be regarded as granting clearance under Article 5.2 (Martin, 1999).

A further report Hill et al, 1999 was also commissioned by the DETR to look at the derivation of UK unconditional clearance levels for solid radioactively contaminated materials. The report did derive such levels however it was also shown that continued use of the levels in existing UK legislation would also meet the radiological criteria for clearance given in the Directive (Hill et al, 1999).

Note that analysis of the doses associated with the SoLA value of 0.4 Bq/g and typical nuclide spectra showed that it complied with the 10 microsievert criterion for clearance and hence there was no need to change.

Schedule 1 of the RSA93 is used to define what is a radioactive material i.e. what is regulated. It is given in elements not radionuclides:

Element	*Becquerels per gram (Bq/g)*		
	Solid	*Liquid*	*Gas or Vapour*
Actinium	*0.37*	*7.4E-2*	*2.59E-6*
Lead	*0.74*	*3.7E-3*	*1.11E-4*
Polonium	*0.37*	*2.59E-2*	*2.22E-4*
Protoactinium	*0.37*	*3.33E-2*	*1.11E-6*
Radium	*0.37*	*3.7E-4*	*3.7E-5*
Radon	-	-	*3.7E-2*
Thorium	*2.59*	*3.7E-2*	*2.22E-5*
Uranium	*11.1*	*0.74*	*7.4E-5*

The Radioactive Substances (Substances of Low Activity) Exemption Order 1986 Radioactive waste as described below is excluded from the requirement for authorisation for disposal:

1. A solid, other than a closed source, which is substantially insoluble in water, the activity of which, when it becomes a waste, does not exceed 0.4Bq/g.

2. An organic liquid which is radioactive solely because of the presence of C-14, H-3, (or both) the activity of which when it becomes a waste does not exceed 4Bq/ml, or

3. A gas containing one or more radionuclides none of which, nor the decay products of which, has a half-life greater than 100 seconds.

2. Which organisation(s) is responsible for issuing regulatory documentation, including exemption and clearance levels and overseeing the practical application of the concepts?

The Environment Agency (EA) is the regulator for England and Wales, the Scottish Environment Protection Agency (SEPA) regulates in Scotland and the Industrial Pollution and Radiochemical Inspectorate of the Environment and Heritage Service, an agency within the Department of the Environment, Northern Ireland, is the regulator for Northern Ireland. Implementing the RSA93 and Exemption orders. These regulatory bodies are responsible for authorising radioactive discharges from all civil sources in their jurisdiction.

The Health and Safety Executive is responsible for regulating exposure to workers and to the public from work practices.

3. What guidance has been issued to ensure compliance with statutory provisions e.g. approved codes of practice?

An approved code of practice has been issued to accompany the IRR99 – 'Work with ionising radiation' Ionising Radiation Regulations 1999 Approved Code of Practice and Guidance L121.

Reg. 5 (Authorisation of specified practices) Generic authorisations have been issued by the HSE to cover each of the practices covered in regulation 5(1)

Reg. 6 (Exemptions from notification) Schedule 8 covers all radionuclides likely to be used in GB. HSE has the power to approve specific values for unlisted radionuclides

There is presently no official statutory guidance to accompany the RSA93. However a report commissioned by the DETR (now DEFRA) does provide an interpretation and guidance on the application of Schedule 1 of the RSA93 and related issues (Hill and Wakerley, 2000).

4. Please describe the processes of exemption and clearance for nuclear installations and other practices i.e. hospitals, research establishments etc.

Description of process of clearance:

Under RSA93 in order to dispose of registered radioactive material an authorisation must be obtained. An application must be made to the appropriate agency (EA in E&W). Proforma exist for small users but larger sites must negotiate with the EA to determine what can be discharged/released and how. There is a requirement for a radiological impact assessment and a statement of expected amounts of waste needing disposal.

Before the granting of an authorisation the chief inspector and the appropriate Minister shall consult with the Local Authority, relevant water bodies or other public bodies, as he feels appropriate. Reg. 16(5)

The authorisation will lay down maximum discharge limits and disposal routes. It will also set monitoring requirements and record keeping conditions. Each authorisation is set on a case-by-case basis.

On granting of the authorisation a copy shall be supplied to the Local Authority of the area where the disposal or accumulation will occur.

The only use of 'clearance' levels would be the use of Exemption Orders as explained in Q1.

There are no nuclear installations in Northern Ireland and the authorisation process was summarised by the NI Inspector as follows:

When an operator applies for a Certificate of Authorisation to dispose of radioactive waste he is required to complete a standard application form and include an environmental impact assessment. This together with the Inspectors own assessment of potential environmental consequences is used to determine site specific conditions. There are no formal consultation procedures prior to the issuing of the Certificate. A copy of both the application form and final certificate are sent to the relevant Local Council. The applicant can appeal to the Chief Radiochemical Inspector and ultimately the Department of the Environment if he is aggrieved by any of the conditions or limitations imposed. All premises authorised to dispose of radioactive waste are required to make an annual return to the Chief Radiochemical Inspector giving details of the radionuclides and activities actually discharged.

5. Was Annex 1 (of BSS Euratom) used for defining exemption levels? If not, what are these other levels. Please describe the reasoning/methodology in their derivation.

Annex 1 was not used to determine levels in Schedule 8 for the exemption of practices, they were previously defined. However Schedule 8 does contain the Annex 1 values plus others, see previous comment.

6. Was EC guidance used in the derivation of clearance levels? Please indicate which guidance and for which materials and practices.

EC guidance has not been used. The only clearance levels are given in Schedule 1 of RSA93 and in the EOs.

Radioactive waste has been regulated for many years and legislation pre-existed the introduction of the 1996 Euratom Basic Safety Standards Directive. The UK Government decided to retain the existing Schedule 1 of RSA93 with its values for radioelements for solids, liquids and gases. The UK reviewed the provisions of RSA93 to see if they were consistent with the BSS and decided that since they were, there was no need for change (see Martin, 1999 and Hill et al, 1999).

7. Please give specific situations, sources, waste streams to which exemption and clearance have been applied. Please list exempt practices. Have both general and specific clearance levels been applied in your country (i.e. after clearance, is material cleared for all uses or are restrictions imposed)? Please give examples.

Use of clearance levels:

The Substances of Low Activity EO has been used to clear Aluminium from Capenhurst and Lead from Harvell for if the material meets SoLA it is no longer subject to control. It is often referred to as 'free release' in the UK.

There has been no use of clearance levels to date in NI so it is difficult to identify any areas for improvement. It is likely that guidance on practical implementation would be requested by operators.

The closest example of the application of clearance in NI would be in relation to the disposal of waste containing short lived radionuclides generated by hospitals. This waste is stored until the activity is less than 0.4Bq/g when it becomes exempt from RSA-93 due to the application of the Substances of Low Activity Exemption Order and can enter the general clinical waste stream.

8. Has clearance been a useful concept or have cleared materials still been rejected as radioactive? Please give details.

Yes see question 7.

9. Please identify needs for improvement (legal, practical application, additional guidance) in this area

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.

Mr Chris Wilson, Head of Technical Policy Branch, RAS, (DEFRA) commented that there is an overlap between the definition of specific clearance and authorised release such that the term is an unnecessary complication.

There has been no use of clearance levels to date in NI so it is difficult to identify any areas for improvement. It is likely that guidance on practical implementation would be requested by operators (Mr Robert Larmour, IPRI).

Benchmark Example:

In order to fairly and simply compare the approaches of different EU Member States it is our hope to analyse the responses Authorities would take to a sample situation. Thus could you consider the following and justify the appropriate proposed course of action:

- Operator of a nuclear installation in your country hopes to clear about 5,000 t steel in the course of decommissioning the site.
- Half the material has surface contamination while the other half is activated.
- The typical surface contamination and activity is given below:

Radionuclide	Surface Contamination (Bq/cm^2)
Cs-137	80
Ce-144	50
Sr-90	15

Radionuclide	Specific Activity (Bq/g)
Co-60	1
Zn-65	0.5
Mn-54	1.2

Is the steel likely to be cleared? What conditions may be applied? Will it be: -

a. Given unconditional clearance

b. Cleared for recycling

c. Cleared for reuse

d. Refused clearance, sent for disposal

e. Refused clearance further decontamination required

f. Other (please give details)

The activated steel is above 0.4 Bq/g and so would not be cleared further decontamination would be required. There is no surface contamination clearance criteria given in the RSA93 however in practice in the UK material with surface contamination of below 4Bq/cm^2 β and 0.4Bq/cm^2 α goes to free release. However none of the steel as given would be released.

