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Proposal for a

COUNCIL DIRECTIVE

**laying down basic safety standards for protection against the dangers arising from
exposure to ionising radiation**

{SWD(2012) 137 final}

{SWD(2012) 138 final}

EXPLANATORY MEMORANDUM

1. CONTEXT

1.1. Background and objectives

Exposure to ionising radiation results in a health detriment. In normal situations doses are very low so that there is no clinically observable tissue effect, but there still is a possible late effect, cancer in particular. It is assumed that there is no dose threshold for this effect: any exposure, however small, can be the cause of cancer later in life. It is further assumed that the probability of occurrence of a late effect is proportional to the dose. This calls for a specific approach in radiation protection based on the three principles of justification, optimisation and dose limitation, which are the cornerstones of the system of protection established many decades ago by the International Commission on Radiological Protection (ICRP).

Euratom legislation has always followed the recommendations of the ICRP. This highly respected scientific organisation has recently issued new guidance on the system of radiation protection (Publication 103, 2007). While preserving the three pillars of the system, the ICRP sets out in more detail the application of the principles throughout any exposure situation and irrespective whether the source of radiation is man-made or natural. Radiation protection indeed covers not only exposures resulting from the operation of radiation sources (planned exposure situations), but also emergency exposure situations, for instance resulting from a nuclear accident, and a range of other situations, in particular those involving exposure to natural radiation sources, termed ‘existing exposure situations’. The ICRP has also updated the methodology for assessment of the effective dose as well as the application of dose limits, in the light of the latest scientific information.

A large proportion of workers in industries processing naturally occurring radioactive materials (NORM) receive doses above the dose limit for members of the public, but still do not benefit from protection as occupationally exposed workers. This anomaly is not sustainable, so the ICRP’s new Recommendations aim to integrate natural radiation sources within the overall system. Already in 1996, the current Euratom legislation¹ had introduced requirements for work activities involving natural radiation sources. These were put together in a separate Title rather than being integrated within the overall radiation protection framework. In addition, maximum flexibility was offered to Member States to decide for instance which NORM industries were of concern. This has led to wide differences in controlling NORM industries and in protecting workers in these industries. This situation is not compatible with Euratom’s role in setting uniform standards.

Exposure to indoor radon, a natural radioactive noble gas entering dwellings from the soil below, is far more important than exposure from any other radiation source. Recent epidemiological studies have confirmed that lung cancer may be caused by exposure to radon, and WHO² now ranks this as a major health issue³. Exposure to radon in dwellings was

¹ Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation, OJ L 159, 29.6.1996, p. 1.

² World Health Organisation.

³ WHO Handbook on indoor radon, World Health Organisation, 2009, ISBN 978 92 4 154767.

addressed in 1990 in a Commission Recommendation. The confirmed causation of lung cancer by exposure to radon calls for strengthening radon mitigation policies in Europe through binding requirements. Radioactivity in building materials has been included in the Construction Products Directive⁴, but this has still not led to any corresponding standards being adopted by the European Committee for Standardisation (CEN). The revision of the Basic Safety Standards (BSS) Directive will not only address the recycling of residues from NORM industries into building materials, but also ensure coherent and harmonised protection against other building materials with enhanced levels of radioactivity.

In addition to the health protection of people, the ICRP radiation protection system now addresses the protection of biota against exposure to ionising radiation. While it is generally assumed that the exposure of biota does not call for additional measures, this assumption now needs to be demonstrated through compliance with criteria and on the basis of an agreed methodology.

There is a significant body of Euratom legislation addressing different radiation protection issues defined as basic safety standards in the Euratom Treaty. As these issues have developed over a long period of time, there are inevitably quite a few inconsistencies between different acts and also obsolete references as a result of updated legislation. These inconsistencies need to be resolved, in line with the Commission's policy for simplification of European legislation.

The problem can be summarised as follows:

- Scientific progress is not fully reflected in present legislation;
- There are inconsistencies between the existing pieces of legislation;
- The scope of the present legislation does not fully cover natural radiation sources or the protection of the environment.

This translates into four specific objectives:

- to introduce the necessary subject-matter amendments in order to respond to the latest scientific data and operational experience,
- to clarify the requirements and to ensure coherence within the body of European legislation,
- to ensure coherence with the international recommendations,
- to cover the whole range of exposure situations and categories of exposure.

⁴ Council Directive 89/106/EEC, Annex 1, states that 'the construction work must be designed and built in such a way that it will not be a threat to the hygiene or health of the occupants or neighbours, in particular as a result of ... the presence of dangerous particles or gases in the air [or] the emission of dangerous radiation'.

1.2. Subsidiarity

According to Article 2(b) of the Euratom Treaty ‘... the Community shall, as provided in this Treaty ... establish uniform safety standards to protect the health of workers and of the general public and ensure that they are applied’. Accordingly, in the Treaty’s preamble, the Member States declare that they are ‘resolved to create the conditions necessary for the development of a strong nuclear industry’ and also ‘anxious to create conditions of safety necessary to eliminate hazards to the life and health of the public’. Euratom is mandated to ‘establish uniform safety standards to protect the health of workers and of the general public and ensure that they are applied.’ Therefore, Euratom’s competence to regulate in the field of health protection against ionising radiation is explicitly recognised by the Euratom Treaty.

The exclusive nature of Euratom’s legislative powers under Articles 30 and 31 of the Euratom Treaty does not in principle require the application of the principle of subsidiarity. These Articles require the Commission to seek for its legislative proposals the opinion of a Group of Experts designated by the Euratom Scientific and Technical Committee.

1.3. Current legislation

Following the entry into force of the Euratom Treaty, a comprehensive set of legislation establishing basic safety standards has been enacted on the basis of Article 31 of the Treaty.

The main pillar of that legislation is Council Directive 96/29/Euratom laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation (Euratom BSS Directive). Further legislation based on Article 31 of the Euratom Treaty comprises:

- Council Decision 87/600/Euratom of 14 December 1987 on Community arrangements for early exchange of information in the event of a radiological emergency;
- Council Regulation 3954/87/Euratom of 22 December 1987 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency and the related legislative acts, Commission Regulation 944/89/Euratom of 12 April 1989 laying down maximum permitted levels of radioactive contamination in minor foodstuffs following a nuclear accident or any other case of radiological emergency, and Commission Regulation 770/90/Euratom of 29 March 1990 laying down maximum permitted levels of radioactive contamination of feedingstuffs following a nuclear accident or any other case of radiological emergency⁵;
- Council Directive 89/618/Euratom of 27 November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency (Public Information Directive);
- Commission Recommendation 90/143/Euratom of 21 February 1990 on the protection of the public against indoor exposure to radon;

⁵ These acts are subject to recast — proposal for a Council Regulation (EURATOM) laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency (recast), [COM/2010/0184 final](#) — CNS 2010/009.

- Council Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionising radiation during their activities in controlled areas (Outside Workers Directive);
- Council Regulation 1493/93/Euratom of 8 June 1993 on shipments of radioactive substances between Member States;
- Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure, repealing Directive 84/466/Euratom of 3 September 1984 (Medical Directive);
- Commission Recommendation 2001/928/Euratom of 20 December 2001 on the protection of the public against exposure to radon in drinking water supplies;
- Council Directive 2003/122/Euratom of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources (HASS Directive);
- Council Directive 2006/117 of 20 November 2006 on the supervision and control of shipments of radioactive waste and spent fuel;
- Council Directive 2009/71/Euratom of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations.

The BSS Directive have been regularly updated in 1962, 1966, 1976, 1980, 1984 and 1996, taking account of advances in scientific knowledge of the effects of ionising radiation in line with the recommendations of the ICRP and on the basis of operational experience. Medical exposures have been included in specific legislation since 1984. Specific problem areas are covered in three ‘associated directives’ – the High-Activity Sealed Radioactive Sources (HASS) Directive, the Outside Workers Directive and the Public Information Directive. An analysis of the legislation enacted under Article 31 of the Euratom Treaty reveals that the Medical Directive, the HASS Directive, the Outside Workers Directive and the Public Information Directive are closely linked with BSS Directive 96/29, in that they develop further the requirements of the BSS Directive or refer to different provisions of the BSS Directive. For this reason the proposal for a new basic safety standard Directive will cover the subject matter and scope of these Directives.

The Commission will propose separately a Directive laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption (COM(2011)385). This Euratom Directive will replace an existing Directive 98/83/EC with regard to its application to radioactive substances and complement it with technical annexes on sampling frequencies, methods of analysis and detection levels. The substance matter of this Directive is such that it could be incorporated in a recast with the basic safety standards at an appropriate point in time. At this stage however, since the Directive is intended to merely transpose existing requirements under EC Treaty legislation, in such a way as to avoid any interpretation as to a possible change in substance, it is considered more appropriate not to incorporate it at this stage in a proposal for a revised Basic Safety Standards Directive. In addition, at the time the Article 31 Group of Experts gave its opinion on the revised Basic safety standards Directive, there was still discussion whether a Directive on radioactive substances in water intended for human consumption should be based on Euratom Treaty or EC Treaty. In these circumstances it was decided to

proceed with the proposal for a revised Basic Safety Standards Directive as agreed upon in February 2010 by Article 31 Group of Experts.

The other legislation based on Article 31 of the Euratom Treaty, as discussed in the Impact Assessment Report, either uses a different instrument, or the scope is essentially outside radiation protection or the legislation is specific to certain types of installation.

1.4. Simplification

In 2005 the European Commission published ‘Implementing the Community Lisbon programme: A strategy for the simplification of the regulatory environment: the better regulation initiative’ (COM/2005/535 final) as a response to the European Parliament’s and Council’s requests to simplify EU legislation and enhance its quality. This initiative is the basis for attempting the consolidation of the five Directives mentioned above. It is neither feasible nor useful to recast these Directives with the other pieces of legislation under Title II, Chapter 3 of the Euratom Treaty.

1.5. International context

The International Basic Safety Standards reflect an international consensus on what constitutes a high level of safety for protecting people and the environment from the harmful effects of ionising radiation. They are approved by the IAEA Board of Governors and are non-binding in nature. The main document on radiation protection is Safety Standards No 115 ‘International Basic Safety Standards for Protection against Ionising Radiation and for the Safety of Radiation Sources’, IAEA, 1996. In 2006, the IAEA, together with other international organisations (FAO, ILO, the NEA/OECD, PAHO and WHO), embarked upon the revision of Safety Standards No 115. This ongoing activity is also driven by the new ICRP Recommendations in Publication 103, published in 2007.

The European Commission has cooperated closely with the IAEA and other international organisations on the revision of the International Basic Safety Standards. However, it should be emphasised that the Euratom Basic Safety Standards Directive is not a means to confer legally binding status on the international requirements. There are two main reasons why referring to or incorporating the international BSS in European legislation is not feasible. On the one hand, the language of the international BSS does not conform to EU legal drafting rules. The international requirements are also sometimes far too detailed and go beyond the idea of ‘basic’ standards in the Euratom Treaty. The requirements of the Euratom BSS also need to take into account internal market rules. On the other hand, the international BSS allow for the fact that countries throughout the world, with different levels of regulatory and technological infrastructure, must be able to comply with them. The European legislation is more ambitious. Euratom is bound by the Treaty to establish uniform basic safety standards. Incorporating the international BSS in a European act is hence not only difficult, but would also be at odds with the major role played by Euratom since 1959 and the significant body of legislation that has already been built up. Nevertheless, the Commission pursues the largest possible coherence between Euratom and international standards, and envisages the eventual sponsorship of the latter on behalf of Euratom.

2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT

2.1. Interested parties

The Commission (DG ENER) has initiated and supported several projects and studies on specific radiation protection issues, the results of which have been published in the Radiation Protection Series of the European Commission⁶. The various projects, studies and conferences identify challenges to the implementation of the current radiation protection legislation and problem areas that are not sufficiently covered by the current system of protection.

In 2009, the Commission launched a consultation on a ‘proposal for new requirements on natural radiation sources in the Basic Safety Standards Directive’. The Working Party ‘Natural Sources’ of the Article 31 Group of Experts proposed a comprehensive approach to the regulation of NORM industries, radon and building materials. This document was published on the Commission website and was also highlighted on the EAN_{NORM} website⁷. The consultation ran from 02 February 2009 to 20 April 2009.

The revision of the Euratom Basic Safety Standards has benefited from continuous interaction with two organisations representing major stakeholders, namely the Heads of European Radiological Protection Competent Authorities (HERCA) and the International Radiation Protection Association (IRPA). An outline of the revision of the BSS was presented to HERCA at meetings in December 2008 and 2009 as well as in June 2010. The response of the radiation protection authorities was positive, and HERCA did not raise any important issue calling for changes in the approach. The revision has been presented at the International IRPA Congress (Buenos Aires 2008) and at European congresses organised by IRPA (Brasov, 2006, Helsinki 2010) as well as at annual meetings of the European IRPA societies. The European IRPA branch has set up a working party to collect input from their societies on the ongoing revision of both the international and Euratom BSS. There was also regular contact with the European Atomic Forum (FORATOM) which represents the stakeholders from the nuclear industry.

The key interaction with stakeholders is through the Article 31 Group of Experts, i.e. the experts to be consulted under Article 31 of the Euratom Treaty. In February 2010, the Group of Experts issued an opinion on the possible revision of European legislation in the form of a draft Directive. This text is the fruit of intensive work by the working parties of the Group of Experts, taking into account the studies conducted by the Commission as well as other sources of information (conferences, networks).

The draft proposed by the Commission is to a large extent the same as the draft on which the Article 31 Group of Experts' Opinion was based. Only some editorial corrections have been made and a few definitions added. The Experts left it for the Commission to decide whether the definition of HASS sources should remain the same as in the current Directive 2003/122/Euratom or whether the definition should be aligned with the IAEA Code of Conduct on the safety and security of radioactive sources. The Commission has opted for the latter.

⁶ Publications in the Radiation Protection Series of the European Commission can be found at http://ec.europa.eu/energy/nuclear/radiation_protection/publications_en.htm.

⁷ The result of the consultation can be found on the website of the European ALARA network for NORM industries (EAN_{NORM}), under http://www.ean-norm.net/lenya/ean_norm/live/news.html.

In its Opinion the Article 31 Group of Experts also suggests maintaining the text of Article 54 of Directive 96/29/Euratom, which allows Member States to opt out from the uniform Basic Safety Standards and introduce stricter dose limits to reflect possible new scientific findings after the adoption of the directive. This would jeopardise the implementation of the Euratom Treaty which requires establishment of uniform standards. The proposed text of the directive therefore does not include such clause. In its judgement of 25 November 1992 in the case Commission of the European Communities v Kingdom of Belgium (Case C-376/90⁸), the Court stated that 'in the absence of an express provision to the contrary, the Directive must be interpreted as allowing the Member States to set, ..., stricter dose limits'. In this respect, an explicit statement on the uniformity of the standards has been introduced in the proposed text of the revised Basic Safety Standards Directive.

2.2. Impact assessment

A comprehensive impact assessment was made to evaluate the possible options for reaching the objectives:

1. to bring the health protection of workers, the public and patients in line with latest scientific data and operational experience,
2. to streamline existing EU legislation in the field of radiation protection,
3. to ensure coherence with international standards and recommendations,
4. to cover the whole range of exposure situations, including exposure to natural radiation sources at home, as well as the protection of the environment.

In the light of these objectives, the impact assessment report considers a broad range of options both with regard to the extent of the consolidation with other legislation and with regard to scope and substance of the incorporated legislation:

Option 1: Maintaining the status quo of existing legislation.

Option 2: Revision of Basic Safety Standards and Medical Directive. This option envisages changes in the two Directives with the aim to align them with the latest ICRP recommendations and with the advance of the scientific knowledge.

Option 3: Revision and consolidation of Basic Safety Standards and Medical Directive, and integration of the Outside Workers Directive, the Public Information Directive and the High Activity Sealed Sources Directive. Non-legislative measures will address natural radiation issues and the protection of non-human species. This option offers a revision of the Basic Safety Standards Directive by extending the requirements to medical exposure, public information, outside workers exposure and high-activity sealed sources. Within this policy option, the BSS Directive 96/29 and the related legislative acts (Medical Directive 97/43/Euratom, Outside Workers Directive 90/641/Euratom, HASS Directive 2003/122/Euratom, Public Information Directive 89/618/Euratom, Commission Recommendation 90/143/Euratom) will merge and the requirements of BSS Directive and of

⁸ European Court reports 1992 Page I-06153

Medical Directive will at the same time be upgraded to the latest scientific knowledge and regulatory experience.

Option 4: Revision of the Basic Safety Standards Directive and broadening the scope to cover exposure to natural radiation at home. With this option, a comprehensive approach to the management of exposures due to natural radiation sources will be incorporated within the overall set of requirements of the Euratom BSS. The requirements will reflect the distinction between planned and existing exposure situations, as made in ICRP Publication 103. While occupational exposure to natural radiation sources (as well as public exposure from residues or effluents from NORM industries) is already considered in Options 1 to 3, the exposures to natural radiation sources that will explicitly be incorporated relate to public exposure in the domestic environment.

Option 5: Revision of the Basic Safety Standards Directive and broadening the scope to cover protection of non-human species. The subject matter and general purpose of the BSS Directive 96/29/Euratom is the health protection of the population and workers against dangers of ionising radiation. This Directive applies to the protection of the human environment, but only as a pathway from environmental sources to the exposure of man. In line with the new ICRP Recommendations, it will be complemented with specific consideration of the exposure of biota in the environment as a whole. The aim would be to require Member States to consider suitable protection of non-human species in their radiation protection legislation.

Option 6: Revision and consolidation of the Basic Safety Standards Directive and Medical Directive, integration of the Outside Workers Directive, the Public Information Directive and the High Activity Sealed Sources Directive, and broadening the scope to cover public exposure to natural radiation and protection of non-human species. This option includes all the elements of Option 3 (revision of the Basic Safety Standards Directive and integration of the other four Directives). The revision of the Basic Safety Standards includes all identified issues, and broadens the scope to include the whole range of exposure situations, including indoor public exposure to radon and to building materials, and all categories of human and non-human exposures.

The effectiveness of the proposed options is assessed towards the objectives, the efficiency of the additional requirements in terms of their health and environmental impact, economic benefit and administrative cost, and the coherence of the Directive with overall Euratom and EU legislation. The amendments to the Basic Safety Standards and to the Medical Directive will have an important impact in the following areas:

- Social and health impact: The social impact relates to providing adequate protection to workers in NORM industries. The health impact will be most noticeable with regard to medical exposures, in particular in preventing unnecessarily frequent or high-dose radiological examinations (for instance CT scans) of patients leading to increased cancer incidence in future. Specific professional groups (for instance cardiologists) will benefit from the reduction of the dose limit for the lens of the eye and avoid contracting radiation-induced cataract.

- Economic impact: While it is not possible at this stage to make a quantified economic assessment, NORM industries will benefit from the harmonisation of requirements between Member States.

- Administrative cost: While the principle of protection optimisation, calling for doses to be ‘as low as reasonably achievable’ (ALARA), taking social and economic factors into account, is key to ensuring a proper cost-benefit balance in operational radiation protection, the new concept of a ‘graded approach’ extends this principle to enhance the effectiveness of regulatory oversight and reduce the administrative cost to industries.

Additional amendments introduced in the three other Directives are the following:

- harmonisation of the definition of high-activity sealed radioactive sources (HASS) with the international standards;

- specific requirements for the protection of outside workers with a clear definition of the responsibilities of their employers and the undertakings conducting the practices in which they are exposed;

- requirements for informing the public before and during an emergency, within the overall revised scope for the management of emergency exposure situations.

Merging the five Directives is a major achievement in terms of the coherence of Euratom legislation. The restructuring required to accommodate this broader scope of the BSS Directive further improves the clarity of the text and ensures better operational implementation of the requirements.

The broader scope of the new Directive entails further substantial amendments:

With regard to ‘existing exposure situations’, reference levels are given for indoor radon concentrations and for external exposure from building materials. Member States will be required to establish a comprehensive and transparent Radon Action Plan, adjusted to national needs and to the geological features of different regions. Harmonised requirements for building materials will permit further standardisation under the Construction Products Directive (Council Directive 89/106/EEC). While consumers and the building professions will benefit from the monitoring and labelling of materials, the administrative burden on industry will be kept to a minimum by the proper choice of reference levels and the list of types of materials deemed to be of concern.

Relevant requirements in the Euratom BSS for the protection of non-human species will allow Member States to incorporate this in national environmental policies, in a way which is coherent with current approaches to health protection against ionising radiation. The environmental impact assessment of these new requirements relates essentially to the prevention of environmental damage in case of an accident. For the normal operation of an installation it is rather a demonstration that there is no impact to the environment.

3. LEGAL ELEMENTS OF THE PROPOSAL

The recast of five Directives yields a voluminous single Directive, with over 100 articles and numerous annexes. In view of the extent and complexity of the changes, a formal recast procedure is not pursued. It is not possible to point to each and every element of the proposal. The following sections give a summary description of the main features of each chapter.

3.1. Chapter I: Subject matter and scope

This chapter defines the scope of the new Directive (general purpose of the Directive across different categories of exposure and different exposure situations and specific purposes resulting from integration of the requirements for high-activity sealed radioactive sources and for public information, and the exclusion of non-controllable exposures). The scope is broadened to include the exposure of space crew to cosmic radiation, domestic exposure to radon gas in indoor air, external exposure to gamma radiation from building materials, and the protection of the environment beyond environmental pathways leading to human exposure.

3.2. Chapter II: Definitions

This chapter includes all definitions given in the earlier Directives, with some adjustments to resolve inconsistencies as well as to adjust to the new terminology introduced in ICRP Publication 103 and in the draft International Basic Safety Standards.

3.3. Chapter III: System of radiation protection

This title includes the general principles of radiation protection: justification, optimisation and dose limitation. It explains the more prominent role of dose constraints and reference levels in the process of optimisation, with Annex I giving the bands of reference levels proposed by the ICRP for existing and emergency exposure situations. The dose limits are not modified, except for a uniform definition of the annual occupational dose limit (no averaging over 5 years) and a lower organ dose limit for the lens of the eye, as recommended by the ICRP. The new Directive no longer includes the technical measurements entering into the definition of the effective dose and other factors entering into the assessment of doses, but refers to ICRP Publication 103 for this purpose. In addition, the Directive no longer includes the long lists of radionuclide-specific dose coefficients (doses per unit intake by ingestion or inhalation), but will refer to a forthcoming consolidated publication of the ICRP which can be downloaded free of charge.

3.4. Chapter IV: Requirements for radiation protection education, training and information

This chapter brings together the miscellaneous requirements governing education and training in the different Directives and includes provisions for recognition of the ‘Radiation Protection Expert’ and ‘Medical Physics Expert’.

3.5. Chapter V: Justification and regulatory control of practices

The application of the principle of justification remains a national responsibility. Specific attention is given to the justification of practices involving the deliberate exposure of humans for non-medical imaging (e.g. security screening in airports).

The regime for regulatory control is now presented as a three-tier system (notification, registration, licensing), replacing the earlier two-tier system of reporting and ‘prior authorisation’. A more detailed list of which types of practice are subject to either registration or licensing is given. As part of the concept of a ‘graded approach’ to regulatory control, there is explicit provision for the specific exemption of practices (from notification and from authorisation) at national level. The default values for exemption on the basis of activity concentrations are now taken from IAEA Safety Guide RS-G-1.7. The same default values

apply to release from regulatory control (clearance levels), but allow for specific values in European guidance. Member States will be allowed to keep default clearance levels in current national legislation, and to keep the existing exemption values for moderate amounts of material. Details of exemption criteria and exemption and clearance levels are given in Annex VI.

This chapter also includes more precise requirements on the information to be provided with a licence application (the issuing of discharge authorisations for radioactive airborne or liquid effluent is covered in Chapter VIII).

3.6. Chapter VI: Protection of workers, apprentices and students

This title includes, with little amendment, the provisions on occupational exposure in Directive 96/29/Euratom. It also includes the specific requirements in the Outside Workers Directive, and introduces a clear allocation of responsibilities between the employer and the undertaking where the practice is conducted. The data system for individual radiological monitoring of exposed workers and the minimum set of data to be communicated for outside workers has been updated in the light of recommendations by HERCA.

No distinction is made between the management of occupational exposures in NORM industries and other practices, but the former will benefit from a graded regulatory approach on the basis of prevailing exposures and their potential to increase with time.

This chapter now covers occupational exposure in all exposure situations, which provides more explicit protection for emergency workers as well as for workers exposed to high levels of indoor radon in their workplace.

3.7. Chapter VII: Protection of patients and other individuals subjected to medical exposure

This chapter includes the relevant requirements from the Medical Directive, but strengthens them, in particular with regard to:

- the application of the justification principle;
- information to patients on the health risks and benefits;
- information on doses;
- diagnostic reference levels;
- involvement of the Medical Physics Expert;
- prevention of accidental and unintended medical exposures.

3.8. Chapter VIII: Protection of members of the public

This chapter includes the public exposure requirements in Directive 96/29/Euratom, with more explicit consideration of the issuing of discharge authorisations for radioactive effluent (also with reference to Commission Recommendation 2004/2/Euratom).

The section on emergency exposure situations includes the requirements of the Public Information Directive.

The section on existing exposure situations addresses indoor exposure to radon, with a somewhat lower maximum reference level for existing dwellings than in Commission Recommendation 90/143/Euratom, in line with ICRP and WHO recommendations. It also includes requirements for the classification of building materials on the basis of a radioactivity index and a uniform reference level for the annual dose resulting from residence in a building constructed with such materials.

3.9. Chapter IX: Protection of the environment

This chapter, in line with the broader scope of the Directive as in the International Basic Safety Standards, aims to provide a means to demonstrate compliance with environmental criteria. While the ICRP has published a methodology for dose assessment for biota, a publication on the application of criteria is still awaited. Pending such further guidance, it is up to national authorities to assess the doses to representative animals and plants in terms of protection of the ecosystem.

Appropriate technical measures also need to be taken to avoid the environmental consequences of an accidental release and to monitor existing levels of radioactivity in the environment, from the perspectives of both environmental protection and human health.

3.10. Chapter X: Requirements for regulatory control

This chapter includes all the responsibilities of the regulatory authorities in all exposure situations. A clear structure is provided by the following sections:

- Institutional infrastructure;
- Control of sealed radioactive sources (with Annexes II, XII, XIII, XIV, XV incorporating different aspects of the Directive on High-Activity Sealed Radioactive Sources);
- Orphan sources (with new requirements with regard to metal contamination);
- Emergency exposure situations (establishment of an emergency management system and international cooperation, while requirements for the protection of workers and members of the public in an emergency exposure situation are addressed in Chapters V and VIII, respectively);
- Existing exposure situations (general provisions for the management of contaminated areas, radon action plan);
- System of enforcement (inspection programme and response to deficiencies).

The first section on ‘institutional infrastructure’ calls for a clear definition of the responsibilities of different authorities. The Commission is to receive periodically updated information and publish this in the Official Journal. This section also defines the responsibilities of the ‘Radiation Protection Expert’, the ‘Radiation Protection Officer’ (in the current BSS these concepts were merged within the function of ‘Qualified Expert’) and the ‘Medical Physics Expert’.

3.11. Chapter XI: Final provisions

The transposition of the new Directive into national law should not require a major legislative effort, so a 2-year transposition deadline is deemed sufficient. Specific new features, such as the protection of the environment, can be transposed later.

In line with the Euratom Treaty, the Basic Standards are to be uniformly applied in the Member States, though without prejudice to those requirements for which flexibility is clear from the wording of the text. However, dose limits, default exemption values, the reference level for building materials, etc. are explicitly intended for uniform transposition and application.

4. BUDGETARY IMPLICATIONS

There are no implications for the EU budget.

Proposal for a

COUNCIL DIRECTIVE

laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Articles 31 and 32 thereof,

Having regard to the proposal from the Commission, drawn up after obtaining the opinion of a group of persons appointed by the Scientific and Technical Committee from among scientific experts in the Member States, and after having consulted the European Economic and Social Committee,

Having regard to the opinion of the European Economic and Social Committee,

Having regard to the opinion of the European Parliament,

Whereas:

- (1) Article 2(b) of the Treaty provides for the establishment of uniform safety standards to protect the health of workers and the general public and Article 30 of the Treaty defines ‘basic standards’ for the health protection of workers and the general public against the dangers arising from ionising radiations.
- (2) In order to perform its task, the Community laid down basic standards for the first time in 1959 pursuant to Article 218 of the Treaty by means of the Directives of 2 February 1959 laying down the basic standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation⁹. The Directives have been revised several times, most recently in 1996 by Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation¹⁰ which repealed the earlier Directives.
- (3) Directive 96/29/Euratom establishes the basic safety standards. This Directive applies to normal and emergency situations and has been supplemented by more specific legislation.

⁹ OJ 11, 20.2.1959, p. 221.

¹⁰ OJ L 159, 29.6.1996, p. 1

- (4) Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure and repealing Directive 84/466/Euratom¹¹, Council Directive 89/618/Euratom of 27 November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency¹², Council Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionising radiation during their activities in controlled areas¹³ and Council Directive 2003/122/Euratom of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources¹⁴ cover different specific aspects complementary to Directive 96/29/Euratom.
- (5) Over time, definitions used in that legislation have evolved and been adjusted to the specific scope, however many requirements laid down therein fit in the original context at the time of adoption of that legislation but cannot be extended for use in Directive 96/29/Euratom.
- (6) The Group of Experts appointed by the Scientific and Technical Committee has advised that the basic safety standards, established according to Articles 30 and 31 of Euratom Treaty should take into account the new recommendations of the International Commission on Radiological Protection (ICRP), in particular those in Publication 103 (2007)¹⁵, and should be revised in the light of new scientific evidence and operational experience.
- (7) This Directive should follow the situation based approach introduced by ICRP Publication 103 and distinguish between existing, planned and emergency exposure situations. Taking into account this new framework the Directive should cover all exposure situations and all categories of exposure, namely occupational, public and medical exposures.
- (8) A new methodology introduced by ICRP to calculate doses based on the latest knowledge on radiation risks should also be taken into account in this Directive.
- (9) The current annual dose limits for occupational and public exposure are maintained. However, there should be no further need for averaging over five years, except in special circumstances specified in national legislation.
- (10) New scientific information on tissue effects calls for the optimisation principle to be applied to organ doses as well, where appropriate, in order to keep doses as low as reasonably achievable. The directive should also follow new ICRP guidance on the organ dose limit for the lens of the eye in occupational exposure.
- (11) Industries processing naturally occurring radioactive material extracted from the earth's crust subject workers and, if material is released into the environment, the public to increased radiation exposure.

¹¹ OJ L 180, 9.7.1997, p. 22.

¹² OJ L 357, 7.12.1989, p. 31.

¹³ OJ L 349, 13.12.1990, p. 21.

¹⁴ OJ L 346, 31.12.2003, p. 57.

¹⁵ The 2007 Recommendations of the International Commission on Radiological Protection

- (12) Protection against natural radiation sources, rather than being addressed separately in a specific title, should be fully integrated within the overall requirements. In particular, industries processing materials containing naturally occurring radionuclides should be managed within the same regulatory framework as other practices.
- (13) The new requirements on radioactivity in building materials should allow for the free circulation of building materials.
- (14) Recent epidemiological findings from residential studies demonstrate a lung cancer risk from exposure to indoor radon at levels of the order of 100 Bq m^{-3} . The new concept of exposure situations allows the provisions of Commission Recommendation 90/143/Euratom on the protection of the public against indoor exposure to radon¹⁶ to be incorporated in the binding requirements of the Basic Safety Standards while leaving enough flexibility for implementation.
- (15) The exposure of aircrew to cosmic radiation should be managed as a planned exposure situation. The operation of spacecraft should come under the scope of this Directive and should be managed as a specially authorised exposure.
- (16) The health protection of the general public allows for the presence of radioactive substances in the environment. In addition to direct environmental exposure pathways, consideration should be given to the protection of the environment as a whole, including the exposure of biota, within a comprehensive and coherent overall framework. As far as mankind is part of its environment, this policy benefits to long term health protection.
- (17) In the medical area, important technological and scientific developments have led to a notable increase in the exposure of patients. In this respect, the Directive should emphasise the need for justification of medical exposure, including the exposure of asymptomatic individuals, and should strengthen the requirements concerning information to be provided to patients, the recording and reporting of doses from medical procedures, the use of diagnostic reference levels and the availability of dose-indicating devices.
- (18) Accidental and unintended medical exposures are a source of continuing concern. Their prevention and follow-up, should they occur, need to be fully addressed. In this respect, the role of quality assurance programmes, including risk analysis in radiotherapy, to avoid such incidents should be emphasised, and recording, reporting, analysis and corrective action should be required in such cases.
- (19) The so-called ‘medico-legal’ exposures introduced in Directive 97/43/Euratom have now been clearly identified as the deliberate exposure of individuals for other than medical purposes, or ‘non-medical imaging exposures’. Such practices need to be placed under appropriate regulatory control and should be justified in a similar way as for medical exposures. However, a different approach is needed on the one hand for procedures implemented by medical staff using medical equipment and on the other hand for procedures implemented by non-medical staff using non-medical equipment.

¹⁶ OJ L 80, 27.3.1990, p. 26.

In general, the annual dose limits and corresponding constraints for public exposure should apply.

- (20) Member States should be required to submit certain practices involving a hazard from ionising radiation to a system of regulatory control or to prohibit certain practices. Member States should benefit from the application of a graded approach to regulatory control, which should be commensurate with the magnitude and likelihood of exposures resulting from the practices, and commensurate with the impact that regulatory control may have in reducing such exposures or improving the safety of installations.
- (21) There is benefit in having the same activity concentration values both for the exemption of practices from regulatory control and for the clearance of materials from regulated practices. After a comprehensive review, it has been concluded that the values recommended in IAEA document RS-G-1.7¹⁷ can be used both as default exemption values, replacing the activity concentration values laid down in Annex I to Directive 96/29/Euratom, and as general clearance levels, replacing the values recommended by the Commission in Radiation Protection No 122¹⁸.
- (22) Member States may grant specific exemption from authorisation for certain practices involving activities above the exemption values.
- (23) Specific clearance levels, above the default values for exemption and clearance, as well as corresponding Community guidance¹⁹ remain important tools for the management of large volumes of materials arising from the dismantling of licensed facilities.
- (24) Member States should ensure that outside workers receive the same protection as exposed workers employed by undertakings performing practices with radiation sources. The specific arrangements for outside workers in Directive 90/641/Euratom should be extended to cover work in supervised areas as well.
- (25) With regard to the management of emergency exposure situations, the current approach based on intervention levels should be replaced by a more comprehensive system comprising threat analysis, an overall emergency management system, emergency response plans for identified threats, and pre-planned strategies for the management of each postulated event.
- (26) The introduction of reference levels in emergency and existing exposure situations allows for the protection of the individual as well as consideration of other societal criteria in the same way as dose limits and dose constraints for planned exposure situations.

17 IAEA 2004 Safety Standards Series RS-G-1.7 "Application of the Concepts of Exclusion, Exemption and Clearance".

18 Radiation Protection 122: Practical use of the Concepts of the Clearance and Exemption — Part I, Guidance on General Clearance Levels for Practices.

19 Radiation Protection 89: Recommended radiological protection criteria for the recycling of metals from dismantling of nuclear installations, Radiation Protection 113: Recommended Radiological Protection Criteria for the Clearance of Buildings and Building Rubble from the Dismantling of Nuclear Installations, Radiation Protection 122: Practical Use of the Concepts of the Clearance and Exemption.

- (27) The efficient management of a nuclear emergency with cross-border consequences calls for enhanced cooperation between Member States in emergency planning and response.
- (28) The International Atomic Energy Agency together with the World Health Organisation, the Food and Agricultural Organisation, the International Labour Organisation, the Nuclear Energy Agency of the Organisation for Economic Cooperation and Development, and the Pan-American Health Organisation are revising the International Basic Safety Standards in the light of the ICRP's new Publication 103.
- (29) The roles and responsibilities of the national services and experts involved in ensuring that the technical and practical aspects of radiation protection are managed with a high level of competence need to be clarified.
- (30) More precise requirements should be introduced for the issuing discharge authorisations and for the monitoring of discharges. Commission Recommendation 2004/2/Euratom of 18 December 2003 on standardised information on radioactive airborne and liquid discharges into the environment from nuclear power reactors and reprocessing plants in normal operation²⁰ introduced standardised information for the reporting of data on discharges from nuclear power plants and reprocessing facilities.
- (31) No major changes need to be made to the most recent Directive 2003/122/Euratom on the control of high-activity sealed radioactive sources and orphan sources, except to broaden some of the requirements to include any sealed radioactive source. However, there are still unresolved problems with orphan sources and there have been significant cases of contaminated metal being imported from third countries. Accordingly, a requirement should be introduced for the notification of incidents with orphan sources or the contamination of metal. With regard to international security, it is also important to harmonise the levels above which a source is regarded as a high-activity sealed source with those established by the IAEA.
- (32) In accordance with the Joint Political Declaration of Member States and the Commission on explanatory documents of 28 September 2011, Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments. With regard to this Directive, the legislator considers the transmission of such documents to be justified.
- (33) Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom should therefore be repealed,

²⁰ OJ L 2, 6.1.2004, p. 36

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

SUBJECT MATTER AND SCOPE

Article 1

Subject matter

1. This Directive establishes the basic safety standards for the protection of the health of workers, general public, patients and other individuals subject to medical exposure against the dangers arising from ionising radiation for the purpose of their uniform implementation by Member States.
2. This Directive applies to the protection of the environment as a pathway from radiation sources to the exposure of man, complemented where appropriate with specific consideration of the exposure of biota in the environment as a whole.
3. This Directive sets out requirements for the control of the safety and security of radioactive sources and the provisions of appropriate information in an emergency exposure situation.
4. This Directive sets out requirements for the prevention of exposure of workers and members of the public to ionising radiation arising from orphan sources and from inadequate control of high-activity sealed radioactive sources and for the harmonisation of controls in place in the Member States by defining specific requirements ensuring that each such source is kept under control.
5. This Directive defines at Community level common objectives with regard to measures and procedures for informing the public for the purpose of improving the operational health protection provided in the event of an emergency.

Article 2

Scope

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

- (a) the production, processing, handling, use, storage, holding, transport, shipment, import to, and export from the Community and the disposal of radioactive material;
 - (b) the operation of electrical equipment emitting ionising radiation and the operation of any electrical equipment operating at a potential difference of more than 5 kV;
 - (c) practices which involve the presence of natural radiation sources that lead to a significant increase in the exposure of workers or members of the public, in particular:
 - i) the operation of aircraft and spacecraft;
 - ii) exposure to radon in workplaces;
 - iii) the activities in industries processing materials with naturally occurring radionuclides, or activities related to such processing.
 - (d) any other practice specified by the Member State.
3. This Directive applies to the management of existing exposure situations, in particular the exposure of the public to indoor radon, the external exposure from building materials and cases of lasting exposure resulting from the after-effects of an emergency or a past activity.
4. This Directive applies to the management of emergency exposure situations to the extent that these are deemed to warrant intervention to protect the health of the public or workers or to protect the environment; potential exposures as well as emergency preparedness and planning are part of planned exposure situations.