References:

Hill M. D., Thorne M. C., Williams P., Leyson-Jones P., *Derivation of UK unconditional clearance levels for solid radioactively contaminated materials*, DETR/RAS/98.004, Department of the Environment, Transport and the Regions Commissioned research for Radioactive Substances Division, UK, April 1999.

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.

Martin A., *Review of compliance of Exemption Orders with requirements of the BSS Directive*, DETR/RAS/99.015, Department of the Environment, Transport and the Regions Commissioned research for Radioactive Substances Division, UK, December 1999.

Thorne M. C., Smith-Briggs J., *Proposed revision of Exemption Orders under the Radioactive Substances Act*, DEFRA/RAS/02.013, Department of the Environment, Transport and the Regions Commissioned research for Radioactive Substances Division, UK, March 2002.

May 2002 (with review and added comment May 2003)

Appendix D - Summary of implementation by Member States and recommended improvements

Implementation by Member States[1]

Evaluation of implementation in the Member States is based on addressing a number of questions relating to the implementation of the concepts of exemption and clearance as outlined below.

Following on from this evaluation, suggestions have been made as to how the application of the concepts could be assisted and improved. The suggestions for improvements are where it is felt a Member State could improve its legislation and better implement the Directive. Advice is also given where it is felt that Members States could improve their legislation for exemption or clearance in the light of the advice from the European Commission. Some Member States have examples of good practice and these are included. Promulgation to other Member States could improve areas of the implementation of the Directive.

Exemption

In the evaluation of exemption the following questions are addressed:

- 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 this 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?

Clearance

In the evaluation of clearance the following questions are addressed:

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

[1] Member States are listed alphabetically using the spelling of their source language see names in brackets i.e. B, DK, D, EL, E, F, IRL, I, L, NL, A, P, FIN, S, UK.

- Does the implementation cover the requirements of the relevant Article 5 of Title III?

- Are specific advantages or weaknesses identifiable in the implementations?

The full titles of the relevant national legislation are listed in Table 1 of the Main report and also in the relevant questionnaire response in Appendix C.

Belgium (Belgique/België) (answers developed by NRG).

Exemption

- New legislation implementing the Directive came into force by the Royal Decree of 20 July 2001 (ARBIS)

- The exemption of practices from regulatory control is dealt with in Chapter II, Art. 3.1 of ARBIS.

- The exemption from reporting and authorisation for installations in which radioactive substances are used or possessed is based on Annex IA of ARBIS.

- Annex IA of ARBIS is consistent with the principles and values of Annex I, Table A of the Directive but is explicitly limited to amounts in the order of 1 tonne from practices.

- Exemption of practices involving the use of sealed sources and apparatus emanating ionising radiation is provided for as in Title III.

Good points:

- Concept of exemption included in current legislation.

- Legislation meets the requirements of the Directive.

- Guidance documents are in place with regard to the regulations.

Areas for improvement:

- Mass limit of 1 t in regulations not absolutely necessary.

- Advice on values for extra nuclides, 10% rule for consideration of nuclides in summation rule, rules for consideration of decay chains needed.

Clearance

- New legislation implementing the Directive came into force by Royal Decree of 20 July 2001 (ARBIS)

- The clearance of solid material from practices from regulatory control, is dealt with in Article 18.1 and Annex IB of ARBIS.

- The nuclide-specific clearance levels for total activity in solids provided in Annex IB:

    - pertain to general clearance,

    - are based on guidance from RP 122, Part I (European Commission, 2000)

    - apply to practices only

- Specific provisions for cleared discharges from authorised practices are laid down in:

    - Annex III, point D and Table H1 for liquid discharges,

    - Annex III, point D and Table H2 for aerial discharges.

It is noted that the clearance levels in Annex IB:

- are based on guidance provided in RP 122, Part I and are stated to fulfil the requirements of Article 5 of Title III regarding the basic criteria for clearance from practices,

- are particularly low for natural radionuclides in view of the normal levels of those radionuclides for instance in building materials.

No information has been obtained on the practical experience with clearance in Belgium.

Good points:

- Concept of general clearance included in current legislation.

- Legislation satisfies requirements of the Directive.

- Decayed storage is allowed for nuclides with half-lives of less than six months.

- Levels based on European guidance documents (RP 122 Part I).

Areas for improvement:

- Need to add provision for surface contaminated material.

- Advice on values for extra nuclides, 10% rule for consideration of nuclides in summation rule, rules for consideration of decay chains, averaging volumes and masses needed.

Denmark (Danmark)

Exemption

- New legislation (Order No 192) came into force May 1st 2002.
- Exemption levels only specified for naturally occurring radioactive substances.
- Annex I, Table A of the Directive is not included.
- Exemption levels for materials containing naturally occurring radionuclides based on guidance of European Commission, RP 122, Part II (European Commission, 2001) are specified in Article 7 of the Order.
- Handling of all other radioactive materials requires prior authorisation, regardless of the amounts involved.
- General exemption of practices involving the use of sealed sources and apparatus emanating ionising radiation is not provided for in this Order. In 1998 the Ministry of Health (now the Ministry of the Interior and Health) published Order No. 708 of 29 September 1998 concerning the use of X-ray installations etc. The National Board of Health in 1999 also amended Order No 918 of 4 December 1995, on the use of sealed radioactive sources in industry, hospitals and laboratories etc with amendments in Order 794 of 19 October 1999. There are also further Orders from the National Board of Health covering apparatus and equipment.

Good points:

- RP 122 Part II values used for NORM.

Areas for improvement:

- Exemption for radionuclides other than naturals needed.
- The Directive Annex I values need to be entered into legislation, along with the requirements for exemption of practices
- Advice on values for extra nuclides, 10% rule for consideration of nuclides in summation rule, rules for consideration of decay chains, averaging volumes and masses needed

Clearance

- New legislation (Order No 192) came into force 1st May 2002.
- No clearance levels have been specified for man-made radionuclides.
- Clearance of substances or materials from authorised practices for disposal, recycling or reuse is dealt with using a case-by-case approach, on the basis of the principles laid down in Annex 3 of Order No. 192. These principles, including the dose criteria are consistent with Annex I of the Directive and reference is made to guidance from the Commission.
- Clearance of substances or materials consisting of naturally occurring radionuclides will be based on a dose criterion of 0.3 mSv y^{-1} effective dose to members of the public as increment to normal radiation background. Reference is made to RP 122, Part II.
- Written approval of recipient is required to show their willingness to accept the cleared material.
- Clearance limits for discharges and waste from non-nuclear practices, hospitals, laboratories are defined by an order of the National Board of Health for:
    - Municipal dumping of solid waste: 10 Bq g^{-1}
    - Discharge into pubic sewer: 10^5 Bq l^{-1} and 5, 50 and 500 MBq/month depending on toxicity class
    - Solid waste for incineration per bag: 5, 50 and 500 MBq depending on toxicity class and $\leq$ 5 μSv h^{-1} on the surface.

Note that, in the past, cleared contaminated scrap containing natural radionuclides has been refused by the intended receiver.

Good points:

- RP 122 Part II values used for NORM.
- Dose criteria from the Directive adopted for non-NPP practices.

Areas for improvement:

- Advice on values for extra nuclides, 10% rule for consideration of nuclides in summation rule, rules for consideration of decay chains, decay storage and averaging volumes and masses needed.

Germany (Deutschland)

Exemption

- New legislation Radiation Protection Ordinance (RPO), came into force 1st August 2001.
- The exemption of practices from authorisation is dealt with in Par. 8 (1) of the RPO.
- The exemption from reporting and authorisation for installations in which radioactive substances are used or possessed is based on Annex I Part A and B of the RPO.
- Annex I Part B of the RPO is consistent with the principles and values of Annex I, Table A of the Directive. The list of radionuclides in Annex III, Table 1 of the RPO has been expanded using the same methodology as used for deriving the values in the Directive. In addition it is explained that 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% (referred to elsewhere in the text as '10% summation rule').
- A specific provision regarding the practical use of the exemption table is that when no exemption levels are provided in Table 1 of Annex III of the RPO the following exemption values may be used:
    - 10^3 Bq and 1 Bq g^{-1} for alpha emitters or nuclides decaying by spontaneous fission,
    - 10^5 Bq and 10^2 Bq g^{-1} for beta and gamma emitters not included below,
    - 10^8 Bq and 10^5 Bq g^{-1} for electron capture nuclides and beta emitters with $E_{\beta max}$ up to 0.2 MeV.
- In addition Annex I, Part A provides exemption from authorisation for the application to humans of substances with specific activities not exceeding 0.5 mBq g^{-1}.
- Exemption of practices involving the use of sealed sources and apparatus emanating ionising radiation is provided for as in Title III.