Article 3

Exclusion from the scope

This Directive shall not apply to radionuclides naturally contained in the human body, to cosmic radiation prevailing at ground level, and to aboveground exposure to radionuclides present in the undisturbed earth's crust.

CHAPTER II

DEFINITIONS

Article 4

For the purpose of this Directive, the following definitions shall apply:

- (1) Medical exposure means exposure incurred by patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment, and

intended to benefit their health or well-being, as well as exposure incurred by carers and comforters and by volunteers in biomedical research;

- (2) Ionising radiation means the transfer of energy in the form of particles or electromagnetic waves of a wavelength of 100 nanometres or less (a frequency of 3×10^{15} Hertz or more) capable of producing ions directly or indirectly;
- (3) Emergency means a non-routine situation or event that necessitates prompt action primarily to mitigate a hazard or adverse consequences for human health and safety, quality of life, property or the environment. This includes nuclear and radiological emergencies;
- (4) Emergency exposure situation means a situation of exposure due to any sudden event which requires urgent decisions to be taken in order to control this situation; the event may result from an accident (whether or not envisaged as a potential exposure) or from a malicious act;
- (5) Exposure means the act of exposing or condition of being exposed to ionising radiation emitted outside the body (external exposure) or within the body (internal exposure);
- (6) Exposure situation means a situation giving rise to exposure, including the radiation sources and the activities or actions which may affect the exposure from these radiation sources;
- (7) Members of the public mean individuals, subject to public exposure;
- (8) Radiation source means an entity that may cause radiation exposure — such as by emitting ionising radiation or by releasing radioactive material — and can be treated as a single entity for protection and safety purposes;
- (9) Radioactive source means a radiation source incorporating radioactive material for the purpose of utilising its radioactivity;
- (10) Radioactive material means material incorporating radioactive substances;
- (11) Orphan source means a sealed source which is neither exempted nor under regulatory control, e.g. because it has never been under regulatory control or because it has been abandoned, lost, misplaced, stolen or otherwise transferred without proper authorisation;
- (12) Building material means a construction product which is produced for incorporation in a permanent manner in a building;
- (13) Disposal means the emplacement of radioactive waste or spent fuel in an authorised facility without the intention of retrieval;
- (14) Existing exposure situation means an exposure situation that already exists when a decision on its control has to be taken and which does not call or no longer calls for urgent measures to be taken;

- (15) Natural radiation source means sources of ionising radiation of natural terrestrial or cosmic origin;
- (16) Planned exposure situation means an exposure situation that arises from the planned operation or introduction of a radiation source or from activities which alter exposure pathways, so as to cause the exposure or potential exposure of people or the environment. Planned exposure situations may include both normal exposures and potential exposures;
- (17) Potential exposure means exposure that is not expected with certainty but may result from an event or sequence of events of a probabilistic nature, including equipment failures and operating errors.
- (18) Radiation protection means the protection of people from harmful effects of exposure to ionising radiation, and the means for achieving this;
- (19) Practice means any activity that involves the operation or introduction of radiation sources or which alters exposure pathways and is managed as a planned exposure situation;
- (20) Radon means the isotope Rn-222 and its progeny, as appropriate (exposure to radon means exposure to radon progeny);
- (21) Storage means the holding of radioactive sources or radioactive waste in a facility that provides adequate containment, with the intention of retrieval;
- (22) Optimisation means a forward-looking iterative process to establish adequate protection measures taking into account the prevailing circumstances, the available options, and the nature of the exposure situation, with the aim of keeping the magnitude and likelihood of exposure and the number of people exposed as low as reasonably achievable;
- (23) Public exposure means exposure of individuals, excluding any occupational or medical exposure;
- (24) Occupational exposure means exposure of workers incurred in the course of their work;
- (25) Health detriment means an estimate of the risk of reduction in length and quality of life occurring in a population following exposure. This includes loss arising from tissue effects, cancer and severe genetic disorder;
- (26) Effective dose (E) means the sum of the weighted equivalent doses in all the tissues and organs of the body from internal and external irradiation. It is defined by the expression:

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

where

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

w_R is the radiation weighting factor and

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

The appropriate w_T and w_R values are specified in Publication 103 of the International Commission on Radiological Protection. The unit for effective dose is the sievert;

- (27) Dose limit means the value of the effective dose or the equivalent dose in a specified period which may not be exceeded for an individual. The dose limit applies to the sum of exposures from all authorised practices;
- (28) Dose constraint means a constraint set as a prospective upper bound of an individual dose, used to define the range of options considered in the process of optimisation for a given radiation source in a planned exposure situation;
- (29) Equivalent dose (H_T) means the absorbed dose, in tissue or organ T weighted for the type and quality of radiation R. It is given by:

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

where

- $D_{T,R}$ is the absorbed dose averaged over tissue or organ T, due to radiation R,
- w_R is the radiation weighting factor.

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

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

The appropriate w_R values are specified in Publication 103 of the International Commission on Radiological Protection. The unit for equivalent dose is the sievert.

- (30) Outside worker means any exposed worker of category A who is not employed by the undertaking responsible for the supervised and controlled areas, but performs activities in these areas, including trainees, apprentices and students;
- (31) Undertaking means a natural or legal person who has legal responsibility for carrying out a practice or who has legal responsibility for a radiation source (including cases where the owner or holder of a radiation source does not conduct related activities);
- (32) Risk constraint means a constraint set as a restriction on the individual risk from a radiation source (risk in the sense of probability of health detriment due to a potential exposure, which is a function of the probability of an unintended event causing a dose and the probability of detriment due to that dose);
- (33) Carers and comforters means individuals knowingly and willingly incurring an exposure to ionising radiation by helping, other than as part of their occupation,

in the support and comfort of individuals undergoing or having undergone medical exposure;

- (34) Reference level means, in an emergency exposure situation or in an existing exposure situation, the level of dose or risk above which it is judged inappropriate to allow exposures to occur, and below which optimisation of protection should continue to be implemented;
- (35) Exposed worker means a person, either self-employed or working under an employer, who is subject to exposure at work carried out within a practice regulated by this Directive and who is liable to receive doses exceeding one or other of the dose limits for public exposure;
- (36) Sievert (Sv) means the special name of the unit of equivalent or effective dose. One sievert is equivalent to one joule per kilogram: $1 \text{ Sv} = 1 \text{ J kg}^{-1}$;
- (37) Intake means the activities of radionuclides entering the body from the external environment;
- (38) Apprentice means a person receiving training or instruction within an undertaking with a view to exercising a specific skill.
- (39) Committed effective dose ($E(\tau)$) means the sum of the committed organ or tissue equivalent doses $H_T(\tau)$ resulting from an intake, each multiplied by the appropriate tissue weighting factor w_T . It is defined by:

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

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

- (40) Medical physics expert means an individual having the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to medical exposure, whose competence to act is recognised by the competent authorities;
- (41) Occupational health service means a health professional or body having competence for the medical surveillance of exposed workers and whose capacity to act in that respect is recognised by the competent authorities;
- (42) Radiation protection expert means an individual having the knowledge, training and experience needed to give radiation protection advice in order to ensure the effective protection of individuals, and whose capacity to act is recognised by the competent authorities;
- (43) High-activity sealed source means a sealed source in which the amount of radioactive material exceeds the values laid down in Annex II;

- (44) Emergency response plan means arrangements to plan for adequate response in the event of an emergency exposure situation related to a specific facility or activity on the basis of postulated events and related scenarios;
- (45) Emergency worker means any person having a defined role as a worker in an emergency and who might be exposed while taking action in response to the emergency;
- (46) Dosimetry service means a body or an individual having the competence for calibration, reading or interpretation of individual monitoring devices, or for measurement of radioactivity in the human body or in biological samples, or for assessment of doses, whose capacity to act in this respect is recognised by the competent authorities;
- (47) Emergency management system means legal or administrative framework establishing responsibilities for emergency preparedness and response, and arrangements for decision making in the event of an emergency exposure situation;
- (48) Medical radiological means pertaining to radiodiagnostic and radiotherapeutic procedures, and interventional radiology or other planning and guiding radiology using ionising radiation;
- (49) Practical aspects of medical exposure procedures means the physical conduct of a medical exposure and any supporting aspects including handling and use of medical radiological equipment, and the assessment of technical and physical parameters, including radiation doses, calibration and maintenance of equipment, preparation and administration of radio-pharmaceuticals, and image processing as carried out by, among others, radiographers and technicians in nuclear medicine and radiotherapy;
- (50) Practitioner means a medical doctor, dentist or other health professional who is entitled to take clinical responsibility for an individual medical exposure in accordance with national requirements.
- (51) Diagnostic reference levels means dose levels in medical radiodiagnostic or interventional radiology practices, or, in the case of radio-pharmaceuticals, levels of activity, for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment;
- (52) Activation means the process through which a stable nuclide is transformed into a radionuclide by irradiating with particles or high-energy photons the material in which it is contained;
- (53) Radioactive substance means any substance that contains one or more radionuclides, the activity concentration of which cannot be disregarded as far as radiation protection is concerned;
- (54) Non-medical imaging exposure means any deliberate exposure of humans for imaging purposes where the primary motivation for the exposure is not related to the health or well-being of the individual being exposed;

- (55) Notification means submission of a document to the competent authority to notify the intention to carry out a practice within the scope of this Directive.
- (56) Registration means permission granted in a document by the competent authority, or granted by national legislation, to carry out an activity in accordance with conditions laid down in national legislation;
- (57) Consumer product means a device or manufactured item into which radionuclides have deliberately been incorporated or produced by activation, or which generates ionising radiation, and which can be sold or made available to members of the public without special surveillance or regulatory control after sale;
- (58) Accelerator means an apparatus or installation in which particles are accelerated, emitting ionising radiation with energy higher than 1 mega-electron volt (MeV);
- (59) Disused sealed source means a sealed source which is no longer used or intended to be used for the practice for which authorisation was granted;
- (60) Inspection means an investigation by any competent authority to verify compliance with national provisions;
- (61) Radiation generator means a device capable of generating ionising radiation, such as X rays, neutrons, electrons or other charged particles, which may be used for scientific, industrial or medical purposes;
- (62) Radioactive waste means radioactive material for which no further use is foreseen.
- (63) Quality assurance means all those planned and systematic actions necessary to provide adequate assurance that a structure, system, component or procedure will perform satisfactorily in compliance with agreed standards. Quality control is a part of quality assurance;
- (64) Licence means permission granted by the competent authority, on application, to carry out a practice subject to conditions laid down in a specific licence document;
- (65) Clearance levels means values established by the competent authority or in national legislation, and expressed in terms of activity concentrations, at or below which materials arising from any practice subject to notification or authorisation may be released from the requirements of this Directive.
- (66) Supervised area means an area subject to supervision for the purpose of protection against ionising radiation;
- (67) Controlled area means an area subject to special rules for the purpose of protection against ionising radiation or preventing the spread of radioactive contamination and to which access is controlled;

- (68) Accidental exposure means an exposure of individuals, other than emergency workers, as a result of an accident;
- (69) Emergency occupational exposure means occupational exposure received in an emergency exposure situation by individuals taking action to mitigate the consequences of the emergency;
- (70) Health screening means a procedure using medical radiological installations for early diagnosis in population groups at risk;
- (71) Radon-prone area means a geographic area or administrative region defined on the basis of surveys indicating that the percentage of dwellings expected to exceed the national reference level is significantly higher than in other parts of the country;
- (72) Medical radiological procedure means any procedure giving rise to medical exposure;
- (73) Referrer means a medical doctor, dentist or other health professional who is entitled to refer individuals for medical radiological procedures to a practitioner, in accordance with national requirements;
- (74) Individual detriment means clinically observable deleterious effects in individuals or their descendants, the appearance of which is either immediate or delayed and, in the latter case, implies a probability rather than a certainty of appearance;
- (75) Interventional radiology means the use of X-ray imaging techniques, in addition to those involving ultrasound or magnetic resonance imaging or other non-ionising radiation techniques, to introduce and guide devices in the body for diagnostic or treatment purposes;
- (76) Radiodiagnostic means pertaining to in-vivo diagnostic nuclear medicine, medical diagnostic radiology using ionising radiation, and dental radiology;
- (77) Radiotherapeutic means pertaining to radiotherapy, including nuclear medicine for therapeutic purposes;
- (78) Clinical responsibility means responsibility of a practitioner for individual medical exposures, notably: justification; optimisation; clinical evaluation of the outcome; cooperation with other specialists and staff, as appropriate, regarding practical aspects of medical exposure procedures; obtaining information, if appropriate, on previous examinations; providing existing medical radiological information and/or records to other practitioners and/or the referrer, as required; and giving information on the risk of ionising radiation to patients and other individuals involved, as appropriate;
- (79) Clinical audit means a systematic examination or review of medical radiological procedures which seeks to improve the quality and outcome of patient care through structured review, whereby medical radiological practices, procedures and results are examined against agreed standards for good medical

radiological procedures, with modification of practices where indicated and the application of new standards if necessary;

- (80) Medical radiological installation means a facility containing medical radiological equipment;
- (81) Unintended exposure means medical exposure that is significantly different from the medical exposure intended for a given purpose;
- (82) Representative person means an individual receiving a dose that is representative of the more highly exposed individuals in the population;
- (83) Radiation protection officer means an individual who is technically competent in radiation protection matters relevant for a given type of practice and is designated by the undertaking to oversee the implementation of the radiation protection arrangements of the undertaking;
- (84) Remedial measures means the removal of a source or the reduction of its magnitude (in terms of activity or amount) for the purposes of avoiding or reducing doses that might otherwise be received in an existing exposure situation.
- (85) Protective measures means measures, other than remedial measures, for the purpose of avoiding or reducing doses that might otherwise be received in an emergency exposure situation or an existing exposure situation.
- (86) Authorisation means the granting by a competent authority of written permission for an undertaking to perform specified activities subject to regulatory control in the form of registration or a licence;
- (87) Sealed source means a radioactive source in which the radioactive material is permanently sealed in a capsule or closely bonded in a solid form;
- (88) Supplier means any natural or legal person who supplies or makes available a sealed source;
- (89) Source container means the containment of a sealed source, where this is not an integral part of the source but is meant for shielding the source during its use, transport, handling, etc.
- (90) Thoron means the isotope Rn-220;
- (91) Residual dose means the dose expected to be incurred from all exposure pathways after protective measures have been fully implemented, or where a decision has been taken not to implement any protective measures;
- (92) Absorbed dose (D) means the energy absorbed per unit mass

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

where

- $d\bar{\varepsilon}$ is the mean energy imparted by ionising radiation to the matter in a volume element,
- dm is the mass of the matter in this volume element.

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

- (93) Gray (Gy) is the unit of absorbed dose. One gray is equal to one joule per kilogram: $1\text{Gy} = 1\text{ J kg}^{-1}$;
- (94) Activity (A) means the activity, A , of an amount of a radionuclide in a particular energy state at a given time. It is the quotient of dN by dt , where dN is the expectation value of the number of spontaneous nuclear transitions from that energy state in the time interval dt :

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

The unit of activity is the becquerel;

- (95) Becquerel (Bq) means the special name of the unit of activity. One becquerel is equivalent to one nuclear transition per second: $1\text{ Bq} = 1\text{ s}^{-1}$;
- (96) Committed equivalent dose ($H_T(\tau)$) means the integral over time (τ) of the equivalent dose rate (in tissue or organ T) that will be received by an individual as a result of an intake. It is given by:

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

for an intake at time t_0 where

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

τ is the time over which the integration is performed.

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

- (97) Normal exposure means exposure expected to occur under the normal operating conditions of a facility or activity (including maintenance, inspection, decommissioning), including possible minor mishaps that can be kept under control, i.e. during normal operation and anticipated operational occurrences;
- (98) Projected dose means the dose that would be expected to be incurred if no protective measures were to be taken;

- (99) Quality control means the set of operations (programming, coordinating, implementing) intended to maintain or to improve quality. It includes monitoring, evaluation and maintenance at required levels of all characteristics of performance of equipment that can be defined, measured, and controlled;
- (100) Response strategy means a set of different protective measures to respond to postulated or actual events so as to manage an emergency exposure situation in accordance with the stated objectives. Within an emergency response plan, response strategies are established for each postulated event and scenario;

CHAPTER III

SYSTEM OF RADIATION PROTECTION

Article 5

General principles

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

- (a) justification: decisions introducing or altering a radiation source, an exposure pathway or actual exposures shall be justified in the sense that such decisions shall be taken with the intent to ensure that the individual or societal benefit resulting from them offsets the detriment that they may cause;
- (b) optimisation: in all exposure situations, radiation protection shall be optimised with the aim of keeping the magnitude and likelihood of exposure and the number of individuals exposed as low as reasonably achievable, taking into account economic and societal factors, whereby optimisation of the protection of individuals undergoing medical exposure shall be commensurate with the medical purpose of the exposure as described in Article 55. This principle shall be applied in terms of effective dose as well as organ doses, as a precautionary measure to allow for uncertainties as to health detriment below the threshold, for deterministic effects;
- (c) dose limitation: in planned exposure situations, the sum of doses to an individual from all regulated radiation sources may not exceed the dose limits laid down for occupational exposure or public exposure. Dose limits shall not apply to medical exposures.

SECTION 1

TOOLS FOR OPTIMISATION

Article 6

Dose constraints for occupational and public exposure

1. For occupational exposure, the dose constraint shall be established as an operational tool for optimisation by the undertaking under the general supervision of the competent authorities. In the case of outside workers the dose constraint shall be established in cooperation between the employer and the undertaking.
2. For public exposure, the dose constraint shall be set for the individual dose that members of the public receive from the planned operation of a specified radiation source. The competent authorities shall set the constraint so as to ensure compliance with the dose limit for the sum of doses to the same individual from all authorised practices.
3. With regard to potential exposures, optimisation shall include adequate management of the safety and security of sources and facilities. Where appropriate risk constraints may be established.
4. Dose constraints shall be established in terms of individual effective or equivalent doses over a year or any other appropriate shorter time period.
5. Where dose constraints are introduced to restrict any protracted accumulated exposure, these shall be established in terms of annual effective doses or equivalent doses to an organ.

Article 7

Dose constraints for medical exposure

Dose constraints shall not apply for the medical exposure of patients.

For carers and comforters and for volunteers participating in medical and biomedical research (for whom no direct medical benefit is expected from the exposure), dose constraints shall be established in terms of the individual dose that is unlikely to be exceeded for the period of the examination, treatment or research project in question.

Article 8

Reference levels

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

SECTION 2

DOSE LIMITATION

Article 9

Age limit for exposed workers

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

Article 10

Dose limits for occupational exposure

1. The limit on the effective dose for occupational exposure shall be 20 mSv in any single year. However, in special circumstances or for certain exposure situations specified in national legislation, a higher effective dose of up to 50 mSv per year may be authorised in a single year, provided that the average dose over any five consecutive years does not exceed 20 mSv per year.

For emergency workers a higher effective dose may be authorised, in accordance with Article 52.
2. In addition to limits of effective dose laid down in paragraph 1, the following limits on equivalent dose shall apply:

- (a) the limit on the equivalent dose for the lens of the eye shall be 20 mSv in a year or, where applicable, the same value as specified for the limit on effective dose;
- (b) the limit on the equivalent dose for the skin shall be 500 mSv in a year; this limit shall apply to the dose averaged over any area of 1 cm², regardless of the area exposed;
- (c) the limit on the equivalent dose for the hands, forearms, feet and ankles shall be 500 mSv in a year.

Article 11

Protection of pregnant women

1. As soon as a pregnant woman informs the undertaking of her condition, in accordance with national legislation or national practice, the protection of the unborn child shall be comparable with that provided for members of the public. The employment conditions for the pregnant woman shall be such that the equivalent dose to the unborn child is as low as reasonably achievable and unlikely to exceed 1 mSv during at least the remainder of the pregnancy.
2. As soon as a breastfeeding woman informs the undertaking of her condition, she shall not be employed in work involving a significant risk of intake of radionuclides.

Article 12

Dose limits for apprentices and students

1. The dose limits for apprentices aged 18 years or over and students aged 18 years or over who, in the course of their studies, are obliged to work with radiation sources shall be the same as the dose limits for occupational exposure laid down in Article 10.
2. The limit on the effective dose for apprentices aged between 16 and 18 years and for students aged between 16 and 18 years who, in the course of their studies, are obliged to work with radiation sources shall be 6 mSv per year.

In addition to limits of effective dose laid down in the first subparagraph, the following limits on equivalent dose shall apply:

- (a) the limit on the equivalent dose for the lens of the eye shall be 20 mSv in a year;
- (b) the limit on the equivalent dose for the skin shall be 150 mSv in a year, averaged over any area of 1 cm², regardless of the area exposed;
- (c) the limit on the equivalent dose for the hands, forearms, feet and ankles shall be 150 mSv in a year.

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

Article 13

Dose limits for public exposure

1. The limit on the effective dose for public exposure shall be 1 mSv in a year.
2. In addition to the dose limit referred to in the paragraph 1, the following limits on the equivalent dose shall apply:
 - (a) the limit on the equivalent dose for the lens of the eye shall be 15 mSv in a year;
 - (b) the limit on the equivalent dose for the skin shall be 50 mSv in a year, averaged over any 1 cm² area of skin, regardless of the area exposed.

Article 14

Estimation of the effective and equivalent dose

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

- (a) for external radiation, the values and relationships laid down in Publication 103 of the International Commission on Radiological Protection shall be used to estimate the effective and equivalent doses;
- (b) for internal exposure from a radionuclide or from a mixture of radionuclides, the values and relationships laid down in Publication 103 of the International Commission on Radiological Protection and the ingestion and inhalation dose coefficients laid down in Publication 72 of the International Commission on Radiological Protection shall be used to estimate the committed effective doses.

CHAPTER IV

REQUIREMENTS FOR RADIATION PROTECTION EDUCATION, TRAINING AND INFORMATION

Article 15

General responsibilities for education, training and provision of information

1. Member States shall establish an adequate legislative and administrative framework for providing appropriate radiation protection education, training and information to all individuals whose tasks require specific competences in radiation protection. The training, retraining and information of relevant individuals shall be repeated at appropriate intervals and documented.
2. Member States shall establish education, training and retraining to allow the recognition of radiation protection experts, medical physics experts, occupational health services, and dosimetry services.

Article 16

Training of exposed workers, apprentices and students and information provided to them

1. Member States shall require the undertaking or the employer to inform exposed workers, apprentices and students who are subject to occupational exposure on:
 - (a) the health risks involved in their work;
 - (b) the general radiation protection procedures and precautions to be taken, in particular those connected with the operational and working conditions of both the practice in general and each type of workstation or work to which they may be assigned;
 - (c) the emergency response plans and procedures;
 - (d) the importance of complying with the technical, medical and administrative requirements;
2. Member States shall require the undertaking or the employer to inform women on the importance of making an early declaration of pregnancy in view of the risks of exposure for the unborn child and the risk of contaminating a nursing infant after intake of radionuclides.

3. Member States shall require that the undertaking or the employer provides appropriate radiation protection training and information programmes for their personnel.
4. In addition to the information and training in the field of radiation protection as provided for in paragraphs 1, 2 and 3, an undertaking responsible for high-activity sealed sources shall ensure that such training includes specific requirements for the safe management and security of high-activity sealed sources with a view to preparing the relevant workers adequately for any events affecting their own safety or the radiation protection of other individuals. The information and training shall place particular emphasis on the necessary safety requirements and shall contain specific information on the possible consequences of the loss of adequate control of high-activity sealed sources.

Article 17

Information and training of workers potentially exposed to orphan sources

Member States shall ensure that the management of and workers in installations where orphan sources are most likely to be found or processed, in particular large metal scrap yards and major metal scrap recycling plants, and in significant nodal transit points, are:

- (a) informed of the possibility that they may be confronted with a source;
- (b) advised and trained in the visual detection of sources and their containers;
- (c) informed of basic facts about ionising radiation and its effects;
- (d) informed about detection systems;
- (e) informed of and trained in the action to be taken on site in the event of the detection or suspected detection of a source.

Article 18

Information and training for emergency workers

1. Member States shall ensure that emergency workers and any other persons who might be involved in the organisation of emergency assistance in the event of an emergency are given adequate and regularly updated information on the health risks their intervention might involve and on the precautionary measures to be taken in such an event. This information shall take into account the range of potential emergencies.
2. As soon as an emergency occurs, the information referred to in paragraph 1 shall be supplemented appropriately, having regard to the specific circumstances.

3. Member States shall ensure that emergency workers receive regular training as provided for in the emergency management system set out in Article 97. Where appropriate, this training shall include practical exercises.
4. Member States shall ensure that, in addition to the emergency response training referred to in paragraph 3 of this Article, the organisation responsible for the protection of emergency workers as referred to in Article 30(1)(b) provides these workers with appropriate radiation protection training and information.

Article 19

Education, information and training in the field of medical exposure

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

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

2. Individuals undergoing relevant training programmes may participate in practical aspects of medical exposure procedures as set out in Article 56(4).
3. Member States shall ensure that continuing education and training after qualification is provided and, in the special case of the clinical use of new techniques, training is provided on these techniques and the relevant radiation protection requirements.
4. Member States shall ensure that mechanisms are in place for the timely dissemination of information relevant to radiation protection for medical exposure regarding lessons learned from significant events.
5. Member States shall ensure the introduction of a course on radiation protection in the basic curriculum of medical and dental schools.

CHAPTER V

JUSTIFICATION AND REGULATORY CONTROL OF PRACTICES

Article 20

Justification of practices

1. Member States shall ensure that new types of practices resulting in exposure to ionising radiation are justified before being approved.
2. Member States shall list the approved types of practices in legislation or administrative acts.
3. Existing types of practices shall be reviewed as to their justification whenever new and important evidence about their efficacy or potential consequences is acquired.

Article 21

Justification of practices with apparatus or products emitting ionising radiation

1. Member States shall require any undertaking intending to manufacture or import or export a new type of apparatus or product emitting ionising radiation to provide the competent authorities with relevant information as set out in Annex III, Section A, in order to enable the authorities, on the basis of assessment of information set out in Annex III, Section B, to decide whether the intended use of the apparatus or product can be justified.
2. The competent authority shall share the information received in accordance with paragraph 1 with the competent authorities of the other Member States to allow them to take their own decision on the justification of the intended use of the apparatus or product.
3. The undertaking shall be informed on the decisions of the Member States' competent authorities within a period of six months.

Article 22

Prohibition of practices

Member States shall prohibit the deliberate addition of radioactive substances in the production of foodstuffs, toys, personal ornaments and cosmetics, and shall prohibit

the import or export of such products. Without prejudice to Directive 1999/2/EC of the European Parliament and of the Council²¹, practices involving the activation of material resulting in an increase in activity in the associated products shall be deemed not to be justified.

Article 23

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

1. Member States shall ensure the identification, by means of surveys or by any other appropriate means, of practices involving non-medical imaging exposure, as set out in Annex IV.
2. Member States shall ensure that special attention is given to the justification of practices involving non-medical imaging exposure, in particular:
 - (a) all types of practices involving non-medical imaging exposure, as listed in Annex IV, shall be justified in advance before being generally accepted;
 - (b) each particular application of a generally accepted type of practice shall be justified in advance;
 - (c) all individual non-medical imaging exposure procedures as listed in Annex IV, section A implemented by medical staff using medical radiological equipment shall be justified in advance taking into account the specific objectives of the procedure and the characteristics of the individual involved;
 - (d) the general and particular justification of practices involving non-medical imaging exposure, as specified in points (a) and (b), shall be subject to periodic review by the competent authority.
3. Where a Member State has determined that a particular practice involving non-medical imaging exposure is justified it shall ensure that:
 - (a) each practice is subject to authorisation;
 - (b) requirements for the practice, including criteria for individual implementation, are established by the competent authority, in cooperation with other relevant agencies and professional bodies as appropriate;
 - (c) dose constraints are established for each practice. Such shall be well below the dose limit for members of the public, including, whenever practicable, for procedures implemented by medical staff using medical equipment as set out in Annex IV, Section A; for other practices set out in Annex IV, section B, the dose constraint shall satisfy the requirements of Article 6(2);

²¹ OJ L 66, 13.3.1999, p.16.

- (d) relevant requirements set out in Chapter VII, including those for equipment, optimisation, responsibilities and special protection during pregnancy, are met for procedures implemented by medical staff using medical radiological equipment;
- (e) the informed consent of the individual to be exposed is sought, allowing for cases where the law enforcement bodies may proceed without consent according to national legislation;
- (f) where the exposure is routinely carried out for security purposes the screened individuals are provided with a choice of an alternative technique which does not involve exposure to ionising radiation.

Article 24

Identification of practices involving naturally occurring radioactive material

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

Article 25

Notification

1. Member States shall require all practices, including practices identified in accordance with Article 24, to be notified, except for justified practices involving the following:
 - (a) materials containing radioactive substances where the quantities of the activity involved do not exceed in total the exemption values set out in Annex VI or higher values that, for specific applications, are authorised by the competent authorities and satisfy the general exemption and clearance criteria set out in Annex VI; or
 - (b) materials containing radioactive substances, provided that the concentrations of activity per unit mass do not exceed the exemption values set out in Table A of Annex VI, or higher values that, for specific applications, are authorised by the competent authorities and satisfy the general exemption and clearance criteria set out in Annex VI; or
 - (c) any cathode ray tube intended for the display of visual images, or other electrical apparatus operating at a potential difference not exceeding 30 kV, or any other apparatus or product which is of a type approved by the competent authorities of the Member State, provided that:

- (i) it does not cause, in normal operating conditions, a dose rate exceeding $1 \mu\text{Sv}\cdot\text{h}^{-1}$ at a distance of 0.1 m from any accessible surface of the apparatus; and
 - (ii) if it contains radioactive substances, these substances are embedded in a capsule or fixed to a solid holder; and
 - (iii) conditions for disposal have been specified by the competent authorities.
2. Member States may exempt further types of practices from the notification requirement subject to compliance with the general exemption criteria established in point 3 of Annex VI, or in such cases where an assessment of the optimisation of protection shows that exemption is the best option.
 3. Practices that involve naturally occurring radioactive material, identified in accordance with Article 24, and produce or process residues which are known to be recycled into identified building materials are subject to notification if the activity concentration index as defined in Annex VII in the resulting building materials is liable to exceed 1. The undertaking shall also in this case inform the user of the residue about the activity concentration of the residue.
 4. In situations identified by Member States where there is concern that a practice identified in accordance with Article 24 may lead to the presence of naturally occurring radionuclides in water liable to affect the quality of drinking water supplies or affect any other exposure pathways, so as to be of concern from a radiation protection point of view, the competent authority may require that the practice be subject to notification irrespective of paragraph 1(b) of this Article.
 5. For types of practices subject to notification, Member States shall specify the information to be provided by the undertaking so as to allow the competent authority to establish appropriate means of regulatory control.
 6. For the purpose of exemption in accordance with paragraph 1(c), Member States shall exchange information on the type approvals that have been granted and on the underlying documentation and assessment. Competent authorities shall take into account such information received, as well as applicable European and international standards, in making their own decisions with regard to the exemption of corresponding practices.

Article 26

Regulatory control

1. Member States shall require any notified practice to be subject to regulatory control commensurate with the magnitude and likelihood of exposures resulting from the practice, and commensurate with the impact that regulatory control may have in reducing such exposures or improving the safety of installations.
2. Notified practices may be exempted from authorisation.

3. In the case of moderate amounts of material as specified by Member States, the activity concentration values laid down in Annex VI, Table B, column 2, may be used for the purpose of exemption.
4. Notified practices which are not exempted shall be subject to authorisation through registration or licensing.

Article 27

Authorisation

1. In cases where a limited risk of exposure does not necessitate the examination of individual cases and the practice is undertaken in accordance with conditions laid down in national legislation, competent authorities may limit regulatory control to registration of the practice and an appropriate frequency of inspections.
2. Member States shall require licensing for the following practices:
 - (a) the operation and decommissioning of any facility of the nuclear fuel cycle and the exploitation and closure of uranium mining;
 - (b) the deliberate addition of radioactive substances in the production and manufacture of consumer products or other products, including medicinal products, and the import or export of such products;
 - (c) the manufacture, use or taking possession of a high-activity sealed source;
 - (d) the operation, decommissioning and closure of any facility for the processing, storage or disposal of radioactive waste;
 - (e) practices in which workers are liable to receive an annual effective dose of more than 6 mSv in normal operation and under normal working conditions;
 - (f) practices discharging significant amounts of airborne or liquid effluent into the environment.
3. Member States shall require either registration or licensing of the following practices:
 - (a) the deliberate administration of radioactive substances to persons and, in so far as the radiation protection of human beings is concerned, animals for the purpose of medical or veterinary diagnosis, treatment or research;
 - (b) the use of radiation generators or radioactive sources for industrial radiography, the processing of products or research, and the use of accelerators, except electron microscopes;
 - (c) the use of radiation generators or radioactive sources for medical exposures;

- (d) the manufacture and operation of electrical equipment emitting ionising radiation and operating at a potential difference of more than 30 kV, as well as the import or export of such equipment;
 - (e) practices in which workers are liable to receive an annual effective dose of more than 1 mSv in normal operation and under normal working conditions;
 - (f) industries involving naturally occurring radioactive material identified by Member States as required in Article 24, and liable to lead to an effective dose to a member of the public equal to or exceeding 0.3 mSv per year.
4. Member States may require registration or licensing for types of practices other than those listed in paragraphs 2 and 3.

Article 28

Authorisation procedure

1. For authorisation purposes, Member States shall require the provision of information commensurate with the nature of the practice and the risks involved.
2. The information required for the purpose of granting a license cover at least the following:
 - (a) responsibilities and organisational arrangements for protection and safety;
 - (b) staff competences, including information and training;
 - (c) design features of the installation and radiation sources;
 - (d) anticipated occupational and public exposures in normal operation;
 - (e) safety assessment of the activities and the installation in order to:
 - (i) identify ways in which potential exposures or accidental and unintended medical exposures could occur;
 - (ii) estimate, to the extent practicable, the probabilities and magnitude of potential exposures;
 - (iii) assess the quality and extent of protection and safety provisions, including engineering features as well as administrative procedures;
 - (iv) define the operational limits and conditions of operation;
 - (f) emergency procedures and communication links;
 - (g) maintenance, testing, inspection and servicing so as to ensure that the radiation source and the installation continue to meet the design requirements, operational limits and conditions of operation throughout their lifetime;

- (h) management of radioactive waste and arrangements for the disposal of such waste in accordance with applicable regulatory requirements;
 - (i) management of disused sealed sources;
 - (j) quality assurance.
3. A licence shall include specific conditions so as to ensure that the elements of the licence are legally enforceable or to impose appropriate restrictions on the operational limits or conditions of operation. The conditions shall also require the formal, documented implementation of the principle of optimisation.
 4. Where applicable, a licence shall include a discharge authorisation issued in accordance with the requirements laid down in Chapter VIII for authorisation of the release of liquid or airborne radioactive effluent into the environment.
 5. Member States shall require the undertaking to promptly notify the occurrence of any significant event resulting or liable to result in the exposure of an individual beyond the operational limits or conditions of operation specified in licensing requirements with regard to occupational or public exposure or as defined by the authorities for medical exposure.

Article 29

Release from regulatory control

1. The disposal, recycling or reuse of radioactive materials arising from any authorised practice is subject to authorisation.
2. The materials for disposal, recycling or reuse may be released from the requirements of this Directive provided that the concentrations of activity per unit mass:
 - (a) do not exceed the values set out in Annex VI, Table A, part 1; or
 - (b) comply with specific clearance levels and associated requirements for specific materials or for materials originating from specific types of practices; these specific clearance levels, in addition to the general clearance levels referred to in point (a), shall be established by the national competent authority following the general exemption criteria set out in Annex VI, point 3 and taking into account technical guidance provided by the Community.
3. For the clearance of materials containing naturally occurring radionuclides, the values for the concentrations of activity per unit mass shall be those laid down in Annex VI, Table A, part 2. Nevertheless the following requirements shall apply:
 - (a) for practices subject to licensing as specified in Article 27(3)(f), the dose criteria for clearance of naturally occurring radionuclides shall be complied with;

- (b) for other licensed practices, in particular those forming part of the nuclear fuel cycle, the clearance levels shall comply with the dose criteria for clearance of materials containing artificial radionuclides;
 - (c) for authorised practices subject to notification as specified under Article 25(3), the corresponding requirements for the placing on the market of building materials shall be complied with.
4. The deliberate dilution of radioactive residues, other than the mixing of materials that takes place in normal operation when radioactivity is not a consideration, shall not be permitted. The competent authority may authorise in specific situations the mixing of radioactive residues containing naturally occurring radioactive material with other materials to promote the reuse and recycling of these materials and to reduce public exposure.

CHAPTER VI

PROTECTION OF WORKERS, APPRENTICES AND STUDENTS

Article 30

Responsibilities

1. The requirements for occupational exposure laid down in this Chapter and in Articles 9, 10, 11 and 12, shall apply to the protection of workers in any exposure situation where their exposure at work or as the result of work is the legal responsibility of an undertaking or another legal person, including for instance:
 - (a) the employer of outside workers;
 - (b) the organisation responsible for the protection of emergency workers;
 - (c) the organisation responsible for the remediation of contaminated land, buildings and other constructions;
 - (d) the employer who has legal responsibility for the exposure of workers to radon at work, in the situation specified in Article 53(4).
2. The responsibility of an undertaking for occupational exposure shall extend to apprentices and students who in the course of their studies are obliged to work with radiation sources and to individuals who are self-employed or work on a voluntary basis or for a charity organisation.
3. The undertaking shall be responsible for assessing and implementing arrangements for the radiation protection of exposed workers.

Article 31

Operational protection of workers

The operational protection of exposed workers shall be based on:

- (a) prior evaluation to identify the nature and magnitude of the radiological risk to exposed workers;
- (b) implementation of the optimisation of radiation protection in all working conditions;
- (c) classification of workers into different categories;
- (d) implementation of control measures and monitoring relating to the different areas and working conditions, including, where necessary, individual monitoring;
- (e) medical surveillance.

Article 32

Consultations with radiation protection expert

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

- (a) prior critical examination of plans for installations from the point of view of radiation protection;
- (b) the acceptance into service of new or modified radiation sources from the point of view of radiation protection;
- (c) regular checking of the effectiveness of protective devices and techniques;
- (d) regular calibration of measuring instruments and regular checking that they are serviceable and correctly used.

Article 33

Arrangements in workplaces

1. For the purposes of radiation protection, arrangements shall be made as regards all workplaces where there is a possibility of exposure to ionising radiation in excess of an effective dose of 1 mSv per year or an equivalent dose of 15 mSv per year for the lens of the eye or 50 mSv per year for the skin and extremities. Such arrangements

shall be appropriate to the nature of the installations and sources and to the magnitude and nature of the risks.