Good points:

- Concept of exemption included in current legislation.
- Legislation meets the requirements of the Directive.

- Extra radionuclides included in the regulations from those listed in Annex I.

- Provision for the exclusion of radionuclides that do not contribute more than 10% of the summed dose for materials containing many radionuclides (referred to elsewhere in the text as the "10% summation rule").

- Provision for exemption of materials based on alpha/beta content if radionuclides not listed in legislation.

Areas for improvement:

- Advice on rules for consideration of decay chains needed.

Clearance

- New legislation, the Radiation Protection Ordinance (RPO), came into force 1st August 2001.

- The criterion for clearance of substances and materials from practices is an effective dose of 10 $\mu Sv\ y^{-1}$ for individual members of the public (Par. 29, (2)).

- In Germany general as well as specific clearance levels have been set.

- General clearance is regulated in Par. 29 (2) of the RPO with reference to:

  - the values in specified columns of Annex III, Table 1,

  - Annex IV Part A for requirements for the assessment of activity concentration and surface contamination,

  - Annex IV Part C-F for further provisions.

- General clearance is regulated in Par. 29 (2), nr. 1 of the RPO for:

  - Solids with concentrations below the clearance levels of column 5 of Annex III, Table 1 and, if applicable, surface contamination values of column 4 of that table;

  - Liquids with concentrations below the clearance levels of column 5;

  - Building rubble and excavated soil of more than 1000 $t\ y^{-1}$ with concentrations below the clearance levels of column 6 and fulfilling the requirements of Annex IV Part A, nr. 1 and Part F;

  - Soil areas below the clearance levels of column 7 and fulfilling the requirements of Annex IV, Part E;

- Buildings for reuse or further use with surface contamination below clearance levels of column 8 and fulfilling the requirements of Annex IV, Part 1, nr. 1 and Part D.

- Specific clearance is regulated in Par. 29 (2), nr. 2 of the RPO for:
  - Solid substances to be disposed of: compliance with the specific clearance levels in column 9 of Annex III, Table 1 and fulfilling the requirements of Annex IV Part A, nr. 1 and as far as solid surfaces are involved column 4 also applies.
  - Liquids for disposal in an incineration plant: compliance with the specific clearance levels of column 9 of Annex III, Table 1.
  - Buildings to be demolished: compliance with the specific clearance levels in column 10 of Annex III, Table 1 and the requirements of Annex IV, Part A, nr. 1 and Part D;
  - Scrap metal to be recycled: compliance with specific clearance levels in column 10a and the requirements of Annex IV, Part A, nr. 1 and Part G and in case of surface contamination column 4 also applies.

- Dose constraint criterion for discharges from practices:
  - Dose limit for members of the public are laid down in Par. 47 (1) that specifies 0.3 mSv y^{-1} effective dose and further limits for organ doses.
  - For establishments not operating under authorisation required by the Atomic Energy Act, the competent authorities may assume that the dose criteria of Par. 47 (1) are met if the discharges into air and water comply with the provisions of Annex VII Part D and may refrain from imposing requirements to determine activities and activity concentrations.
  - Annex VII, Part D provides rules for limitation of activity concentrations in air and water at the point of discharge from the establishment based on Table 4, 5 and 6 of the Annex.

- Release of residues from work activities that required surveillance is dealt with in Par. 98 of the RPO.

- The basic criterion for release of residues that required surveillance is that, as a result of the release, without further measures, members of the public are not exposed to an effective dose in excess of 1 mSv y^{-1}.

- The competent authorities can assume that for mixed disposal of residues requiring surveillance, with other residues or wastes, the dose criterion is met in specified cases.

- For these cases the average activity concentrations of the radionuclides of the decay chains of ^{238}U and ^{232}Th with the highest concentration, can be calculated as the total activity disposed of with the residues requiring surveillance in 12 months, divided by the total mass of all residues and wastes disposed of in that period. To this calculated average concentration C^M the rule applies:

  $C^M_{U\text{-}238max} + C^M_{Th\text{-}232max} \leq C^M$.

  With the following values for C^M:

  - $C^M = 0.05$ Bq g^{-1} for land fills with a surface area of more than 15 hectare;
  - $C^M = 0.1$ Bq g^{-1} for land fills with a surface area of less than 15 hectare;
  - $C^M = 1$ Bq g^{-1} independent of surface area for land fills isolated by specific measures from contamination of ground water;
  - $C^M = 5$ Bq g^{-1} for underground disposal;

- In addition the following provisions apply to mixed disposal of residues requiring surveillance:

  - The specific activity of any of the radionuclides from the decay chain of ^{238}U and ^{232}Th may not exceed 10 Bq g^{-1} and 50 Bq g^{-1}respectively, in the case of landfills for specific wastes requiring surveillance.
  - If in a specific batch of residue the specific activity of $^{210}Pb+$ is a factor of five higher than that of the other radionuclides of the ^{238}U decay chain, the total activity of that batch may be calculated as described previously with an additional reduction factor R applied to the calculated $C^M_{U\text{-}238max}$ for the batch considered. R takes the value of:
    - $R = 0.3$ for disposal at land fills,
    - the factors provided in the table in Annex XII, Part B, nr. 4 for underground disposal.
  - If in a specific batch of residue the specific activity of all radionuclides of the decay chains of ^{238}Usec or ^{232}Thsec is below 0.2 Bq g^{-1}, that decay chain can be omitted in the summing.

- Actual clearance or release will require written proof to be provided by the applicant that the receiver who will process or dispose the material to be cleared, or the residue to be released, will indeed accept the material.

- Notwithstanding compliance with the provisions of the RPO any actual clearance or release also has to comply with the provisions of the Law on Recycling and Waste Management, and regulations based on that Law, with respect to the non-radioactive constituents of the residues.

Good points:

- Specific and general clearance values provided, based on European Commission guidance reports (but not exactly).
- Definition of measuring volumes and areas in the regulations.
- General clearance levels for surface contamination given.
- Clearance for disposal to landfill for naturals detailed for various activity concentrations with respect to types of landfill. Guidance on how the contributions from the natural chains are to be calculated.

Areas for improvement:

- Decay storage advice needed.

Greece (Elláda)

Exemption

- New legislation implementing the Directive is laid down in the Radiation Protection Regulations enforced in the form of a Joint Ministerial Order (No 1014(ϕOP)94), Official Gazette No 216B, of 6th March 2001 (RPR).
- The exemption of practices from regulatory control is dealt with in Par. 1 of the RPR.
- The exemption from reporting and authorisation for installations in which radioactive substances are used or possessed is based on Annex I of the Directive.
- The Annex providing exemption conditions is consistent with the principles and values of Annex I of the Directive.
- Exemption of practices involving the use of sealed sources and apparatus emanating ionising radiation is provided for as in Title III.

Good points:

- Concept of exemption included in current legislation.
- Legislation meets the requirements of the Directive.

Areas for improvement:

- Advice on values for extra nuclides, 10% rule for consideration of nuclides in summation rule, rules for consideration of decay chains, averaging volumes and masses needed.

Clearance

- New legislation implementing the Directive is laid down in the Radiation Protection Regulations enforced in the form of a Joint Ministerial Order (No 1014(ϕOP)94), Official Gazette No 216B, of 6th March 2001 (RPR).
- The clearance of radioactive substances from practices is regulated in Par. 6.1.3 of the RPR.
- Par. 6.1.3 of the RPR states that radioactive substances complying with the exemption values of Annex I, Table A of the RPR are not considered as radioactive waste (clearance levels equal to exemption levels).
- Annex I, Table A of the RPR is based on Annex I, Table A of the Directive.
- Cleared liquid discharges from authorised practices into a public sewer are regulated in Par. 6.2 of the RPR:
    - The total concentration may not exceed 1 GBq m^{-3};
    - The maximum discharge may not exceed the levels provided in Table 6.1 or in special circumstances the daily maximum for different types of laboratories.
- Cleared discharges from authorised practices into the air are regulated in Art. 6.7 of the RPR.
    - The average activity discharged per day may not exceed the levels specified in Table 6.1 of the RPR. (*Table 6.1 seems however to pertain to discharges into a public sewer*).
- The clearance of solid radioactive waste from practices not to be reused is regulated in Art. 6.6 of the RPR.
    - The activity concentrations should not exceed the levels provided in Table 6.2 of the RPR.
    - The activity concentration values specified in Table 6.2 of the RPR are for a number of radionuclides identical to those provided as guidance on general clearance in RP 122, Part I, and lower or higher for others.

- Table 6.2 contains short-lived radionuclides also occurring in Annex I of the Directive but not in RP 122, Part I. The usefulness of their inclusion in a table of clearance levels is doubtful.