2. For practices involving naturally occurring radioactive material where the effective dose to workers is liable to exceed 6 mSv per year, the requirements set out in this Chapter shall apply. Where the effective dose to workers is less than or equal to 6 mSv per year the competent authorities shall at least require undertakings to keep exposures under review, taking into account the potential for protection to be improved or the potential for doses to increase over time or as a result of changes in the process or the work arrangements.
3. For undertakings operating aircraft where the effective dose to the crew from cosmic radiation is liable to exceed 6 mSv per year, the relevant requirements set out in this Chapter shall apply. Where the effective dose to the crew is less than or equal to 6 mSv per year and liable to be above 1 mSv per year, the competent authorities shall at least require undertakings to keep exposures under review, taking into account the potential for doses to change over time or as a result of changes in the work arrangements. The undertakings shall take appropriate measures, in particular:
 - (a) to assess the exposure of the crew concerned;
 - (b) to take into account the assessed exposure when organising working schedules with a view to reducing the doses of highly exposed crew;
 - (c) to inform the workers concerned of the health risks their work involves and their individual dose.

Article 34

Classification of workplaces

1. Workplaces shall be classified into different areas, where appropriate, on the basis of an assessment of the expected annual doses and the probability and magnitude of potential exposures.
2. A distinction shall be made between controlled areas and supervised areas. The competent authorities shall establish guidance on the classification of controlled and supervised areas with regard to particular circumstances.
3. The undertaking shall keep under review the working conditions in controlled and supervised areas.

Article 35

Requirements for controlled areas

1. The minimum requirements for a controlled area shall be the following:

- (a) the controlled area shall be delineated and access to it shall be restricted to individuals who have received appropriate instructions and shall be controlled in accordance with written procedures provided by the undertaking. Wherever there is a significant risk of the spread of radioactive contamination, specific arrangements shall be made, including for the access and exit of individuals and goods and for monitoring contamination within the controlled area and in the adjacent area;
 - (b) taking into account the nature and extent of radiological risks in the controlled area, radiological surveillance of the working environment shall be organised in accordance with Article 37;
 - (c) signs indicating the type of area, the nature of the sources and their inherent risks shall be displayed;
 - (d) working instructions appropriate to the radiological risk associated with the sources and the operations involved shall be laid down.
2. The undertaking shall be responsible for implementation of these requirements following consultations with the radiation protection expert.

Article 36

Requirements for supervised areas

1. The requirements for a supervised area shall be the following:
 - (a) taking into account the nature and extent of radiological risks in the supervised area, radiological surveillance of the working environment shall be organised in accordance with Article 37;
 - (b) signs indicating the type of area, the nature of the sources and their inherent risks shall be displayed;
 - (c) working instructions appropriate to the radiological risk associated with the sources and the operations involved shall be laid down.
2. The undertaking shall be responsible for implementation of these requirements following consultations with the radiation protection expert.

Article 37

Radiological surveillance of the working environment

1. The radiological surveillance of the working environment referred to in Articles 35(1)(b) and 36(1)(a) shall comprise, where appropriate:

- (a) the measurement of external dose rates, indicating the nature and quality of the radiation in question;
 - (b) the measurement of the air activity concentration and the surface density of contaminating radionuclides, indicating their nature and their physical and chemical states;
 - (c) the measurement of radon concentrations in the workplace.
2. The results of these measurements shall be recorded and shall be used, if necessary, for estimating individual exposure, as provided for in Article 39.

Article 38

Categorisation of exposed workers

1. For the purposes of monitoring and surveillance, a distinction shall be made between two categories of exposed workers:
 - (a) category A: exposed workers who are liable to receive an effective dose greater than 6 mSv per year or an equivalent dose greater than 15 mSv per year for the lens of the eye or greater than 150 mSv per year for skin and extremities;
 - (b) category B: exposed workers who are not classified as category A workers.
2. The distinction between two categories of exposed workers referred to in paragraph 1 shall be made prior to employment for work involving exposure and shall be subject to regular review on the basis of working conditions and medical surveillance.
3. For emergency workers, the distinction between two categories of exposed workers referred to in paragraph 1 of this Article, where appropriate, shall have no effect on the requirements for monitoring set out in Articles 37, 39 – 43 as long as the workers are not involved in an actual emergency exposure situation.

Article 39

Individual monitoring

1. Category A workers shall be systematically monitored based on individual measurements performed by a dosimetry service. In cases where category A workers are liable to receive significant internal exposure or significant exposure of the lens of the eye or extremities an adequate system for monitoring shall be set up. The competent authority shall give special attention to the identification of such workers.
2. Monitoring for category B workers shall be at least sufficient to demonstrate that such workers are correctly classified in category B. Member States may require individual monitoring and if necessary individual measurements, performed by a dosimetry service, for category B workers.

3. In cases where individual measurements are impossible or inadequate, the individual monitoring shall be based on an estimate arrived at either from individual measurements made on other exposed workers or from the results of the surveillance of the working environment provided for in Article 37.

Article 40

Monitoring in the case of accidental exposure

In the case of accidental exposure, the undertaking in collaboration with the dosimetry service shall assess the relevant doses and their distribution in the body.

Article 41

Recording and reporting of results

1. A record containing the results of individual monitoring shall be made for each exposed worker for whom such monitoring is performed.
2. For the purposes of paragraph 1, the following information on exposed workers shall be retained:
 - (a) a record of the exposures measured or estimated, as the case may be, of individual doses pursuant to Articles 39, 40, 51, and 52;
 - (b) in the case of exposures as referred to in Articles 40 and 52, the reports relating to the circumstances and the action taken;
 - (c) the results of workplace monitoring used to assess individual doses where necessary.
3. The information referred in paragraph 1 shall be retained during the period of their working life involving exposure to ionising radiation and afterwards until they have or would have attained the age of 75 years, but in any case not less than 30 years after termination of the work involving exposure.
4. Exposure as referred to in Articles 40, 51, and 52 shall be recorded separately in the record referred to in paragraph 1.
5. Where the results of monitoring are used for the management of planned exposure situations, appropriate arrangements shall be made for not including in the records exposures attributed to an existing exposure situation namely background external radiation or radon ingress from soil in the case of industries processing naturally occurring radioactive material.

Article 42

Access to the results

1. The Member States shall require that the results of the individual monitoring set out in Articles 39, 40 and 52 be:
 - (a) made available to the competent authorities, to the undertaking, and to the employer of outside workers;
 - (b) made available to the worker concerned in accordance with Article 43(1);
 - (c) submitted to the occupational health services in order for them to interpret the implications of the results for human health, as provided for in Article 44;
 - (d) submitted to the data system for individual radiological monitoring established by the Member State in accordance with paragraph 2.
2. Member States shall determine the arrangements under which the results of individual monitoring are conveyed.
3. The data system for individual radiological monitoring shall communicate at least the data listed in Annex VIII, Section A.
4. In the case of an accidental or emergency exposure, the results of individual monitoring shall be communicated without delay.

Article 43

Workers' access to the results

1. Member States shall require workers to have access at their request to the results of their individual monitoring, including the results of measurements which may have been used in estimating these results, or to the results of the assessment of their doses made as a result of workplace measurements.
2. Member States shall facilitate the exchange among competent authorities, occupational health services, radiation protection experts, or dosimetry services within the Union of all relevant information on the doses previously received by a worker in order to perform the medical examination prior to employment or classification as a category A worker pursuant to Article 44 and to control the further exposure of workers.

Article 44

Medical surveillance of exposed workers

1. The medical surveillance of exposed workers shall be based on the principles that govern occupational medicine generally.
2. The medical surveillance of category A workers shall be the responsibility of occupational health services.

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

3. Medical surveillance shall include:
 - (a) A medical examination prior to employment or classification as a category A worker to determine the worker's fitness for a post as a category A worker for which the worker is being considered.
 - (b) Periodic reviews of health.

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

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

Article 45

Medical classification

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

- (a) fit;
- (b) fit, subject to certain conditions;
- (c) unfit.

Article 46

Prohibition to employ or classify unfit workers

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

Article 47

Medical records

1. A medical record shall be opened for each category A worker and kept up to date so long as the worker remains a worker in that category. Thereafter, it shall be retained until the individual has or would have attained the age of 75 years, but in any case not less than 30 years after termination of the work involving exposure to ionising radiation.
2. The medical record shall include information regarding the nature of the employment, the results of the medical examinations prior to employment or classification as a category A worker, the periodic reviews of health and the record of doses required by Article 41.

Article 48

Special medical surveillance

1. In addition to the medical surveillance of exposed workers provided for in Article 44, provision shall be made for any further action considered necessary by the occupational health services for the health protection of exposed individuals, such as further examinations, decontamination measures or urgent remedial treatment.
2. Special medical surveillance shall be performed in each case where an annual effective dose of 50 mSv in a year or any of the other dose limits laid down in Article 10(2) has been exceeded.
3. Subsequent exposure conditions shall be subject to the agreement of the occupational health services.

Article 49

Appeals

Member States shall lay down the procedure for appeal against the findings and decisions made pursuant to Articles 45, 46 and 48.

Article 50

Protection of outside workers

1. Member States shall ensure that the system for individual radiological monitoring affords outside workers equivalent protection to that for workers employed on a permanent basis by the undertaking.
2. The undertaking shall be responsible, either directly or through contractual agreements with the employer of outside workers, for the operational aspects of the radiation protection of outside workers.
3. In particular, the undertaking shall:
 - (a) check that the outside worker concerned has been passed as medically fit for the activities to be assigned to the worker;
 - (b) ensure that, in addition to the basic training in radiation protection referred to in Article 16, the outside worker has received specific training in connection with the characteristics of both the controlled area and the activities;
 - (c) ensure that the outside worker has been issued with the necessary personal protective equipment;
 - (d) ensure that the outside worker receives individual exposure monitoring appropriate to the nature of the activities, and any operational dosimetric monitoring that may be necessary;
 - (e) ensure compliance with the system of protection as defined in Chapter III;
 - (f) ensure or take all appropriate steps to ensure that after every activity the radiological data referred to in Annex VIII, Section B, point 2. from individual exposure monitoring of each outside worker are recorded.
4. Employers of outside workers shall, either directly or through contractual agreements with the undertaking, ensure that the radiation protection of their workers is in accordance with the relevant provisions of this Directive, in particular by:
 - (a) ensuring compliance with the system of protection as defined in Chapter III;
 - (b) providing the information and training in the field of radiation protection referred to in Article 16;
 - (c) guaranteeing that their workers are subject to the assessment of exposure and medical surveillance under the conditions laid down in Articles 37, 39 to 48;
 - (d) ensuring that the radiological data from the individual exposure monitoring of each of their workers within the meaning of Annex VIII, Section B, point 1, are kept up to date in the data system for individual radiological monitoring referred to in Article 42(1)(d).

5. All outside workers shall be obliged to make their own contribution as far as practicable towards the protection to be afforded to them by the radiological monitoring system referred to in paragraph 1.

Article 51

Specially authorised exposures

1. In exceptional circumstances evaluated case by case, excluding emergencies, the competent authorities may, where a specific operation so requires, authorise individual occupational exposures of identified volunteer workers exceeding the dose limits set out in Article 10, provided that such exposures are limited in time, confined to certain working areas and within the maximum exposure levels defined for the particular case by the competent authorities. The following conditions shall be taken into account:
 - (a) only category A workers as defined in Article 38 may be subject to such exposures;
 - (b) apprentices, students, pregnant women, and, if there is a risk of intake of radionuclides, breastfeeding women shall be excluded from such exposures;
 - (c) the undertaking shall carefully justify such exposures in advance and thoroughly discuss them with the voluntary workers, their representatives, the occupational health services or the radiation protection expert;
 - (d) information about the risks involved and the precautions to be taken during the operation shall be provided to the relevant workers in advance;
 - (e) all doses relating to such exposures shall be separately recorded in the medical record referred to in Article 47 and the individual record referred to in Article 41.
2. The exceeding of dose limits as a result of specially authorised exposures shall not necessarily constitute a reason for excluding workers from their usual occupation or relocating them, without their agreement.
3. The exposure of space crew above the dose limits shall be managed as a specially authorised exposure.

Article 52

Emergency occupational exposure

1. Emergency response organisations shall ensure that no emergency worker undertakes actions resulting in doses in excess of 50 mSv, except in specific cases identified in the national emergency plan. In such cases, appropriate reference levels above 50 mSv shall be defined. In exceptional situations, in order to save life, prevent severe

radiation-induced health effects, or prevent the development of catastrophic conditions, a reference level above 100 mSv may be set.

2. Emergency response organisations shall ensure that emergency workers who are liable to undertake actions whereby 50 mSv may be exceeded are volunteers who have been clearly and comprehensively informed in advance of the associated health risks and the available protection measures.
3. In the event of an emergency exposure, Member States shall require radiological monitoring and medical surveillance of emergency workers. Individual monitoring or assessment of the individual doses shall be carried out as appropriate to the circumstances.

Article 53

Radon in workplaces

1. Within the action plan referred to in Article 103, Member States shall establish national reference levels for indoor radon concentrations. Such reference levels shall not exceed an annual average of 1 000 Bq m⁻³ for workplaces.
2. Under the national action plan, Member States shall ensure that radon measurements are carried out in workplaces located on the ground floor or at basement level within radon-prone areas and in specific types of workplaces as identified in the action plan.
3. Member States shall require undertakings in which the national reference level for existing workplaces is exceeded to take appropriate action in order to reduce radon concentrations or exposures, in accordance with the principle of optimisation set out in Chapter III.
4. Where workplaces or specific rooms within a building continue to exceed the reference level despite the action taken in accordance with paragraph 3, the Member States shall manage this situation as a planned exposure situation and apply the relevant requirements for occupational exposure as specified in Article 30.1(d).

CHAPTER VII

PROTECTION OF PATIENTS AND OTHER INDIVIDUALS SUBJECTED TO MEDICAL EXPOSURE

Article 54

Justification

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

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

In particular the following requirements shall be applied:

- (a) all new types of practices involving medical exposure shall be justified in advance before being generally adopted;
- (b) existing types of practices involving medical exposure shall be reviewed whenever new, important evidence about their efficacy or consequences is acquired;
- (c) all individual medical exposures shall be justified in advance taking into account the specific objectives of the exposure and the characteristics of the individual involved.

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

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

2. Medical exposure for biomedical and medical research shall be examined by an ethics committee, set up in accordance with national procedures and/or by the competent authorities;
3. Specific justification for medical radiological procedures to be performed as part of a health screening programme shall be carried out by the health authority in conjunction with appropriate professional bodies.

4. The exposure of carers and comforters shall show a sufficient net benefit, taking into account the direct health benefits to a patient, the benefits to the carer / comforter and the detriment that the exposure might cause.
5. Any medical radiological procedure on an asymptomatic individual, to be performed for the early detection of disease, shall be part of a health screening programme, or shall require specific documented justification for that individual by the practitioner, in consultation with the referrer, following guidelines from relevant professional bodies and competent authorities. Special attention shall be given to the provision of information to the patients, as required by Article 56(3).
6. If an exposure cannot be justified in accordance with paragraphs 1 to 5, it shall be prohibited.

Article 55

Optimisation

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

For all medical exposure of individuals for radiotherapeutic purposes, exposures of target volumes shall be individually planned, taking into account that doses of non-target volumes and tissues shall be as low as reasonably achievable and consistent with the intended radiotherapeutic purpose of the exposure.
2. Member States shall ensure the establishment, regular review and use of diagnostic reference levels for radiodiagnostic examinations, and when appropriate, for interventional radiology procedures, and the availability of guidance for this purpose.
3. Member States shall ensure that for each biomedical and medical research project:
 - (a) the individuals concerned participate voluntarily;
 - (b) these individuals are informed about the risks of exposure;
 - (c) a dose constraint is established for individuals for whom no direct medical benefit is expected from exposure;
 - (d) in the case of patients who voluntarily accept to undergo an experimental diagnostic or therapeutic practice and who are expected to receive a diagnostic or therapeutic benefit from this practice, the dose levels concerned shall be considered on an individual basis by the practitioner and/or referrer.
4. The optimisation shall include the selection of equipment, the consistent production of adequate diagnostic information or therapeutic outcomes, the practical aspects of medical exposure procedures, quality assurance, and the assessment and evaluation

of patient and staff doses or administered activities, taking into account economic and social factors.

5. Member States shall ensure that:
 - (a) dose constraints are established for the exposure of carers and comforters;
 - (b) appropriate guidance is established for the exposure of carers and comforters;
6. Member States shall ensure that in the case of a patient undergoing treatment or diagnosis with radionuclides, the practitioner or the undertaking, as appropriate, provides the patient or legal guardian with written instructions with a view to restricting doses to persons in contact with the patient as far as reasonably achievable and providing information on the risks of ionising radiation.

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

Article 56

Responsibilities

1. The referrer and the practitioner shall be involved in the justification process as specified by Member States.
2. Member States shall ensure that any medical exposure takes place under the clinical responsibility of a practitioner.
3. The practitioner shall ensure that the patient or legal guardian is provided with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure to enable informed consent. Similar information as well as relevant guidance in accordance with Article 55(5)(b) shall be given to carers and comforters.
4. Practical aspects of medical exposure procedures may be delegated by the undertaking or the practitioner, as appropriate, to one or more individuals entitled to act in this respect in a recognised field of specialisation.

Article 57

Procedures

1. Written protocols for every type of standard medical radiological procedure shall be established for each equipment.
2. Member States shall ensure that referral guidelines for medical imaging, taking into account the radiation doses, are available to the referrers.

3. In medical radiological practices, a medical physics expert shall be appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice. In particular:
 - (a) in radiotherapeutic practices other than standardised therapeutic nuclear medicine practices, a medical physics expert shall be closely involved;
 - (b) in standardised therapeutical nuclear medicine practices as well as in radiodiagnostic and interventional radiology practices, a medical physics expert shall be involved;
 - (c) for other simple radiodiagnostic procedures, a medical physics expert shall be involved, as appropriate, for consultation and advice on matters relating to radiation protection concerning medical exposure.
4. Clinical audits shall be carried out in accordance with national procedures.
5. Member States shall ensure that appropriate local reviews are undertaken whenever diagnostic reference levels are consistently exceeded and that corrective action is taken where appropriate.

Article 58

Training

Member States shall ensure that training and recognition requirements, as laid down in Articles 15, 19 and 81, are met for the practitioner, the medical physics expert and the individuals referred to in Article 56(4).

Article 59

Equipment

1. Member States shall take such steps as they consider necessary with a view to avoiding unnecessary proliferation of medical radiological equipment.
2. Member States shall ensure that:
 - (a) all medical radiological equipment in use is kept under strict surveillance regarding radiation protection;
 - (b) an up-to-date inventory of medical radiological equipment for each medical radiological installation is available to the competent authorities;
 - (c) appropriate quality assurance programmes and dose or administered activity assessments are implemented by the undertaking; and

- (d) acceptance testing, involving the medical physics expert, is carried out before the first use of the equipment for clinical purposes, and performance testing is carried out thereafter on a regular basis, and after any major maintenance procedure.
- 3. Competent authorities shall take steps to ensure that the necessary measures are taken by the undertaking to improve inadequate or defective features of medical radiological equipment. They shall also adopt specific criteria for the acceptability of equipment in order to indicate when appropriate corrective action is necessary, including, if appropriate, taking the equipment out of service.
- 4. The use of fluoroscopy equipment without a device to control the dose rate, or without an image intensifier or equivalent device, shall be prohibited.
- 5. Any equipment used for interventional radiology and computed tomography shall have a device or a feature informing the practitioner of the quantity of radiation produced by the equipment during the medical radiological procedure. Any other medical radiodiagnostic equipment brought into use after this Directive has entered into force shall have such a device or a feature or equivalent means of determining the quantity of radiation produced. The radiation dose shall form part of the report on the examination.

Article 60

Special practices

- 1. Member States shall ensure that appropriate medical radiological equipment, practical techniques and ancillary equipment are used for medical exposure
 - (a) of children;
 - (b) as part of a health screening programme;
 - (c) involving high doses to the patient, such as interventional radiology, computed tomography or radiotherapy.

Special attention shall be given to quality assurance programmes and the assessment of dose or administered activity, as mentioned in Article 59(2)(c), for these practices.

- 2. Member States shall ensure that practitioners and those individuals referred to in Article 56(4) who perform the exposures referred to in paragraph 1 of this Article obtain appropriate training in these medical radiological practices as required by Article 19.

Article 61

Special protection during pregnancy and breastfeeding

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

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

2. In the case of breastfeeding women, in nuclear medicine, depending on the type of medical examination or treatment, special attention shall be given to the justification, particularly the urgency, and to the optimisation of the medical exposure, taking into account the exposure both of the mother and the child.
3. Without prejudice to paragraphs 1 and 2, Member States shall take measures to increase the awareness of women to whom this Article applies, such as public notices in appropriate places.

Article 62

Accidental and unintended exposures

Member States shall ensure that:

- (a) all reasonable steps are taken to minimise the probability and magnitude of accidental or unintended exposures of patients from all medical radiological procedures, taking into account economic and social factors;
- (b) for radiotherapeutic practices the quality assurance programme includes a study of the risk of accidental or unintended exposures;
- (c) for all medical exposures the undertaking implements a system for the registration and analysis of events involving or potentially involving accidental or unintended exposures;
- (d) the undertaking declares as soon as possible to the competent authorities the occurrence of significant events as defined by the authorities, including the results of the investigation and the corrective measures to avoid such events. The competent authorities shall share this information with the competent authorities for post-market surveillance established in Council Directive 93/42/EEC concerning medical devices;
- (e) arrangements are made to inform the referrer, the practitioner and the patient about an unintended or accidental exposure.

Article 63

Estimates of population doses

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

CHAPTER VIII

PROTECTION OF MEMBERS OF THE PUBLIC

SECTION 1

PROTECTION OF MEMBERS OF THE PUBLIC IN NORMAL CIRCUMSTANCES

Article 64

Principles of protection of members of the public

Member States shall create the conditions necessary to ensure the best possible protection of members of the public under the prevailing circumstances, based on the principles set out in Chapter III on the system of radiation protection and applying the requirements laid down in this Chapter.

Article 65

Operational protection of members of the public

1. The operational protection of members of the public in normal circumstances from practices subject to licensing shall include all arrangements and surveys for detecting and eliminating factors which, in the course of any operation involving exposure to ionising radiation, are liable to create a risk of exposure for members of the public which cannot be disregarded from the radiation protection point of view. Such protection shall include the following tasks:
 - (a) examination and approval of plans for installations involving an exposure risk, and of the proposed siting of such installations within the territory concerned, from the point of view of radiation protection;
 - (b) acceptance into service of new installations involving an exposure risk, subject to adequate protection being provided against any exposure or radioactive contamination liable to extend beyond the perimeter, taking into account, if

relevant, demographic, meteorological, geological, hydrological and ecological conditions;

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

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

2. The competent authority shall establish authorised limits for discharging radioactive effluents. These discharge authorisations shall
 - (a) take into account the results of the optimisation of public exposure;
 - (b) reflect good practice in the operation of similar facilities;
 - (c) allow a margin for operational flexibility of a facility.

Article 66

Estimation of doses to members of the public

1. Member States shall, on the basis of the exposure risk involved, establish a system for the estimation of doses to members of the public from planned exposure situations.
2. The competent authorities shall identify practices where a realistic assessment of doses to members of the public shall be carried out. For other practices Member States may require only a screening assessment with generic data.
3. For the realistic assessment of doses to members of the public, the competent authority shall:
 - (a) ensure that dose estimates for practices as referred to in Article 65 are made as realistic as possible for representative persons;
 - (b) decide on the frequency of assessments and take all necessary steps to identify the representative person, taking into account the effective pathways for transmission of the radioactive substances;
 - (c) ensure, taking into account the radiological risks, that the estimates of doses to members of the public include:
 - (i) assessment of the doses due to external radiation, indicating, where appropriate, the quality of the radiation in question;
 - (ii) assessment of the intake of radionuclides, indicating the nature of the radionuclides and, where necessary, their physical and chemical states, and determination of the activity and concentrations of these radionuclides;

- (iii) assessment of the doses that the representative person is liable to receive and specification of the characteristics of the representative person;
- (d) require records to be kept and be made available to all stakeholders relating to measurements of external exposure, estimates of intakes of radionuclides and radioactive contamination, and the results of the assessment of the doses received by the representative person.

Article 67

Monitoring of radioactive discharges

1. Member States shall require the undertaking responsible for practices where a discharge authorisation is granted to monitor appropriately the radioactive airborne or liquid discharges into the environment and to report the results of this monitoring to the competent authority.
2. Member States shall require any undertaking responsible for a nuclear power reactor or reprocessing plant to monitor discharges in normal operation in accordance with the standardised information selected for monitoring and reporting to the European Commission as laid down in Commission Recommendation 2004/2/Euratom²².

Article 68

Tasks for the undertakings

1. Member States shall require the undertaking to carry out the following tasks:
 - (a) achieving and maintaining an optimal level of protection;
 - (b) checking the effectiveness and maintenance of technical devices;
 - (c) acceptance into service, from the point of view of surveillance of radiation protection, of equipment and procedures for measuring and assessing, as appropriate, exposure of members of the public and radioactive contamination of the environment;
 - (d) regular calibration of measuring instruments and regular checking that they are serviceable and correctly used.
2. Radiation protection experts and, as appropriate, radiation protection officers shall be involved in the performance of the tasks referred to in paragraph 1.

²² OJ L 2/36, 6.1.2000.

Article 69

Environmental monitoring programme

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

SECTION 2

EMERGENCY EXPOSURE SITUATIONS

Article 70

Emergency response

1. Member States shall require the undertaking responsible for a practice to notify the competent authorities immediately of any emergency occurring in its facility or related to its activities and to take all appropriate action to reduce the consequences.
2. Member States shall ensure that, in the event of an emergency on its own territory, the undertaking makes an initial provisional assessment of the circumstances and consequences of the emergency and assists with protective measures.
3. Member States shall ensure that provision is made for protective measures with regard to:
 - (a) the radiation source, to reduce or stop the direct radiation and emission of radionuclides, or to prevent exposure or contamination resulting from orphan sources;
 - (b) the environment, to reduce the transfer of radioactive substances to individuals;
 - (c) individuals, to reduce exposure.
4. In the event of an emergency on or outside its territory, the Member State or the emergency response authority shall require:
 - (a) the organisation of appropriate protective measures, taking account of the real characteristics of the emergency and in accordance with the optimised protection strategy as part of the emergency response plan, whereby the elements to be included in an emergency response plan are indicated in Annex IX, Section B;
 - (b) the assessment and recording of the consequences of the emergency and of the effectiveness of the protective measures.

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

Article 71

Information to members of the public likely to be affected in the event of an emergency

1. Member States shall ensure that members of the public likely to be affected in the event of an emergency are given information about the health protection measures applicable to them and about the action they should take in the event of such an emergency.
2. The information supplied shall include at least the elements set out in Annex X, Section A.
3. The information shall be communicated to the members of the public referred to in paragraph 1 without any request being made.
4. Member States shall update the information and circulate it at regular intervals and whenever significant changes take place. This information shall be permanently available to the public.

Article 72

Information to the members of the public actually affected in the event of an emergency

1. Member States shall ensure that, when an emergency occurs, the members of the public actually affected are informed without delay of the facts of the emergency, the steps to be taken and, as appropriate, the health protection measures applicable to these members of the public.
2. The information provided shall cover those points contained in Annex X, Section B which are relevant to the type of emergency.

SECTION 3

EXISTING EXPOSURE SITUATIONS

Article 73

Contaminated areas

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

- (a) delineation of the affected regions and identification of the affected members of the public;
 - (b) consideration of the need for and extent of protective measures applied to the affected regions and members of the public;
 - (c) consideration of the need to prevent or control access to the affected regions, or to impose restrictions on living conditions in these regions;
 - (d) assessment of the exposure of different groups in the population and assessment of the means available to individuals for controlling their own exposure;
 - (e) objectives and long-term goals pursued by the strategy and corresponding reference levels.
2. For areas with long-lasting residual contamination in which the Member State has decided to allow habitation and the resumption of social and economic activities, Member States shall ensure, in consultation with stakeholders, that arrangements are in place, as necessary, for the ongoing control of exposure with the aim of establishing living conditions that can be considered as normal, including:
- (a) establishment of reference levels consistent with day-to-day life;
 - (b) establishment of an infrastructure to support continuing self-help protective measures in the affected areas, such as information provision, advice and monitoring.

Article 74

Radon in dwellings and buildings with public access

1. Within the action plan referred to in Article 103, Member States shall establish national reference levels for indoor radon concentrations, which shall not exceed (as an annual average):
- (a) 200 Bq m⁻³ for new dwellings and new buildings with public access;
 - (b) 300 Bq m⁻³ for existing dwellings;
 - (c) 300 Bq m⁻³ for existing buildings with public access. In specific cases where the occupancy time is low, a reference level of up to 1 000 Bq m⁻³ can be set.
2. Under the national action plan, Member States shall
- (a) identify existing dwellings exceeding the reference level and to encourage radon-reducing measures in existing dwellings where the reference levels are exceeded;

- (b) ensure that radon measurements are carried out in buildings with public access within radon-prone areas.
- 3. Member States shall establish specific building codes to prevent radon ingress from the soil and, as specified in the national action plan, from building materials, and require compliance with such building codes, in particular in radon-prone areas, so as to avoid radon concentrations exceeding the reference level for new buildings.
- 4. Member States shall provide local and national information on prevailing radon concentrations, on the associated health risks and on the technical means available for reducing existing radon concentrations.

Article 75

Building materials

1. The requirements laid down in this Article shall apply to the following:
 - (a) building materials which are identified and listed by the relevant competent authority as being of concern from the radiation protection point of view, taking into account the indicative list of materials set out in Annex XI with regard to their emitted gamma radiation; or
 - (b) building materials which the authority has assessed to be of concern in the national action plan for radon, as specified in Article 103.
2. For identified types of building materials, the industries placing such materials on the market
 - (a) shall determine the concentrations of the radionuclides specified in Annex VII;
 - (b) shall provide information to the competent authority on the results of measurements and the corresponding activity concentration index, as defined in Annex VII.
3. The competent authority shall ensure that identified types of building materials are classified, as laid down in Annex VII, on the basis of their intended use and activity concentration index.
4. Identified types of building materials which are not liable to give doses exceeding the reference level of 1 mSv per year for indoor external exposure from building materials, in excess of prevailing outdoor external exposure, shall be exempt from requirements at national level, without prejudice to Article 103. Such building materials shall nevertheless be further monitored to ensure that the activity concentration continues to comply with this reference level. Building materials of category A as specified in Annex VII shall be exempt from any restrictions with regard to their placing on the market in the Union.

5. For identified types of building materials which are liable to give doses exceeding the reference level of 1 mSv per year for indoor external exposure from building materials, in excess of the prevailing outdoor external exposure, the competent authority shall decide on appropriate measures, ranging from registration and general application of relevant building codes to specific restrictions on the envisaged use of such materials.
6. Information on identified types of building materials, relevant to the implementation of building codes, including their radionuclide concentrations, activity concentration index and corresponding classification, shall be made available prior to their placing on the market.

CHAPTER IX

PROTECTION OF THE ENVIRONMENT

Article 76

Environmental criteria

Member States shall include, in their legal framework for radiation protection and in particular within the overall system of human health protection, provision for the radiation protection of non-human species in the environment. This legal framework shall introduce environmental criteria aiming to protect populations of vulnerable or representative non-human species in the light of their significance as part of the ecosystem. Where appropriate, types of practices shall be identified for which regulatory control is warranted in order to implement the requirements of this legal framework.

Article 77

Authorised limits on discharges

Member States' competent authorities, when establishing authorised limits on discharges of radioactive effluents, in accordance with Article 65(2), shall also ensure adequate protection of non-human species. For this purpose, a generic screening assessment may be conducted to provide assurance that the environmental criteria are met.

Article 78

Accidental releases

Member States shall require undertakings to take appropriate technical measures to avoid significant environmental damage in the event of an accidental release or to mitigate the extent of such damage.

Article 79

Environmental monitoring

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

CHAPTER X

REQUIREMENTS FOR REGULATORY CONTROL

SECTION 1

INSTITUTIONAL INFRASTRUCTURE

Article 80

Competent authority

1. Member States shall designate the competent authority or authorities to carry out tasks provided for in this Directive.
2. Member States shall forward to the Commission the name and address of the competent authority or authorities and their respective areas of competence to ensure rapid communication with such authorities.
3. Where a Member State has more than one competent authority for the control of high-activity sealed sources and orphan sources, it shall designate one point of contact for communication with the competent authorities of other Member States.
4. Member States shall forward to the Commission any changes to the information referred to in paragraphs 2 and 3.

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

Article 81

Recognition of services and experts

1. Member States shall make the necessary arrangements for the recognition of:
 - (a) occupational health services;
 - (b) dosimetry services;
 - (c) radiation protection experts;
 - (d) medical physics experts.

Member States shall lay down provisions to ensure the continuity of expertise of these services and experts.

2. Member States shall specify the recognition requirements and communicate them to the Commission together with the name and address of the competent authorities in charge of recognition. Member States shall communicate any changes to this information.
3. Member States shall specify other services or experts requiring particular radiation protection qualifications and, where appropriate, the process for the recognition of such qualifications.
4. The Commission shall make the information received in accordance with paragraph 2 available to the Member States.

Article 82

Occupational health services

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

Article 83

Dosimetry services

Dosimetry services shall determine the internal and external dose to exposed workers subject to individual monitoring in order to record the dose in cooperation with the undertaking and the occupational health service. Dosimetry services shall include the calibration, reading and

interpretation of individual monitoring devices, and the measurement of radioactivity in the human body and in biological samples.

Article 84

Radiation protection expert

1. The radiation protection expert shall, on the basis of professional judgment, measurements and assessments, give competent advice to the undertaking on matters relating to occupational exposure and public exposure.
2. The advice of the radiation protection expert shall cover, but not be limited to, the following:
 - (a) plans for new installations and the acceptance into service of new or modified radiation sources in relation to any engineering controls, design features, safety features and warning devices relevant to radiation protection;
 - (b) the categorisation of controlled and supervised areas;
 - (c) the classification of workers;
 - (d) the content of workplace and individual monitoring programmes;
 - (e) the appropriate radiation monitoring instrumentation to be used;
 - (f) the appropriate methods of personal dosimetry;
 - (g) the optimisation and establishment of appropriate dose constraints,
 - (h) quality assurance;
 - (i) the environmental monitoring programme;
 - (j) radioactive waste disposal requirements;
 - (k) the arrangements for prevention of accidents and incidents;
 - (l) preparedness and response in emergency exposure situations;
 - (m) training and retraining programmes for exposed workers.
3. Where appropriate, the task of the radiation protection expert may be carried out by a group of specialists who together have the necessary expertise.

Article 85

Medical physics expert

1. Within the health care environment, the medical physics expert shall, as appropriate, act or give specialist advice on matters relating to radiation physics as applied to medical exposure.
2. Depending on the medical radiological practice, the medical physics expert shall take responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient, give advice on medical radiological equipment, and contribute in particular to the following:
 - (a) optimisation of the radiation protection of patients and other individuals subjected to medical exposure, including the application and use of diagnostic reference levels;
 - (b) the definition and performance of quality assurance of the medical radiological equipment;
 - (c) the preparation of technical specifications for medical radiological equipment and installation design;
 - (d) the surveillance of the medical radiological installations with regard to radiation protection;
 - (e) the selection of equipment required to perform radiation protection measurements;
 - (f) the training of practitioners and other staff in relevant aspects of radiation protection.

Where appropriate, the task of the medical physics expert may be carried out by a medical physics service.

Article 86

Radiation protection officer

1. Member States shall decide in which practices the designation of a radiation protection officer is necessary to perform radiation protection tasks within an undertaking. Member States shall require undertakings to provide the radiation protection officers with the means necessary for them to carry out their duties. The radiation protection officer shall report directly to the undertaking.
2. Depending on the nature of the practice, the tasks of the radiation protection officer may include the following:

- (a) ensuring that work with radiation is carried out in accordance with the requirements of any specified procedures or local rules;
- (b) supervise implementation of the programme for workplace monitoring;
- (c) maintaining adequate records of radioactive sources;
- (d) carrying out periodic assessments of the condition of the relevant safety and warning systems;
- (e) supervise implementation of the personal monitoring programme;
- (f) supervise implementation of the health surveillance programme;
- (g) providing new employees with an introduction to local rules and procedures;
- (h) giving advice and comments on work plans;
- (i) authorising work plans;
- (j) providing reports to the local management;
- (k) participating in the arrangements for prevention, preparedness and response for emergency exposure situations;
- (l) liaising with the radiation protection expert.

The task of the radiation protection officer may be carried out by a radiation protection unit established within an undertaking.

SECTION 2

CONTROL OF SEALED SOURCES

Article 87

General requirements

1. Member States shall make arrangements for keeping adequate control of sealed sources with regard to their location, use and disuse.
2. Member States shall require the undertaking to keep records of all such sources under its responsibility, their location and their transfer.
3. Member States shall set up a system to enable them to be adequately informed of individual transfers of sealed sources, where necessary, and in any event of transfers of high-activity sealed sources.

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

Article 88

Requirements for control of high-activity sealed sources

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

- (a) adequate arrangements have been made for the safe management and security of sources, including when they become disused sources. Such arrangements may provide for the transfer of disused sources to the supplier or their placement in a disposal or storage facility or an obligation for the manufacturer or the supplier to receive them;
- (b) adequate provision, by way of a financial security or any other equivalent means appropriate for the source in question, has been made for the safe management of sources when they become disused sources, including the case where the undertaking becomes insolvent or ceases its activities.

Article 89

Specific requirements for licensing of high-activity sealed sources

In addition to the general licensing requirements set out in Chapter V, Member States shall ensure that the licence for the manufacture, use or taking possession of a high-activity sealed source includes:

- (a) minimum performance criteria for the source, source container and additional equipment;
- (b) work procedures to be followed;
- (c) adequate management of disused sources, including agreements regarding the transfer, if appropriate, of disused sources to a manufacturer, a supplier, another authorised undertaking or a waste disposal or storage facility.

Article 90

Record keeping by the undertakings

Member States shall require that the records for high-activity sealed sources include the information set out in Annex XII and that the undertaking provides the competent authorities

with a copy of all or part of these records upon request and at least as set out in Annex XIII. The undertaking's records shall be available for inspection by the competent authority.

Article 91

Record keeping by the competent authorities

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

Article 92

Security of high-activity sealed sources

1. The undertaking carrying out activities involving high activity sealed sources shall comply with requirements set out in Annex XIV.
2. The manufacturer, the supplier, and each undertaking shall ensure that high-activity sealed sources and containers comply with the requirements for identification and marking as set out in Annex XV.

SECTION 3

ORPHAN SOURCES

Article 93

Detection of orphan sources

1. Member States shall require any person encountering an orphan source to promptly notify the emergency organisation or the competent authority and to refrain from any further action on the source until these bodies have given appropriate instructions.
2. Member States shall make arrangements for the establishment of systems to detect orphan sources in places such as large metal scrap yards and major metal scrap recycling installations where orphan sources may generally be encountered, or at significant nodal transit points, wherever appropriate, such as customs posts.
3. Member States shall ensure that specialised technical advice and assistance is promptly made available to persons who work in the places referred to in paragraph

2 and who are not normally involved in operations subject to radiation protection requirements. The primary aim of advice and assistance shall be the protection of workers and members of the public from radiation and the safety of the source.