Good points:

- Specific and general clearance values provided, based on RP 122 Part I, with only a few deviations.
- Decayed storage is allowed.

Areas for improvement:

- Advice on values for extra nuclides, 10% rule for consideration of nuclides in summation rule, rules for consideration of decay chains, averaging volumes and masses needed.

Spain (España)

Exemption

- New legislation implementing the Directive came into force by Royal Decree (RD) No.1836 of 3rd December 1999.
- The exemption of practices from regulatory control is dealt with in Article 34 that refers to Annex I of the RD.
- 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). Category 2 and 3 premises using unsealed sources correspond for example to small industries and users of radionuclides such as universities and hospitals.
- The exemption from reporting and authorisation for installations in which radioactive substances are used or possessed is based on Table A of Annex I of the RD.
- Annex I, Table A of the RD is consistent with the principles and values of Annex I, Table A of the Directive.
- Exemption of practices involving the use of sealed sources and apparatus emanating ionising radiation is provided for, as in Title III, in Annex I and Annex II of the RD.

Good points:

- Concept of exemption included in current legislation
- Legislation meets the requirements of the Directive.

- Exemption values for extra nuclides not covered by the Directive have been published in the Spanish Official Journal, BOE of 10th April 2003. The values have been taken from NRPB-R306 (Mobbs et al, 1999).

- Rules for the consideration of decay chains were also given in the Spanish Official Journal, BOE of 10th April 2003.

Areas for improvement:

- Advice on the 10% rule for consideration of nuclides in summation rule, averaging volumes and masses needed.

Clearance

- New legislation implementing the Directive came into force by the Royal Decree (RD) No. 1836 of 3rd December 1999 and provides the framework for implementing clearance.

- Guidance on the clearance of solid radioactive residues from small industries and users of radionuclides such as universities and hospitals (Category 2 and 3 premises under Spanish legislation) are given in Spanish Guide 9.2 of 12th December 2001.

- Guide 9.2 provides in its annex clearance levels identical to the generic clearance levels for solid wastes provided in IAEA-TECDOC-1000 (IAEA, 1998). CSN Guide 9.2 is in the form of a recommendation to potential users, and would require a legal dispensation to be in force.

- The values in the annex of Guide 9.2 (which is specific clearance) are several orders of magnitude higher than those in RP 122, Part I for general clearance.

- The values in the Annex of Guide 9.2 cover only a limited number of radionuclides and apply to amounts less than 3 tonnes per establishment per year as in IAEA-TECDOC-1000 (IAEA, 1998).

- Interim storage is allowed for a period of 5 years.

- Clearance of materials from Nuclear Power Plants (NPP) is organised in the "Common Project"[2] for each potentially clearable waste stream.

- Guidance RP 89 (European Commission, 1998) and RP 113 (European Commission, 2000b) on specific clearance levels for metal scrap and building rubble have been used in the Common Project.

[2] A description of the "common project" was provided by the Spanish in their response to the questionnaire, see Appendix C (specifically answers to questions 4 and 6 and to annex 1 provided in the Spanish reply)

- Specific clearance levels based on RP-89 and RP-113 have been used on a case-by-case basis to clear steel scrap for recycling and building rubble. Specific clearance levels, derived through a radiological impact study for the clearance of active charcoal, ion exchange resins and oil from a NPP have also been used on a case-by-case basis.

Good points:

- Guidance has been issued.
- Specific clearance levels are in use.
- Storage is allowed for periods up to 5 years.
- A methodology (see "Common Project") has been established to derive clearance levels for many waste streams for all NPP by means of a collaboration among operators with the co-operation of the regulator.

Areas for improvement:

- Clearance is based on a case-by-case approach or using levels equal to those in TECDOC-1000 (although these values are currently listed in a guide and not in legislation). The use of values from TECDOC-1000 is inconsistent with current European Commission advice as the clearance levels are higher than those described in RP122 Part I. TECDOC-1000 also specifies the use of a 3 t mass limit. Although some use has been made of European Commission reports on a case-by-case basis the use of levels from other sources should be reviewed with a view to improving the harmonisation with European Commission guidance where available.
- Advice on values for extra nuclides, 10% rule for consideration of nuclides in summation rule, rules for consideration of decay chains, averaging volumes and masses needed.

France

Exemption

- New legislation implementing the Directive is laid down in the Decree N^{o} 2002-460 of 4th April 2002.
- The exemption of practices from regulatory control is dealt with in Article R. 43-22 of the Decree.
- The exemption from authorisation for installations in which radioactive substances are used or possessed is based on Annex 2 of the Decree.

- Annex 2 of the Decree is consistent with the principles and values of Annex I, Table A of the Directive but is explicitly limited to amounts in the order of 1 tonne from practices (Article R. 43-22, 1^{o}, (b)).

- Exemption of practices involving the use of sealed sources and apparatus emanating ionising radiation is provided for Article R. 43-22 as in Title III.

Good points:

- Concept of exemption included in current legislation

- Legislation meets the requirements of the Directive.

Areas for improvement:

- Mass limit of 1 t in regulations not really needed

- Advice on values for extra nuclides, 10% rule for consideration of nuclides in summation rule, rules for consideration of decay chains, averaging volumes and masses needed.

Clearance

- The concept of clearance is implemented by Ordinance No 2001-270 of the 28^{th} March 2001

- The new legislation covering the implementation of the Directive is not yet complete but will not include the establishment of general clearance levels for materials from practices nor from work activities.

- Clearance of materials from practices is approached on a case-by-case basis with different systems for nuclear and non-nuclear practices.

- Information obtained suggests a novel approach. It is not envisaged that threshold levels for the clearance of radioactive wastes will be established. 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 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 $10\mu Sv\ y^{-1}$.

Good points:

- Allowance made for decay storage for radionuclides with half-lives less than 100 days.

- Idea of defining zones within a site from where wastes could originate so that the type of waste can be identified.

Areas for improvement:

- Implementation of clearance levels to be considered.
- Clearance to be recognized for all practices.
- Advice on values for extra nuclides, 10% rule for consideration of nuclides in summation rule, rules for consideration of decay chains, averaging volumes and masses needed.

Ireland

Exemption

- New legislation implementing the Directive has been laid down in the Radiological Protection Act, 1991 (Ionising Radiation) Order, 2000 (S.I. No. 125 of 2000) (IRO).
- The exemption of practices from regulatory control is dealt with in Art. 4 of the IRO.
- The exemption from reporting and authorisation for installations in which radioactive substances are used or possessed is based on Schedule 5 of the IRO.
- Schedule 5 of IRO is a direct reproduction of the whole of Annex I including Table A of the Directive, and so is fully consistent with the Directive.
- All practices involving the use of sealed sources and apparatus emanating ionising radiation is provided for in Article 5.1 as in Title III.

Good points:

- Concept of exemption included in current legislation
- Legislation meets the requirements of the Directive.

Areas for improvement:

- Guidance documents needed.
- Advice on values for extra nuclides, 10% rule for consideration of nuclides in summation rule, rules for consideration of decay chains, averaging volumes and masses needed.

Clearance

- The concept of clearance levels is 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 will be approached on a case-by-case basis.
- There is no facility in Ireland to dispose of materials as radioactive waste.

Good points:

- Concept of clearance recognised.

Areas for improvement:

- Concept of clearance is only incorporated on a case-by-case basis; this could be changed so that it is generally applicable.
- Guidance documents needed.
- Advice on values for extra nuclides, 10% rule for consideration of nuclides in summation rule, rules for consideration of decay chains, decay storage and averaging volumes and masses needed.

Italy (Italia)

Exemption

- New legislation implementing the Directive is laid down in Legislative Decree 230 of 1995 as amended by Legislative Decree no 241 of 2000 (LD).
- Practices are exempt from the scope of the LD on the basis of provisions laid down in Annex I, par. 1-5 of LD no. 230, in Article 1 par. 2-bis of LD 230 and in Article 36 of LD 241.
- The exemption from the scope of radiological protection legislation is determined by overall numerical threshold values, i.e. material must meet the following criteria to be included within the scope:
    - Total activity concentration for all the radionuclides: ≥ 1 Bq g^{-1} and
    - Total activity $\geq$ the values from Directives 84/467/Euratom (European Commission, 1984) or 96/29 Euratom (European Commission, 1996), whichever is smaller.

- The exemption from reporting for installations in which radioactive substances are used or possessed is based on LD 230, pursuant to Article 22, to Annex VII, par. 4 and Tables VII-1 and VII-2.

- The provisions for exemption indicated in 2.8.4 are consistent with the principles and values of Annex I, Table A of the Directive.