Article 94

Metal contamination

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

Article 95

Recovery, management and disposal of orphan sources

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

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

Article 96

Financial security for orphan sources

Member States shall ensure that, on the basis of arrangements to be decided by Member States, a financial security system or other equivalent means is established to cover intervention costs relating to the recovery of orphan sources and which may result from implementation of Article 95.

SECTION 4

EMERGENCY EXPOSURE SITUATIONS

Article 97

Emergency management system

1. Member States shall ensure that account is taken of the fact that emergencies may occur on their territory and that they may be affected by emergencies occurring outside their territory. Member States shall establish an emergency management system and adequate administrative provisions to maintain such a system.
2. The emergency management system shall be designed to be commensurate with the results of a threat assessment and to be able to respond effectively to emergency exposure situations in connection with practices or unforeseen events, including malevolent acts and the discovery of orphan sources.
3. The emergency management system shall provide for the establishment of emergency response plans with the objective of avoiding deterministic effects in any individual from the affected members of the public and reducing the risk of stochastic effects, taking account of the general principles of radiation protection and the reference levels referred to in Chapter III. The emergency management system shall include the elements listed in Annex IX, Section A.

Article 98

Emergency preparedness

1. Member States shall ensure that emergency response plans are established in advance for the various types of emergencies identified by the threat assessment.
2. Member States shall ensure that emergency response plans are tested, reviewed and revised at regular intervals.
3. The emergency response plans shall, where appropriate, incorporate relevant elements of the emergency management system referred to in Article 97.
4. The emergency response plans shall include the elements defined in Annex IX, Section B.

Article 99

International cooperation

1. Member States shall cooperate with other Member States and third countries in addressing possible emergencies on their own territory which may affect other Member States or third countries, in order to facilitate the organisation of radiological protection in these Member States or third countries.
2. Member States shall, in the event of an emergency occurring on their territory or likely to have radiological consequences on its territory, establish contact to obtain the cooperation of any other Member State or third country which may be involved.
3. Member States shall promptly exchange information and cooperate with other relevant Member States or third countries and with relevant international organisations regarding the loss, removal, theft or discovery of high-activity sealed sources, other radioactive sources and radioactive material of concern and regarding related follow-up or investigations, without prejudice to relevant confidentiality requirements and relevant national legislation.

SECTION 5

EXISTING EXPOSURE SITUATIONS

Article 100

Programmes on existing exposure situations

1. Member States shall ensure that programmes are established to identify and evaluate existing exposure situations and to determine which occupational and public exposures are of concern from a radiation protection point of view.
2. The requirements for existing exposure situations shall apply to:
 - (a) exposure due to contamination of areas by residual radioactive material from:
 - (i) past activities that were never subject to regulatory control or were not regulated in accordance with the requirements laid down by this Directive;
 - (ii) an emergency, after the emergency exposure situation has been declared ended, as provided for in the emergency management system;
 - (iii) residues from past activities for which the undertaking is no longer legally accountable;
 - (b) exposure to natural radiation sources, including:

- (i) indoor exposure to radon and thoron, in workplaces, dwellings and other buildings;
 - (ii) indoor external exposure from building materials;
 - (c) exposure to commodities incorporating
 - (i) radionuclides from contaminated areas specified in point (a), or
 - (ii) naturally occurring radionuclides, in particular in foodstuffs, drinking water and building materials;
 - (d) other existing exposure situations which cannot be disregarded from a radiation protection point of view.
3. Member States may decide, having regard to the general principle of justification, that an existing exposure situation warrants no consideration of protective measures.
4. Existing exposure situations which are the legal responsibility of an undertaking and which are of concern from a radiation protection point of view shall be subject to the relevant requirements for planned exposure situations.

Article 101

Establishment of strategies

1. Member States shall arrange for the establishment of strategies to ensure that existing exposure situations are managed appropriately and that the resources made available for their management are commensurate with the risks and with the effectiveness of protective measures.
2. The competent authority charged with establishing a strategy for managing an existing exposure situation shall ensure that the strategy contains:
- (a) the objectives pursued by the strategy;
 - (b) appropriate reference levels, taking into account the bands of reference levels laid down in Annex I.

Article 102

Implementation of strategies

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

involvement of stakeholders in decisions regarding the development and implementation of strategies for managing exposures.

2. The form, scale and duration of all protective measures considered for implementation of a strategy shall be optimised.
3. The distribution of residual doses that has resulted from the implementation of a strategy shall be assessed. Further efforts shall be considered with the aim of reducing any exposures that are still above the reference level.
4. Throughout the implementation of a strategy, the competent authority shall regularly:
 - (a) evaluate the available remedial and protective measures for achieving the objectives and the efficiency of planned and implemented measures;
 - (b) provide information to exposed individuals on the potential health risks and on the available means for reducing their own exposure;
 - (c) provide guidance for the management of exposures at individual or local level;
 - (d) with regard to activities that involve naturally occurring radioactive material and are not managed as planned exposure situations, provide information to undertakings on appropriate means for monitoring concentrations and exposures and for taking protective measures in the context of overall health and safety requirements.

Article 103

Radon action plan

1. Member States shall establish an action plan to manage long-term risks from radon exposures in dwellings, buildings with public access and workplaces for any source of radon ingress, whether from soil, building materials or water. The action plan shall take into account the issues set out in Annex XVI.
2. Member States shall forward the action plan and information on any identified radon-prone areas to the Commission. Member States shall update the action plan and information on radon-prone areas on a regular basis.

SECTION 6

SYSTEM OF ENFORCEMENT

Article 104

Inspections

1. Member States shall establish a system or systems of inspection to enforce the provisions adopted pursuant to this Directive and to initiate surveillance and corrective action wherever necessary.
2. The competent authority shall establish a systematic inspection programme taking into account the potential magnitude and nature of the hazard associated with practices, a general assessment of radiation protection issues in the practices, and the state of compliance with the provisions adopted pursuant to this Directive.
3. Member States shall ensure that the findings from each inspection are recorded and the reports communicated to the undertaking concerned.
4. Member States shall make the inspection programme and the main findings from its implementation available to the public.
5. The competent authority shall ensure that mechanisms are in place for the timely dissemination to relevant parties, including manufacturers and suppliers of sources and, where appropriate, international organisations, of protection and safety information concerning lessons learned from inspections and from reported incidents and accidents and related findings.

Article 105

Enforcement

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

Article 106

Penalties

The Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by the date specified in Article 107 at the latest and shall notify it without delay of any subsequent amendment affecting them.

CHAPTER XI

FINAL PROVISIONS

Article 107

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [00.00.0000] at the latest. The provisions laid down in Chapter IX with regard to the protection of the environment shall be transposed by [00.00.0000] at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt these provisions, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive.

Article 108

Repeal

Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom, 2003/122/Euratom shall be repealed with effect from [00.00.0000].

Article 109

Entry into force

The Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

Article 110

Addressees

This Directive is addressed to the Member States.

Done at Brussels,

For the Council
The President

ANNEX I

Bands of reference levels for public exposure

1. The optimisation of public exposures in emergency and existing exposure situations shall be based on a reference level to be established within the following bands, expressed in mSv effective dose (acute or annual):

- (a) greater than 20 and less or equal to 100
- (b) greater than 1 and less or equal to 20
- (c) 1 or less.

The choice of the reference level shall fulfil the conditions set out in points 2-5.

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

3. In specific situations, a reference level below ranges referred to in point 1 may be considered, in particular:

(a) a reference level below 20 mSv may be set in an emergency exposure situation where appropriate protection can be provided without causing a disproportionate detriment from the corresponding countermeasures or an excessive cost;

(b) a reference level below 1 mSv per year may be set, where appropriate, in an existing exposure situation for specific source-related exposures or pathways of exposure.

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

5. The reference levels set shall take account of the features of prevailing situations as well as societal criteria, which may include the following:

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

ANNEX II

Activity values defining high-activity sealed sources

For radionuclides not listed in the table below, the relevant activity level is identical to the D-value defined in the IAEA publication 'Dangerous quantities of radioactive material (D-values)', (EPR-D-VALUES 2006).

Radionuclide	Activity level (TBq)
Am-241	6×10^{-2}
Am-241/Be	6×10^{-2}
Cf-252	2×10^{-2}
Cm-244	5×10^{-2}
Co-60	3×10^{-2}
Cs-137	1×10^{-1}
Gd-153	1×10^0
Ir-192	8×10^{-2}
Pm-147	4×10^1
Pu-238	6×10^{-2}
Pu-239/Be ²³	6×10^{-2}
Ra-226	4×10^{-2}
Se-75	2×10^{-1}
Sr-90 (Y-90)	1×10^0
Tm-170	2×10^1
Yb-169	3×10^{-1}

²³ The activity given is that of the alpha-emitting radionuclide

ANNEX III

Placing on the market of apparatus or products

A. Any undertaking intending to place on the market apparatus or products shall provide the competent authorities with all relevant information, including the following:

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

B. The competent authorities shall assess the information, listed in Section A and in particular shall assess:

- (1) whether the performance of the apparatus or product justifies its intended use;
- (2) whether the design is adequate in order to reduce exposures in normal use and the likelihood and consequences of misuse or accidental exposures;
- (3) in the case of a consumer product, whether the product is adequately designed to meet the exemption criteria and does not necessitate specific precautions for disposal when no longer in use;
- (4) in the case of apparatus or products for use in practices exempted from authorisation, whether conditions for disposal are adequate;
- (5) whether the apparatus or product is appropriately labelled and suitable documentation is provided to the customer with instructions for proper use and disposal.

ANNEX IV

Practices involving non-medical imaging exposure

For the purposes of Article 23, the following list of practices involving non-medical imaging exposure shall be taken into account:

A. Procedures implemented by medical staff using medical radiological equipment:

1. Radiological health assessment for employment purposes;
2. Radiological health assessment for immigration purposes;
3. Radiological health assessment for insurance purposes;
4. Radiological health assessment for other purposes not intended to benefit the health and well-being of the exposed individual;
5. Radiological evaluation of the physical development of children and adolescents with a view to a career in sports, dancing, etc.;
6. Radiological age assessment;
7. Use of ionising radiation for the identification of concealed objects within the human body.

B. Procedures implemented by non-medical staff using non-medical equipment:

1. Use of ionising radiation for detection of concealed objects on or attached to the human body;
2. Use of ionising radiation for detection of concealed humans as part of cargo screening;
3. Other practices involving the use of ionising radiation for legal or security purposes.

ANNEX V

List of industrial practices involving naturally occurring radioactive material

For the purposes of Article 24, the following list of industrial practices involving naturally occurring radioactive material, including relevant secondary processes, shall be taken into account:

- (1) extraction of rare earths from monazite;
- (2) production of thorium compounds and manufacture of thorium-containing products;
- (3) processing of niobium/tantalum ore;
- (4) oil and gas production;
- (5) geothermal energy production;
- (6) TiO₂ pigment production;
- (7) thermal phosphorus production;
- (8) zircon and zirconium industry;
- (9) production of phosphate fertilisers;
- (10) cement production, maintenance of clinker ovens;
- (11) coal-fired power plants, maintenance of boilers;
- (12) phosphoric acid production;
- (13) primary iron production;
- (14) tin/lead/copper smelting;
- (15) ground water filtration facilities;
- (16) mining of ores other than uranium ore.

ANNEX VI

Exemption and clearance criteria

1. Exemption

Practices may be exempted from requirements of this Directive either directly, on the basis of compliance with numerical exemption criteria (activity values (Bq) or concentration values (Bq g⁻¹)) laid down in Section 2, or through a regulatory decision, on the basis of the information provided in conjunction with the notification of the practice and in line with general exemption criteria set out in Section 3, to exempt the practice from further requirements.

2. Exemption and clearance values

The total activity values (Bq) for exemption apply to the total activity involved in a practice and are laid down in column 3 of Table B for artificial radionuclides and for some naturally occurring radionuclides used in consumer products. For other practices involving naturally occurring radionuclides, such values are in general not applicable.

The exempt activity concentration values (Bq g⁻¹) for the materials involved in the practice are laid down in Table A, Part 1 for artificial radionuclides and in Table A, Part 2 for naturally occurring radionuclides. The values in Table A₁, Part 1 are given for individual radionuclides, where applicable including short-lived radionuclides in equilibrium with the parent nuclide as indicated. The values in Table A, Part 2 apply to all radionuclides in the decay chain of U-238 or Th-232, but for segments of the decay chain which are not in equilibrium with the parent radionuclide higher values may be applied.

The concentration values in Table A, Part 1 or in Table A, Part 2 also apply to the clearance of solid materials for re-use, recycling, conventional disposal or incineration. Higher values may be defined for specific materials or specific pathways, taking Community guidance into account, including where appropriate additional requirements in terms of surface activity or monitoring requirements.

For mixtures of artificial radionuclides, the weighted sum of nuclide-specific activities or concentrations (for various radionuclides contained in the same matrix) divided by the corresponding exemption value shall be less than unity. Where appropriate this condition can be verified on the basis of best estimates of the composition of the radionuclide mix. The values in Table A, Part 2 apply individually to each parent nuclide. Some elements in the decay chain, e.g. Po-210 or Pb-210, may warrant the use of values significantly higher, by up to two orders of magnitude, taking Community guidance into account.

The values in Table A, Part 2 may not be used to exempt the incorporation into building materials of residues from industries processing naturally occurring radioactive material. Such recycling of residues from identified industries shall be managed as an authorised practice or be exempted on the basis of the general exemption criteria laid down in Section 3. For this purpose, compliance of the sum of radionuclide concentrations with the appropriate value of the radionuclide index I for building materials as defined in Annex VII shall be verified.

The values laid down in Table B, column 3, apply to the total inventory of radioactive substances held by a person or undertaking as part of a specific practice at any point in time. However, the regulatory authority may apply these values to smaller entities or packages, for instance to exempt the transport or storage of exempted consumer products, if the general exemption criteria in Section 3 are satisfied.

3. General exemption and clearance criteria

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

- (a) the radiological risks to individuals caused by the practice are sufficiently low as to be of no regulatory concern; and
- (b) the type of practice has been determined to be justified; and
- (c) the practice is inherently safe.

Practices involving small amounts of radioactive substances or low activity concentrations, comparable to the exemption values laid down in Tables A, Part 1 or B, and in general all practices involving naturally occurring radionuclides are deemed to fulfil criterion (c).

Practices involving amounts of radioactive substances or activity concentrations below the exemption values laid down in Table A, Part 1 or Table B automatically comply with criterion (a) without further consideration. This is also the case for the values in Table A, Part 2, with the exception of the recycling of residues in building materials or the case of specific exposure pathways, for instance drinking water.

For notified practices not complying with these values, an assessment shall be made of the resulting exposure of individuals. For compliance with the general criterion (a), it shall be demonstrated that the following dose criteria are met in all feasible circumstances:

For artificial radionuclides:

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

For naturally occurring radionuclides:

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

The assessment of doses to members of the public shall take into account not only pathways of exposure through airborne or liquid effluent, but also pathways resulting from the disposal or recycling of solid residues.

TABLE A:

Activity concentration values for exemption or clearance of materials which can be applied by default to any amount and to any type of solid material.

TABLE A Part 1: Artificial radionuclides

Activity Radionuclide concentration (Bq g ⁻¹)		Activity Radionuclide concentration (Bq g ⁻¹)		Activity Radionuclide concentration (Bq g ⁻¹)	
H-3	100	Mn-52m	10	Ga-72	10
Be-7	10	Mn-53	100	Ge-71	10000
C-14	1	Mn-54	0.1	As-73	1000
F-18	10	Mn-56	10	As-74	10
Na-22	0.1	Fe-52 ^a	10	As-76	10
Na-24	1	Fe-55	1000	As-77	1000
Si-31	1000	Fe-59	1	Se-75	1
P-32	1000	Co-55	10	Br-82	1
P-33	1000	Co-56	0.1	Rb-86	100
S-35	100	Co-57	1	Sr-85	1
Cl-36	1	Co-58	1	Sr-85m	100
Cl-38	10	Co-58m	10000	Sr-87m	100
K-42	100	Co-60	0.1	Sr-89	1000
K-43	10	Co-60m	1000	Sr-90a	1
Ca-45	100	Co-61	100	Sr-91a	10
Ca-47	10	Co-62m	10	Sr-92	10
Sc-46	0.1	Ni-59	100	Y-90	1000
Sc-47	100	Ni-63	100	Y-91	100
Sc-48	1	Ni-65	10	Y-91m	100
V-48	1	Cu-64	100	Y-92	100
Cr-51	100	Zn-65	0.1	Y-93	100
Mn-51	10	Zn-69	1000	Zr-93	10
Mn-52	1	Zn-69m ^a	10	Zr-95 ^a	1

Radionuclide	Activity concentration (Bq g ⁻¹)	Radionuclide	Activity concentration (Bq g ⁻¹)	Radionuclide	Activity concentration (Bq g ⁻¹)
Zr-97 ^a	10	Pd-109 ^a	100	Te-131m ^a	10
Nb-93m	10	Ag-105	1	Te-132 ^a	1
Nb-94	0.1	Ag-110m ^a	0.1	Te-133	10
Nb-95	1	Ag-111	100	Te-133m	10
Nb-97 ^a	10	Cd-109 ^a	1	Te-134	10
Nb-98	10	Cd-115 ^a	10	I-123	100
Mo-90	10	Cd-115m ^a	100	I-125	100
Mo-93	10	In-111	10	I-126	10
Mo-99a	10	In-113m	100	I-129	0.01
Mo-101 ^a	10	In-114m ^a	10	I-130	10
Tc-96	1	In-115m	100	I-131	10
Tc-96m	1000	Sn-113 ^a	1	I-132	10
Tc-97	10	Sn-125	10	I-133	10
Tc-97m	100	Sb-122	10	I-134	10
Tc-99	1	Sb-124	1	I-135	10
Tc-99m	100	Sb-125 ^a	0.1	Cs-129	10
Ru-97	10	Te-123m	1	Cs-131	1000
Ru-103 ^a	1	Te-125m	1000	Cs-132	10
Ru-105 ^a	10	Te-127	1000	Cs-134	0.1
Ru-106 ^a	0.1	Te-127m ^a	10	Cs-134m	1000
Rh-103m	10000	Te-129	100	Cs-135	100
Rh-105	100	Te-129m ^a	10	Cs-136	1
Pd-103 ^a	1000	Te-131	100	Cs-137 ^a	0.1

Radionuclide	Activity concentration (Bq g ⁻¹)	Radionuclide	Activity concentration (Bq g ⁻¹)	Radionuclide	Activity concentration (Bq g ⁻¹)
Cs-138	10	Dy-165	1000	Pt-191	10
Ba-131	10	Dy-166	100	Pt-193m	1000
Ba-140	1	Ho-166	100	Pt-197	1000
La-140	1	Er-169	1000	Pt-197m	100
Ce-139	1	Er-171	100	Au-198	10
Ce-141	100	Tm-170	100	Au-199	100
Ce-143	10	Tm-171	1000	Hg-197	100
Ce-144	10	Yb-175	100	Hg-197m	100
Pr-142	100	Lu-177	100	Hg-203	10
Pr-143	1000	Hf-181	1	Tl-200	10
Nd-147	100	Ta-182	0.1	Tl-201	100
Nd-149	100	W-181	10	Tl-202	10
Pm-147	1000	W-185	1000	Tl-204	1
Pm-149	1000	W-187	10	Pb-203	10
Sm-151	1000	Re-186	1000	Bi-206	1
Sm-153	100	Re-188	100	Bi-207	0.1
Eu-152	0.1	Os-185	1	Po-203	10
Eu-152m	100	Os-191	100	Po-205	10
Eu-154	0.1	Os-191m	1000	Po-207	10
Eu-155	1	Os-193	100	At-211	1000
Gd-153	10	Ir-190	1	Ra-225	10
Gd-159	100	Ir-192	1	Ra-227	100
Tb-160	1	Ir-194	100	Th-226	1000