- Exemption of practices involving the use of sealed sources and apparatus emanating ionising radiation is provided for in Art 22 of LD 230 as in Title III.

Good points:

- Concept of exemption included in current legislation.

- Legislation meets the requirements of the Directive.

Areas for improvement:

- Some values based on 84/467/Euratom, which has been superseded by 96/29/Euratom. All values need to be checked to make sure that they are consistent with the current Euratom Directive.

- Advice on values for extra nuclides, 10% rule for consideration of nuclides in summation rule, rules for consideration of decay chains, averaging volumes and masses needed.

Clearance

- Clearance of materials from practices has to comply with Article 154, Par. 2 of the Legislative Decree 230 of 1995 as amended by the Legislative Decree no. 241 of 26th May 2000.

- Materials from practices can be <u>unconditionally</u> cleared for discharge, recycling, reuse or as waste if the two conditions are met:

    - Activity concentration of all radionuclides ≤ 1 Bq g^{-1} and

    - Half-life ≤ 75 days.

- If the conditions specified above are not met clearance of materials requires prior authorisation and relevant technical specifications are established in the licence.

- In defining the technical specifications for authorised clearance the Directives of the European Union and the technical guidance provided by the Commission have to be taken into account.

- Thresholds for authorised clearance of materials from a specific nuclear power plant have been set for scrap, building material (activity concentration and surface contamination) and for other materials within the constraint of ≤ 1 Bq g^{-1} and the total activities as provided in Directive 84/467 Euratom or 96/29/Euratom (levels for exemption of practices).

- The clearance levels set for the materials indicated above are equal to those provided as guidance in RP 89, RP 113 and RP 122 Part I for a number of radionuclides but considerably lower for others.

Good points:

- Concept of general clearance included in current legislation

- Legislation satisfies requirements of the Directive.

- Italian regulations for clearance require the disposer to negotiate with the foundry for disposal of scrap metal, thus preventing rejection of the metal.

- Decayed storage allowed for radionuclides with half-lives less than 75 days.

- Some guidance documents issued for nuclear sites

Areas for improvement:

- Guidance documents for other sites needed.

- Where possible clearance levels should be harmonised with those recommended by the European Commission.

- Advice on values for extra nuclides, 10% rule for consideration of nuclides in summation rule, rules for consideration of decay chains, averaging volumes and masses needed.

Luxembourg

Exemption

- New legislation implementing the Directive came into force by the Regulation of the Grand Duchy of 14 December 2000 (RGD).

- The exemption criteria and levels specified in Annex 2 of the RGD are identical to those of Annex I of the Directive.

- The exemption levels from Annex 2, Table A for total activity as well as mass activity are used for the classification of practices requiring different levels of control (Article 2 of RGD):

- Practices involving materials with an activity level below 1/100 of the exemption level are excluded from reporting and authorisation requirement;
- Practices involving materials with an activity level between the exemption level and 1/100 of the exemption level require prior reporting;
- Practices involving materials with an activity level > the exemption levels require prior authorisation.
- Work activities involving materials containing natural radionuclides with a total mass concentration of long-lived mother radionuclides > 100 Bq g^{-1} require prior authorisation. This refers to the 'old' Directive 84/467/Euratom and is much higher than the activity concentration proposed in RP 122 Part II.

- Exemption of practices involving the use of sealed sources and apparatus emanating ionising radiation is provided for Article 2.1 of RGD as in Title III.

Good points:

- Concept of exemption included in current legislation
- Legislation meets the requirements of the Directive

Areas for improvement:

- No guidance documents have been issued.
- It is recommended that for exemption of materials in work activities reference is made to the recently published RP 122 Part II.
- Advice on values for extra nuclides, 10% rule for consideration of nuclides in summation rule, rules for consideration of decay chains, averaging volumes and averaging masses needed.

Clearance

- New legislation, the Regulation of the grand duchy of 14 December 2000 (RGD), implemented the Directive.
- Levels for general clearance of materials from authorised practices and practices requiring reporting are specified in Article 2.12.
- The criteria for clearance are the same as for exemption specified in Annex 2 of the RGD and are based on the Directive.

- The clearance levels in Annex 2 of the RGD are based on recommendations of German Commission on Radiological Protection (SSK), and pertain to activity concentration (Table A) and surface contamination (Table B).

- The clearance levels apply to general clearance of amounts not exceeding 1 t and dilution with non-radioactive material to reduce the original activity concentration is not allowed.

- For specific (conditional) clearance higher levels can be set by the competent authorities on a case-by-case basis for material exceeding the general clearance level and/or exceeding the amount of 1 t.

- The general clearance levels for naturally occurring radionuclides are set at levels which occur quite normally in building materials and soil.

- If the clearance levels for natural radionuclides were applied with the summation rule of Annex 2 of the RGD, general clearance of building material and soil would become practically impossible.

- The clearance levels in principle apply to practices as well as work activities and are consequently based on the same dose criteria.

- Clearance of materials from medical establishments and laboratories is responsibility of the users. Guidance is needed for evaluation of specific activity.

Good points:

- Concept of general clearance included in current legislation.

- Legislation satisfies requirements of the Directive.

- Decay storage allowed for short lived radionuclides

- Clearance levels for surface activity given

Areas for improvement:

- Mass limit of 1 t in regulations for general clearance, needs to be removed as soon as possible

- General clearance levels for NORM need to be changed to RP 122 Part II to avoid problems with natural levels normally found in uncontaminated soil/building rubble.

- A review of the clearance levels currently in the legislation is required to make sure that the criteria for clearance are compatible with advice from the European Commission (RP 122 part I for example).

- Guidance required on the evaluation of specific activity.

- Advice on values for extra nuclides, 10% rule for consideration of nuclides in summation rule, rules for consideration of decay chains, averaging volumes and masses needed.

Netherlands (Nederland)

Exemption

- New legislation implementing the Directive is laid down in the Royal Decree on radiation protection (BS) of 16th July 2001 that came into force 1st March 2002.

- The exemption of solids in practices, but not discharges from practices, involving radioactive substances from authorisation requirements is dealt with in Article 25 of BS.

- The exemption of these practices from authorisation is based on Annex 1 of BS.

- Annex 1 of BS is consistent with the exemption principles of the Directive but the exemption levels for several radionuclides are set in Table 1 at values different from those in Annex I, Table A of the Directive: ^{228}Ra, ^{226}Ra and ^{60}Co at a 10 times lower value and ^{210}Pb and ^{210}Po at a ten times higher value (see Appendix C, p C-82 for details). ^{210}Pb and ^{210}Po values are high when compared to those recommended in RP 122 Part II.

- The exemption values in Annex 1 of BS apply to practices as well as work activities.

- The exemption from reporting requirements of work activities is set at a weighted sum of both activity and specific activity of 1.

- The exemption from authorisation requirements is set at a weighted sum of activities of 1 and of weighted specific activity of 10.

- Specific provisions apply to how to sum activities and concentrations of natural decay chains and which radionuclides can be disregarded (similarities with RP 122 Part II where the ^{235}U decay chain is disregarded).

- The exemption values in Annex 1 of BS apply also to clearance.

- Exemption of practices involving the use of sealed sources and apparatus emanating ionising radiation is provided for in Article 21, 23 and 26, consistent with Title III.

- Employers are required to establish the exposure of their workers in work activities and to establish whether the materials they keep or process exceed

the exemption levels specified in BS. If doses exceed 1 mSv y^{-1} and/or when the exemption levels are exceeded, the reporting requirements apply.

Good points:

- Concept of exemption included in current legislation
- Legislation meets the requirements of the Directive
- Guidance on how to calculate/sum activities in natural decay chains given.

Areas for improvement:

- Some exemption values differ from the Directive Annex I; there is a need to be consistent with the Annex I values or with the criteria used in the derivation of the Annex I values.
- Advice on values for extra nuclides, 10% rule for consideration of nuclides in summation rule, rules for consideration of decay chains, averaging volumes and masses needed.

Clearance

- New legislation implementing the Directive is laid down in the Royal Decree on radiation protection (BS) of 16th July, 2001 that came into force 1st March 2002
- Exemption levels provided in Annex 1, Table 1 apply also to general clearance, but not to discharges.
- The clearance levels of Annex 1, Table 1 apply to practices as well as work activities.
- The clearance levels of Annex 1, Table 1 are based on Annex I, Table A of the Directive but are set at 10 times lower levels for ^{228}Ra, ^{226}Ra and ^{60}Co and at 10 times higher levels for ^{210}Pb+ and ^{210}Po. (See Table 7 in the main report for a comparison of selected nuclides).
- The clearance levels of Annex 1, Table 1 of BS comply with a dose constraint of 10 μSv y^{-1} for members of the public for practices.
- The exemption/clearance levels of Annex 1, Table 1 of BS comply with a dose constraint of 300 μSv y^{-1} for members of the public for work activities.
- The general clearance level for materials from work activities (not discharges) is set at a weighted sum of both activity and specific activity of 1.
- If the total activity exceeds the level specified in Annex 1, Table 1 and the activity concentration is below 10 times the level specified in that table

materials can be cleared under the reporting requirements in the draft Ministerial regulation, which has not yet been finalised as of 18th March 2003.

- Specific provisions apply to how to sum activities and concentrations of natural decay chains and which radionuclides can be disregarded.

- Cleared levels of discharges into air and water from work activities are specified in Annex 1, Table 2 of BS.

- Cleared levels of discharges from work activities are based on a dose criterion of 10 μSv y^{-1} effective dose to members of the public.

- Cleared discharges from practices are expressed as radiotoxicity equivalents explained in Annex 2 of BS, and set at different levels for different discharge conditions.

Good points:

- Specific and general clearance in regulations.

- Practices and work activities considered.

- Guidance on how to calculate/sum activities in natural decay chains given.

Areas for improvement:

- Where possible clearance levels should be harmonised with those recommended by the European Commission.

- Surface contamination needs to be considered, (as it is currently being considered for NORM).

- Advice on values for extra nuclides, 10% rule for consideration of nuclides in summation rule, rules for consideration of decay chains, decay storage and averaging volumes and masses needed.

Austria (Österreich)

Exemption

- New legislation implementing the Directive is laid down in the Radiation Protection-EU-Adaptation Law (RPAL) 2002 of 20th August 2002, which will come into force on 1st January 2003.

- The new Radiation Protection Ordinance (RPO), (Strahlenschutzgesetz), is expected to come into force January/February 2003.

- It is not yet clear how the principle of exemption will be implemented in the new RPO but Annex I of the Directive is likely to be included and applied to practices.

Good points:

- Legislation too recent to analyse.

Areas for improvement:

- Guidance documents needed.
- Advice on values for extra nuclides, 10% rule for consideration of nuclides in summation rule, rules for consideration of decay chains, averaging volumes and masses needed.

Clearance

- New legislation implementing the Directive is laid down in the Radiation Protection-EU-Adaptation Law (RPAL) of 20th August 2002, which will come into force on 1st January 2003.
- The new Radiation Protection Ordinance (RPO), (Strahlenschutzgesetz), is expected to come into force January/February 2003 and at the time of this evaluation still an incomplete draft.
- Provisions for clearance of materials from practices are given in Par. 13a of the draft RPO:
    - Clearance of these materials depends on approval by the competent authority.
    - General clearance is expected to be based on a dose constraint of 10 $\mu Sv\ y^{-1}$ effective dose for members of the public (1/100 of the dose limits for members of the public).
    - The State Minister for Agriculture and Forestry, Environment and Water Management lays down conditions under which it can be assumed that the dose criterion is met.
    - The conditions to meet the criteria for clearance may not be attained by wilful dilution.
- 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.

- It is not yet sure if the new RPO will incorporate guidance on clearance from the European Commission.

Good points:

- Decay storage allowed.

Areas for improvement:

- Clearance needs to be implemented in legislation as soon as possible, and be harmonised with guidance from the European Commission.
- Guidance documents needed.
- Advice on values for extra nuclides, 10% rule for consideration of nuclides in summation rule, rules for consideration of decay chains, averaging volumes and masses needed.

Portugal

Exemption

- New legislation implementing the Directive is laid down in Legislative Decree 165/200 (LD).
- LD adopts the same scope as the Directive.
- The exemption from reporting and authorisation for installations in which radioactive substances sources are used or possessed and practices involving apparatus and sealed is dealt with in Chapter III, Article 8, Par. 1 of the LD.
- Article 8 Par. 1 does not specify exemption conditions as in Art. 3 of the Directive but stipulates that exemptions can be regulated in specific legislation.

Good points:

- Concept of exemption included in current legislation.

Areas for improvement:

- Annex I values should be adopted.
- Guidance documents needed.
- Advice on values for extra nuclides, 10% rule for consideration of nuclides in summation rule, rules for consideration of decay chains, averaging volumes and masses needed.

Clearance

- New legislation implementing the Directive is laid down in Legislative Decree 165/200 (LD).
- LD adopts the same scope as the Directive.
- The LD contains no provisions for clearance.

Good points:

- None

Areas for improvement:

- Clearance needs to be implemented in legislation as soon as possible.
- Advice on values for extra nuclides, 10% rule for consideration of nuclides in summation rule, rules for consideration of decay chains, averaging volumes and masses needed.

Finland (Suomi)

Exemption

- The Radiation Act 592/1991 (RA-1991), which applies to practices in which radiation or nuclear reactions are not used as a source of nuclear energy, lists a number of practices exempt from authorisation (safety licence), in section 17.
- Radiation Safety Guides (ST Guides) are issued by STUK under Section 70 of the Radiation Act 592/1991 (RA-1991). The Radiation Act stipulates that the levels of safety specified in these ST Guides must be attained and maintained.
- The exemption of practices from regulatory control is dealt within STUK Guide ST 1.5.
- The exemption from the requirements of having a safety license and reporting for installations in which radioactive substances are used or possessed, is laid down in ST 1.5, section 2.1.
- ST 1.5, section 2.1 with its associated annexes is consistent with the principles and values of Annex I, Table A of the Directive.
- The exemption provisions do not apply to work activities or to the use of nuclear energy.
- Exemption of practices involving the use of sealed sources and apparatus emanating ionising radiation is provided for in ST 1.5 and in ST 5.4 (on trade in radiation sources) consistent with Title III.

Good points:

- Concept of exemption included in current legislation.
- Legislation meets the requirements of the Directive.
- Large number of guides.
- List of exempt practices provided in the Legislation.

Areas for improvement:

- 10% rule for consideration of nuclides in summation rule, rules for consideration of decay chains, averaging volumes and masses needed.

Clearance

- Radiation Safety Guides (ST Guides) are issued by STUK under Section 70 of the Radiation Act 592/1991 (RA-1991), which applies to practices in which radiation or nuclear reactions are not used as a source of nuclear energy.
- Section 23 of RA-1991 authorises STUK to issue limits for quantities of radioactive substances discharged into the air, sewage systems or otherwise in the environment.
- Guide ST 1.5 (1999) on exemption of non-nuclear practices states that the exemption levels provided do not apply in the case of clearance for final disposal, reuse or recycling of radioactive substances from practices nor for materials from work activities.
- Clearance of materials from non-nuclear practices requiring reporting or authorisation must have approval of STUK.
- The same basic criteria as laid down for exemption in Appendix C of ST 1.5 must be met in clearance.
- Activity concentrations in materials to be cleared must not exceed the values provided in the guidance on clearance from the European Commission and can be significantly lower than the exemption levels provided in Appendix A of ST 1.5 which are identical to Annex I, Table A of the Directive.
- Guide YVL 8.2 prescribes the general principles to be applied in prospective planning and in clearing waste containing very low concentrations of radioactive substances. This guide is applicable to waste resulting from nuclear power generation and provides three categories of limits for alpha emitters, weak beta and gamma emitters and significant beta and gamma emitters.

Good points:

- Large number of guides.
- General and specific clearance allowed.
- Surface contamination clearance levels defined.

Areas for improvement:

- 10% rule for consideration of nuclides in summation rule, rules for consideration of decay chains, decay storage and averaging volumes and masses needed.

Sweden (Sverige)

Exemption

- The principle of exemption has been implemented in the Swedish Radiation Protection Ordinance (RPO) 1988:293 incorporating amendments up to and including SCS 2001:618 that came into force 1st September 2001.
- Provisions for exemption from the licensing requirement specified in the Radiation Protection Act (1988:220), are laid down in RPO, par. 2.
- Exemption for practices in which radioactive substances are used or possessed is based on the Appendix of RPO, which is identical to Annex I, Table A of the Directive, but does not provide the principles nor a clear explanation what progeny is included as is provided in Annex I, Table B of the Directive.
- Exemption of practices involving the use of sealed sources and apparatus emanating ionising radiation is provided for in the RPO consistent with Title III.

Good points:

- Concept of exemption included in current legislation.
- Legislation meets the requirements of the Directive.

Areas for improvement:

- Guidance on what progeny should be considered when using the RPO needed; e.g. reference to the Directive (Annex I, Table B).
- Advice on values for extra nuclides, 10% rule for consideration of nuclides in summation rule, rules for consideration of decay chains, averaging volumes and masses needed.

Clearance

- Clearance is not specifically defined in the Swedish Radiation Protection Ordinance (RPO) (incorporating amendments up to and including SCS 2001:618), which came into force 1st September 2001.

- Par. 7 and 8 of the RPO appoint the Radiation Protection Authority (SSI) as the competent authority for issuing regulations required for protection against, or control of, radiation and regulations concerning radioactive waste etc.

- SSI FS 1996:2 provides clearance levels for materials from nuclear installations:

    - Levels based on IAEA-TECDOC-855 (IAEA, 1996) and on a dose criterion of 10 μSv y^{-1}.

    - Levels provided for:

        - general clearance (0.5 kBq kg^{-1} beta/gamma, 0.1 kBq kg^{-1} alpha and surface contamination limits of 40 kBq m^{-2} and 4 kBq m^{-2} respectively.)

        - disposal as waste (5 kBq kg^{-1} beta/gamma, 0.5 kBq kg^{-1} alpha and 1 GBq y^{-1} total per site)

        - incineration of oil (5 kBq kg^{-1} beta/gamma, 0.1 kBq kg^{-1} alpha and 0.5 GBq y^{-1} per site)

- SSI FS 1983:7 provides clearance levels for solid waste and discharges from non-nuclear practices expressed as total activities and as minimum values of the annual limits on intake (ALI_{min}) for workers based on ICRP Publication 30 (ICRP, 1980) and included as Annex 1 of FS 1983:7.

Good points:

- Area for measurement defined, and clearance levels for surface contamination given.

- Levels provided for general radiation (alpha, beta/gamma).

- Some guidance documents issued.

- General and specific clearance allowed.

- Decay storage allowed.

Areas for improvement:

- Where possible clearance levels should be harmonised with those recommended by the European Commission.

- Clearance guidance is needed for although the existing legislation in the form of SSI FS 1983:7 relates to the non-nuclear industry and guidance is incorporated in it. In the questionnaire SSI identified a need for regulations on clearance of materials from non-nuclear activities and clearance of large amounts of material arising from decommissioning of nuclear facilities. SSI has also identified the need for review of the existing regulations in the light of the European Commission recommendations on clearance.

- Advice on the 10% rule for consideration of nuclides in summation rule needed.

United Kingdom

Exemption

- Exemption principles are incorporated in the Ionising Radiations Regulations (IRR99) that came into force 1st January 2000.

- According to Reg. 3 the scope of the IRR99 extends to

    - any practice

    - any work involving specified levels of exposure to radon and short-lived radon daughters

    - any other work with any radioactive substance containing naturally occurring radionuclides.

- Exemption of practices from notification is regulated in Reg. 6, which refers to Schedule 1.

- Schedule 1 exempts work involving radioactive substances from notification on the basis of Schedule 8 Part 1.

- The exemption levels of Schedule 8 are identical to those of Annex I, Table A of the Directive; values for other radionuclides were derived on the same basis as the values from the Directive and included.

- Exemption of practices involving the use of sealed sources and apparatus emanating ionising radiation is provided for in Schedule 1 consistent with Title III.

- To accompany IRR99 an approved code of practice has been issued and within this it is explained (para 11) that employers are required to establish the exposure of workers or other persons resulting from work with naturally occurring radionuclides and only if exposures can exceed 1 mSv y^{-1} do the provisions of IRR99 apply.

Good points:

- Concept of exemption included in current legislation.
- Legislation meets the requirements of the Directive.
- Guidance issued.
- Extra radionuclides included.
- Regulations apply to both practices and work activities (if above 1 mSv y^{-1}).

Areas for improvement:

- Advice on values for extra nuclides, 10% rule for consideration of nuclides in summation rule, rules for consideration of decay chains, averaging volumes and masses needed.

Clearance

- Disposal of radioactive waste is controlled and regulated under the Radioactive Substances Act 1993 (RSA93).
- Prior authorisation by the appropriate regulatory authority is required for the keeping and use of radioactive materials (Reg. 6).
- Radioactive materials, not being wastes, are defined in Reg. 1, which refers to Schedule 1 of RSA93 for materials containing natural radionuclides that should be regarded as 'radioactive materials' on the bases of activity concentration levels being exceeded for specified elements in solids, liquids and gases or vapours.
- Within the current UK framework the Schedule 1 (RSA93) values could also be viewed as unconditional clearance levels (Hill et al, 2000). Such clearance levels allow the unrestricted disposal, re-use or recycling of solid materials, with no further control once the material leaves the originating facility or practice being regulated (Hill et al, 2000).
- Disposal of radioactive waste requires authorisation from the appropriate agency according to Reg. 13.
- Exemption from authorisation requirement to dispose of and accumulate radioactive waste is laid down in Reg. 15 for:
    - Radioactive waste from clocks or watches not resulting from their production or repair,
    - Particular descriptions of radioactive waste as may be specified by the Secretary of State in an Order; currently there are 18 such orders.

- The Exemption Orders (Reg. 15(2)) may exclude particular descriptions of radioactive waste from the provision relating to disposal (Reg. 13 or 14) either absolutely (general clearance) or subject to limitations or conditions these Orders could be regarded as granting generic authorisation under Article 5.1, by reference to the mechanism permitted under Article 4.3(b) (Martin, 1999).

- The Radioactive Substances (Substances of Low Activity) Exemption Order 1986 No 1002 as amended by the Order 1992 No. 647, (EO(SoLA)) excludes from authorisation requirements the disposal as waste of:

    - a solid, other than a closed source, which is substantially insoluble in water, the activity of which when it becomes waste, does not exceed 0.4 Bq g^{-1},

    - an organic liquid waste which is radioactive solely because of the presence of ^{14}C or tritium or both at a level not exceeding 4 Bq ml^{-1},

    - a gas containing radionuclides none of which, nor the decay products of which, has a half-life greater than 100 seconds.

    - In determining the activity of any solid radioactive material or waste for the purpose of applying this Exemption Order (EO) to disposal of solids the activities of the elements in Schedule 1 of the Order can be disregarded to the extent that they do not exceed the levels specified in column 2 of Schedule 1 which are identical to the exemption levels for solids containing naturally occurring radioactive elements provided in Schedule 1 of RSA93. These values are:

Element	Ac	Pb	Po	Pa	Ra	Th	U
Bq g^{-1}	0.37	0.74	0.37	0.37	0.37	2.59	11.1

    - Discharges below the exemption levels specified in Schedule 1 of RSA93 can be regarded as clearance levels as they are outside the scope of the regulations. These levels are provided for naturally radioactive elements only and are given as elemental activity concentrations for liquids as well as gasses and vapours. These values are $3.70.10^{-2}$ for Rn in gas and vapour and provided in the following table for the other elements:

Element	Ac	Pb	Po	Pa	Ra	Th	U
Bq g^{-1} liquid	$7.4.10^{-2}$	$3.7.10^{-3}$	$2.59.10^{-2}$	$3.33.10^{-2}$	$3.70.10^{-4}$	$3.70.10^{-2}$	0.74^{-}
Bq g^{-1} gas/vapour	$2.59.10^{-6}$	$1.11.10^{-4}$	$2.22.10^{-4}$	$1.11.10^{-6}$	$3.70.10^{-5}$	$2.22.10^{-5}$	$7.40.10^{-5}$

- In all other cases not provided for in the exemption regulations laid down in RSA93 and the EO(SoLA) or other Exemption Orders the disposal of radioactive waste and discharges into air and water will require authorisation.

Good points:

- General and specific clearance allowed.
- Extra radionuclides included.
- Regulations apply to both practices and work activities.
- Guidance has been provided on the interpretation of Schedule 1 of the RSA93 and related issues in a report commissioned by the DETR (Hill et al, 2000). Note this report does not represent Government policy or carry legal weight but nevertheless may assist technical specialists.

Areas for improvement:

- Where possible clearance levels should be harmonised with those recommended by the European Commission.
- Removal of restrictions associated with clearance under SoLA EO (solid wastes that are not substantially insoluble and above limits in the RSA93, liquid wastes containing radionuclides in solution above RSA93 limits and gaseous materials above RSA93 limits – especially not containing U and Th compounds) to allow clearance when dose criterion satisfied.
- Criteria for surface contamination needed.
- Guidance on how to interpret values given for radioelements with respect to decay chains.
- Advice on 10% rule for consideration of nuclides in summation rule, rules for consideration of decay chains, averaging volumes and masses needed.

References

European Commission, *Council Directive 84/467/Euratom of 3 September 1984 amending Directive 80/836/Euratom as regards the basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation,* Official Journal of the European Communities, OJ L265 5/10/1984 p0004 - 0156.

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European Commission, 'Recommended Radiological Protection Criteria For The Recycling Of Metals From The Dismantling Of Nuclear Installations', *Radiation Protection 89*, European Commission, 1998.

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Appendix E - Late Comments from Italy

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

AGENCY FOR THE PROTECTION OF THE ENVIRONMENT

and for Technical Services (APAT), Italy

Comments on Part I: Main Report

1. Paragraph 3.2 third bullet

"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)."

In the sentence above Italy is quoted among countries that have not used Annex I Table A of Directive 96/29/Euratom in order to define exemption levels for practices with radioactive substances. In this respect it is unclear whether the report means exemption from reporting or exemption from the requirements of the Directive. In Italian legislation the two concepts are different, see paragraph 1 of Appendix C of the Italian response to the questionnaire.

It must also be pointed out that for those radionuclides that are not included in Annex I of Directive 96/29/Euratom, the Italian legislation introduces two default values (established in relation to the decay mode of radionuclide) for the threshold levels for exemption of practices, exemption from prior reporting and authorization of practices.

2. Table 1

Relevant national legislation

"Legislative Decree nr 230 of 17th March 1995, published in the Official Journal No 136 of the 13th June 1995, as modified inter alia by Legislative Decree No 241 of 26th May 2000 published in Official Journal No 136 of 31st August 2000 (ordinary supplement 140/L) (LD)".

The sentence should be amended as follows:

"Legislative Decree no. 230 of 17th March 1995, published in the Official Journal No 136 of the 13th June 1995, as modified inter alia by Legislative Decree No. 241 of 26th May 2000 published in Official Journal No 203 of 31st August 2000 (ordinary supplement 140/L) and by Legislative Decree No. 257 of 9th May 2001 published in Official Journal No 153 of 4th July 2001 (LD)"

In fact, Legislative Decree no. 230 was amended by Legislative Decree no. 241 of 26 May 2000, which transposed Directive 96/29/Euratom into Italian legislation. Legislative Decree

In fact, Legislative Decree no. 230 was amended by Legislative Decree no. 241 of 26 May 2000, which transposed Directive 96/29/Euratom into Italian legislation. Legislative Decree no. 241 has been in force in Italy since January 1st 2001 and it replaces, in some parts, the previous radiation protection provisions laid down in Legislative Decree no. 230.

Besides, Legislative Decree no. 257 of 9th May 2001 (published in the Italian Republic's Official Journal no. 153 of 4 July 2001) was promulgated in order to modify certain requirements in Legislative Decree no. 241 of 2000 concerning notification and authorisation of non nuclear installations, *i.e.* where ionising radiation is used for industrial, research and medical purposes.

Associated guidance

We are not clear why only two Technical guidance issued by UNI on the subject of decommissioning are mentioned.

3. Table 2 second column

"Yes - Legislative Decree 230 of 1995 as modified by Legislative Decree 241 of 2000."

The sentence should be amended as follows:

"Yes - Legislative Decree 230 of 1995 as modified by Legislative Decree 241 of 2000 and Legislative Decree 257 of 2001."

See comment in 2. above.

4. Table 4

The overview of the implementation in Italy of exemption provisions from the Directive reported in the table is not in accordance with the requirements in Italian legislation and the relevant information provided by us. In particular (see paragraphs 1, 1.1.a), 1.1.b), 1.1.c), 1.2 and 4 of Appendix C of the Italian response to the questionnaire) threshold levels for exemption from prior reporting of practices in Italian legislation coincide with activity and concentration values tabled in Annex I of Directive 96/29/Euratom without distinction between sealed and unsealed sources; as for authorisation, thresholds are set out as a multiple of thresholds for exemption from reporting.

5. Table 5 second column

"The definition of release is addressed in Decree 230 of 1995 in Art. 30 para. 1 and in Art. 154 para. 3-bis, as being any act of discharge, clearance, disposal, recycle or reuse of radioactive requirements. Art. 4 para. 2q) addresses release levels."

The sentence should be amended as follows:

"The definition of release is addressed in Art. 30 para. 1 and in Art. 154 para. 3-bis of Legislative Decree 230 of 1995, as being any act of discharge, clearance, disposal, recycle or reuse of radioactive materials. Art. 4 para. 2q) addresses the definition of release levels."

6. Table 6

We are not completely clear on the meaning of "non-nuclear practices" you used in Table 6; we understand this term as meaning "non nuclear installations" where ionising radiation is used for medical, industrial and research purposes.

It must be pointed out that the Italian legislation, besides introducing the "Below Regulatory Concern" criterion, lays down a general rule for unrestricted release from regulatory control (see paragraphs 1.3 and 1.4 of Appendix C of the Italian response to the questionnaire). We feel these provisions should be mentioned in the table or in the text of the main report for the sake of completeness.

As far as discharges are concerned, we point out that a dose constraint of 10 μSv/y is adopted in Italian legislation.

7. Table 7

Specific clearance levels for metals and building materials from the Caorso NPP should be introduced in the table for those radionuclides with alpha decay (see paragraph 7 of Appendix C of the Italian response to the questionnaire), *i.e.* Am-241, Pu-239, U-238, Th-232, Th-228, Ra-226 and Po-210 for which the specific clearance levels are 0.1 Bq/g.

8. Figures 5 and 8

As far as general clearance levels are concerned, it must be pointed out that Articles 30, paragraph 1, and 154, paragraph 3-*bis*, of Legislative Decree no. 230 of 1995 as subsequently amended explicitly state that, when defining technical specifications in authorising releases, reference has to be made to the European Union's relevant directives, technical recommendations and reports, *e.g.* RP 122 Part I (see paragraph 6 of Appendix C of the Italian response to the questionnaire). Besides, the strict specific requirements of the Italian legislation concerning the scope also have to be borne in mind, *i.e.* the overall threshold of 1 Bq/g (see paragraph 1.1.b) of Appendix C of the Italian response to the questionnaire).

For these reasons figure 5 and 8 should be amended considering the general clearance levels of 0.1 Bq/g for Pu-239 and 1 Bq/g for Zn-65.

Comments on Part II: Appendix D

9. Exemption, first bullet

"New legislation implementing the Directive is laid down in Legislative Decree 230 of 1995 as amended by Legislative Decree no 241 of 2000 (LD)."

The sentence should be amended as follows:

"New legislation implementing the Directive is laid down in Legislative Decree 230 of 1995 as amended by Legislative Decree no 241 of 2000 and Legislative Decree 257 of 2001 (LD)."

See comment in 2 above.

10. Exemption, second bullet

"Practices are exempt from the scope of the LD on the basis of provisions laid down in Annex I, par. 1-5 of LD no. 230, in Article 1 par. 2-bis of LD 230 and in Article 36 of LD 241."

The sentence should be amended as follows:

"Practices are exempt from the scope of the LD on the basis of provisions laid down in Annex I, paragraphs 0.1 to 5 of LD no. 230, pursuant to Article 1, para. 2-bis, of LD 230, and in Article 36 of LD 241."

See paragraph 1.1.a) of Appendix C of the Italian response to the questionnaire.

11. Exemption, sixth bullet

"Exemption of practices involving the use of sealed sources and apparatus emanating ionising radiation is provided for in Art 22 of LD 230 as in Title III."

The sentence should be amended as follows:

"Exemption from reporting of practices involving the use of sealed sources and apparatus emitting ionising radiation is provided for in Art 22 of LD 230 as in Title III."

See paragraph 1.2 of Appendix C of the Italian response to the questionnaire.

12. Clearance, first bullet

"Clearance of materials from practices has to comply with Article 154, Par. 2 of the Legislative Decree no. 230 of 1995 as amended by the Legislative Decree no. 241 of 26th May 2000."

The sentence should be amended as follows:

"A general rule for unconditional release of materials from practices is laid down in Article 154, Par. 2, of the Legislative Decree no. 230 of 1995 as amended by the Legislative Decree no. 241 of 2000 and Legislative Decree 257 of 2001."

See paragraph 1.4 of Appendix C of the Italian response to the questionnaire.

13. Clearance, fifth bullet

"Thresholds for authorised clearance of materials from a specific nuclear power plant have been set for scrap, building material (activity concentration and surface contamination) and for other materials within the constraint of ≤ 1 Bq·g^{-1} above and total activities as provided in Directive 84/467 Euratom or 96/29/Euratom (levels for exemption of practices)."

The sentence should be amended as follows:

"Thresholds for authorised clearance of materials from a specific nuclear power plant have been set for metal scrap, for building materials (in terms of activity concentration and of surface contamination) and for other materials (in activity concentration) within the constraint of ≤ 1 Bq·g^{-1} above."

See paragraph 7 of Appendix C of the Italian response to the questionnaire.

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