Activity Radionuclide concentration (Bq g ⁻¹)		Activity Radionuclide concentration (Bq g ⁻¹)		Activity Radionuclide concentration (Bq g ⁻¹)	
Th-229	0.1	Pu-243	1000	Es-254 ^a	0.1
Pa-230	10	Pu-244 ^a	0.1	Es-254m ^a	10
Pa-233	10	Am-241	0.1	Fm-254	10000
U-230	10	Am-242	1000	Fm-255	100
U-231 ^a	100	Am-242m ^a	0.1		
U-232 ^a	0.1	Am-243 ^a	0.1		
U-233	1	Cm-242	10		
U-236	10	Cm-243	1		
U-237	100	Cm-244	1		
U-239	100	Cm-245	0.1		
U-240 ^a	100	Cm-246	0.1		
Np-237 ^a	1	Cm-247 ^a	0.1		
Np-239	100	Cm-248	0.1		
Np-240	10	Bk-249	100		
Pu-234	100	Cf-246	1000		
Pu-235	100	Cf-248	1		
Pu-236	1	Cf-249	0.1		
Pu-237	100	Cf-250	1		
Pu-238	0.1	Cf-251	0.1		
Pu-239	0.1	Cf-252	1		
Pu-240	0.1	Cf-253	100		
Pu-241	10	Cf-254	1		
Pu-242	0.1	Es-253	100		

a Parent radionuclides, and their progeny whose dose contributions are taken into account in the dose calculation (thus requiring only the exemption level of the parent radionuclide to be considered), are listed in the following table:

Parent radionuclide	Progeny	Te-127m	Te-127
Fe-52	Mn-52m	Te-129m	Te-129
Zn-69m	Zn-69	Te-131m	Te-131
Sr-90	Y-90	Te132	I-132
Sr-91	Y-91m	Cs-137	Ba-137m
Zr-95	Nb-95	Ce-144	Pr-144, Pr-144m
Zr-97	Nb-97m, Nb-97	U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208
Nb-97	Nb-97m	U-240	Np-240m, Np-240
Mo-99	Tc-99m	Np237	Pa-233
Mo-101	Tc-101	Pu-244	U-240, Np-240m, Np-240
Ru-103	Rh-103m	Am-242m	Np-238
Ru-105	Rh-105m	Am-243	Np-239
Ru-106	Rh-106	Cm-247	Pu-243
Pd-103	Rh-103m	Es-254	Bk-250
Pd-109	Ag-109m	Es-254m	Fm-254
Ag-110m	Ag-110		
Cd-109	Ag-109m		
Cd-115	In-115m		
Cd-115m	In-115m		
In-114m	In-114		
Sn-113	In-113m		
Parent radionuclide	Progeny		
Sb-125	Te-125m		

For radionuclides not listed in Table A, Part 1 the competent authority shall assign appropriate values for the quantities and concentrations of activity per unit mass where the need arises. Values thus assigned shall be complementary to those in Table A, Part 1.

TABLE A Part 2: naturally occurring radionuclides

Values for exemption or clearance for naturally occurring radionuclides in solid materials in secular equilibrium with their progeny:

Natural radionuclides from the U-238 series	1 Bq g ⁻¹
Natural radionuclides from the Th-232 series	1 Bq g ⁻¹
K-40	10 Bq g ⁻¹

TABLE B:

Total activity values for exemption (column 3) and exemption values for the activity concentration in moderate amounts of any type of material (column 2).

Radionuclide	Activity concentration (Bq g ⁻¹)	Activity (Bq)	Radionuclide	Activity concentration (Bq g ⁻¹)	Activity (Bq)
H-3	1 × 10 ⁶	1 × 10 ⁹	Sc-46	1 × 10 ¹	1 × 10 ⁶
Be-7	1 × 10 ³	1 × 10 ⁷	Sc-47	1 × 10 ²	1 × 10 ⁶
C-14	1 × 10 ⁴	1 × 10 ⁷	Sc-48	1 × 10 ¹	1 × 10 ⁵
O-15	1 × 10 ²	1 × 10 ⁹	V-48	1 × 10 ¹	1 × 10 ⁵
F-18	1 × 10 ¹	1 × 10 ⁶	Cr-51	1 × 10 ³	1 × 10 ⁷
Na-22	1 × 10 ¹	1 × 10 ⁶	Mn-51	1 × 10 ¹	1 × 10 ⁵
Na-24	1 × 10 ¹	1 × 10 ⁵	Mn-52	1 × 10 ¹	1 × 10 ⁵
Si-31	1 × 10 ³	1 × 10 ⁶	Mn-52m	1 × 10 ¹	1 × 10 ⁵
P-32	1 × 10 ³	1 × 10 ⁵	Mn-53	1 × 10 ⁴	1 × 10 ⁹
P-33	1 × 10 ⁵	1 × 10 ⁸	Mn-54	1 × 10 ¹	1 × 10 ⁶
S-35	1 × 10 ⁵	1 × 10 ⁸	Mn-56	1 × 10 ¹	1 × 10 ⁵
Cl-36	1 × 10 ⁴	1 × 10 ⁶	Fe-52	1 × 10 ¹	1 × 10 ⁶
Cl-38	1 × 10 ¹	1 × 10 ⁵	Fe-55	1 × 10 ⁴	1 × 10 ⁶
Ar-37	1 × 10 ⁶	1 × 10 ⁸	Fe-59	1 × 10 ¹	1 × 10 ⁶
Ar-41	1 × 10 ²	1 × 10 ⁹	Co-55	1 × 10 ¹	1 × 10 ⁶
K-40 ²⁴	1 × 10 ²	1 × 10 ⁶	Co-56	1 × 10 ¹	1 × 10 ⁵
K-42	1 × 10 ²	1 × 10 ⁶	Co-57	1 × 10 ²	1 × 10 ⁶
K-43	1 × 10 ¹	1 × 10 ⁶	Co-58	1 × 10 ¹	1 × 10 ⁶
Ca-45	1 × 10 ⁴	1 × 10 ⁷	Co-58m	1 × 10 ⁴	1 × 10 ⁷
Ca-47	1 × 10 ¹	1 × 10 ⁶	Co-60	1 × 10 ¹	1 × 10 ⁵
			Co-60m	1 × 10 ³	1 × 10 ⁶
			Co-61	1 × 10 ²	1 × 10 ⁶

²⁴ Potassium salts in quantities less than 1000 kg are exempted.

Radionuclide	Activity concentration (Bq g ⁻¹)	Activity (Bq)	Radionuclide	Activity concentration (Bq g ⁻¹)	Activity (Bq)
Co-62m	1 × 10 ¹	1 × 10 ⁵	Kr-85	1 × 10 ⁵	1 × 10 ⁴
Ni-59	1 × 10 ⁴	1 × 10 ⁸	Kr-85m	1 × 10 ³	1 × 10 ¹⁰
Ni-63	1 × 10 ⁵	1 × 10 ⁸	Kr-87	1 × 10 ²	1 × 10 ⁹
Ni-65	1 × 10 ¹	1 × 10 ⁶	Kr-88	1 × 10 ²	1 × 10 ⁹
Cu-64	1 × 10 ²	1 × 10 ⁶	Rb-86	1 × 10 ²	1 × 10 ⁵
Zn-65	1 × 10 ¹	1 × 10 ⁶	Sr-85	1 × 10 ²	1 × 10 ⁶
Zn-69	1 × 10 ⁴	1 × 10 ⁶	Sr-85m	1 × 10 ²	1 × 10 ⁷
Zn-69m	1 × 10 ²	1 × 10 ⁶	Sr-87m	1 × 10 ²	1 × 10 ⁶
Ga-72	1 × 10 ¹	1 × 10 ⁵	Sr-89	1 × 10 ³	1 × 10 ⁶
Ge-71	1 × 10 ⁴	1 × 10 ⁸	Sr-90 ^b	1 × 10 ²	1 × 10 ⁴
As-73	1 × 10 ³	1 × 10 ⁷	Sr-91	1 × 10 ¹	1 × 10 ⁵
As-74	1 × 10 ¹	1 × 10 ⁶	Sr-92	1 × 10 ¹	1 × 10 ⁶
As-76	1 × 10 ²	1 × 10 ⁵	Y-90	1 × 10 ³	1 × 10 ⁵
As-77	1 × 10 ³	1 × 10 ⁶	Y-91	1 × 10 ³	1 × 10 ⁶
Se-75	1 × 10 ²	1 × 10 ⁶	Y-91m	1 × 10 ²	1 × 10 ⁶
Br-82	1 × 10 ¹	1 × 10 ⁶	Y-92	1 × 10 ²	1 × 10 ⁵
Kr-74	1 × 10 ²	1 × 10 ⁹	Y-93	1 × 10 ²	1 × 10 ⁵
Kr-76	1 × 10 ²	1 × 10 ⁹	Zr-93 ^b	1 × 10 ³	1 × 10 ⁷
Kr-77	1 × 10 ²	1 × 10 ⁹	Zr-95	1 × 10 ¹	1 × 10 ⁶
Kr-79	1 × 10 ³	1 × 10 ⁵	Zr-97 ^b	1 × 10 ¹	1 × 10 ⁵
Kr-81	1 × 10 ⁴	1 × 10 ⁷	Nb-93m	1 × 10 ⁴	1 × 10 ⁷
Kr-83m	1 × 10 ⁵	1 × 10 ¹²	Nb-94	1 × 10 ¹	1 × 10 ⁶

Radionuclide	Activity concentration (Bq g ⁻¹)	Activity (Bq)	Radionuclide	Activity concentration (Bq g ⁻¹)	Activity (Bq)
Nb-95	1 × 10 ¹	1 × 10 ⁶	Ag-108m	1 × 10 ¹	1 × 10 ⁶
Nb-97	1 × 10 ¹	1 × 10 ⁶	Ag-110m	1 × 10 ¹	1 × 10 ⁶
Nb-98	1 × 10 ¹	1 × 10 ⁵	Ag-111	1 × 10 ³	1 × 10 ⁶
Mo-90	1 × 10 ¹	1 × 10 ⁶	Cd-109	1 × 10 ⁴	1 × 10 ⁶
Mo-93	1 × 10 ³	1 × 10 ⁸	Cd-115	1 × 10 ²	1 × 10 ⁶
Mo-99	1 × 10 ²	1 × 10 ⁶	Cd-115m	1 × 10 ³	1 × 10 ⁶
Mo-101	1 × 10 ¹	1 × 10 ⁶	In-111	1 × 10 ²	1 × 10 ⁶
Tc-96	1 × 10 ¹	1 × 10 ⁶	In-113m	1 × 10 ²	1 × 10 ⁶
Tc-96m	1 × 10 ³	1 × 10 ⁷	In-114m	1 × 10 ²	1 × 10 ⁶
Tc-97	1 × 10 ³	1 × 10 ⁸	In-115m	1 × 10 ²	1 × 10 ⁶
Tc-97m	1 × 10 ³	1 × 10 ⁷	Sn-113	1 × 10 ³	1 × 10 ⁷
Tc-99	1 × 10 ⁴	1 × 10 ⁷	Sn-125	1 × 10 ²	1 × 10 ⁵
Tc-99m	1 × 10 ²	1 × 10 ⁷	Sb-122	1 × 10 ²	1 × 10 ⁴
Ru-97	1 × 10 ²	1 × 10 ⁷	Sb-124	1 × 10 ¹	1 × 10 ⁶
Ru-103	1 × 10 ²	1 × 10 ⁶	Sb-125	1 × 10 ²	1 × 10 ⁶
Ru-105	1 × 10 ¹	1 × 10 ⁶	Te-123m	1 × 10 ²	1 × 10 ⁷
Ru-106 ^b	1 × 10 ²	1 × 10 ⁵	Te-125m	1 × 10 ³	1 × 10 ⁷
Rh-103m	1 × 10 ⁴	1 × 10 ⁸	Te-127	1 × 10 ³	1 × 10 ⁶
Rh-105	1 × 10 ²	1 × 10 ⁷	Te-127m	1 × 10 ³	1 × 10 ⁷
Pd-103	1 × 10 ³	1 × 10 ⁸	Te-129	1 × 10 ²	1 × 10 ⁶
Pd-109	1 × 10 ³	1 × 10 ⁶	Te-129m	1 × 10 ³	1 × 10 ⁶
Ag-105	1 × 10 ²	1 × 10 ⁶	Te-131	1 × 10 ²	1 × 10 ⁵

Radionuclide	Activity concentration (Bq g ⁻¹)	Activity (Bq)	Radionuclide	Activity concentration (Bq g ⁻¹)	Activity (Bq)
Te-131m	1 × 10 ¹	1 × 10 ⁶	Cs-134	1 × 10 ¹	1 × 10 ⁴
Te-132	1 × 10 ²	1 × 10 ⁷	Cs-135	1 × 10 ⁴	1 × 10 ⁷
Te-133	1 × 10 ¹	1 × 10 ⁵	Cs-136	1 × 10 ¹	1 × 10 ⁵
Te-133m	1 × 10 ¹	1 × 10 ⁵	Cs-137 ^b	1 × 10 ¹	1 × 10 ⁴
Te-134	1 × 10 ¹	1 × 10 ⁶	Cs-138	1 × 10 ¹	1 × 10 ⁴
I-123	1 × 10 ²	1 × 10 ⁷	Ba-131	1 × 10 ²	1 × 10 ⁶
I-125	1 × 10 ³	1 × 10 ⁶	Ba-140 ^b	1 × 10 ¹	1 × 10 ⁵
I-126	1 × 10 ²	1 × 10 ⁶	La-140	1 × 10 ¹	1 × 10 ⁵
I-129	1 × 10 ²	1 × 10 ⁵	Ce-139	1 × 10 ²	1 × 10 ⁶
I-130	1 × 10 ¹	1 × 10 ⁶	Ce-141	1 × 10 ²	1 × 10 ⁷
I-131	1 × 10 ²	1 × 10 ⁶	Ce-143	1 × 10 ²	1 × 10 ⁶
I-132	1 × 10 ¹	1 × 10 ⁵	Ce-144 ^b	1 × 10 ²	1 × 10 ⁵
I-133	1 × 10 ¹	1 × 10 ⁶	Pr-142	1 × 10 ²	1 × 10 ⁵
I-134	1 × 10 ¹	1 × 10 ⁵	Pr-143	1 × 10 ⁴	1 × 10 ⁶
I-135	1 × 10 ¹	1 × 10 ⁶	Nd-147	1 × 10 ²	1 × 10 ⁶
Xe-131m	1 × 10 ⁴	1 × 10 ⁴	Nd-149	1 × 10 ²	1 × 10 ⁶
Xe-133	1 × 10 ³	1 × 10 ⁴	Pm-147	1 × 10 ⁴	1 × 10 ⁷
Xe-135	1 × 10 ³	1 × 10 ¹⁰	Pm-149	1 × 10 ³	1 × 10 ⁶
Cs-129	1 × 10 ²	1 × 10 ⁵	Sm-151	1 × 10 ⁴	1 × 10 ⁸
Cs-131	1 × 10 ³	1 × 10 ⁶	Sm-153	1 × 10 ²	1 × 10 ⁶
Cs-132	1 × 10 ¹	1 × 10 ⁵	Eu-152	1 × 10 ¹	1 × 10 ⁶
Cs-134m	1 × 10 ³	1 × 10 ⁵	Eu-152m	1 × 10 ²	1 × 10 ⁶

Radionuclide	Activity concentration (Bq g ⁻¹)	Activity (Bq)	Radionuclide	Activity concentration (Bq g ⁻¹)	Activity (Bq)
Eu-154	1 × 10 ¹	1 × 10 ⁶	Os-191	1 × 10 ²	1 × 10 ⁷
Eu-155	1 × 10 ²	1 × 10 ⁷	Os-191m	1 × 10 ³	1 × 10 ⁷
Gd-153	1 × 10 ²	1 × 10 ⁷	Os-193	1 × 10 ²	1 × 10 ⁶
Gd-159	1 × 10 ³	1 × 10 ⁶	Ir-190	1 × 10 ¹	1 × 10 ⁶
Tb-160	1 × 10 ¹	1 × 10 ⁶	Ir-192	1 × 10 ¹	1 × 10 ⁴
Dy-165	1 × 10 ³	1 × 10 ⁶	Ir-194	1 × 10 ²	1 × 10 ⁵
Dy-166	1 × 10 ³	1 × 10 ⁶	Pt-191	1 × 10 ²	1 × 10 ⁶
Ho-166	1 × 10 ³	1 × 10 ⁵	Pt-193m	1 × 10 ³	1 × 10 ⁷
Er-169	1 × 10 ⁴	1 × 10 ⁷	Pt-197	1 × 10 ³	1 × 10 ⁶
Er-171	1 × 10 ²	1 × 10 ⁶	Pt-197m	1 × 10 ²	1 × 10 ⁶
Tm-170	1 × 10 ³	1 × 10 ⁶	Au-198	1 × 10 ²	1 × 10 ⁶
Tm-171	1 × 10 ⁴	1 × 10 ⁸	Au-199	1 × 10 ²	1 × 10 ⁶
Yb-175	1 × 10 ³	1 × 10 ⁷	Hg-197	1 × 10 ²	1 × 10 ⁷
Lu-177	1 × 10 ³	1 × 10 ⁷	Hg-197m	1 × 10 ²	1 × 10 ⁶
Hf-181	1 × 10 ¹	1 × 10 ⁶	Hg-203	1 × 10 ²	1 × 10 ⁵
Ta-182	1 × 10 ¹	1 × 10 ⁴	Tl-200	1 × 10 ¹	1 × 10 ⁶
W-181	1 × 10 ³	1 × 10 ⁷	Tl-201	1 × 10 ²	1 × 10 ⁶
W-185	1 × 10 ⁴	1 × 10 ⁷	Tl-202	1 × 10 ²	1 × 10 ⁶
W-187	1 × 10 ²	1 × 10 ⁶	Tl-204	1 × 10 ⁴	1 × 10 ⁴
Re-186	1 × 10 ³	1 × 10 ⁶	Pb-203	1 × 10 ²	1 × 10 ⁶
Re-188	1 × 10 ²	1 × 10 ⁵	Pb-210 ^b	1 × 10 ¹	1 × 10 ⁴
Os-185	1 × 10 ¹	1 × 10 ⁶	Pb-212 ^b	1 × 10 ¹	1 × 10 ⁵

Radionuclide	Activity concentration (Bq g ⁻¹)	Activity (Bq)	Radionuclide	Activity concentration (Bq g ⁻¹)	Activity (Bq)
Bi-206	1 × 10 ¹	1 × 10 ⁵	Th-230	1 × 10 ⁰	1 × 10 ⁴
Bi-207	1 × 10 ¹	1 × 10 ⁶	Th-231	1 × 10 ³	1 × 10 ⁷
Bi-210	1 × 10 ³	1 × 10 ⁶	Th-234 ^b	1 × 10 ³	1 × 10 ⁵
Bi-212 ^b	1 × 10 ¹	1 × 10 ⁵	Pa-230	1 × 10 ¹	1 × 10 ⁶
Po-203	1 × 10 ¹	1 × 10 ⁶	Pa-231	1 × 10 ⁰	1 × 10 ³
Po-205	1 × 10 ¹	1 × 10 ⁶	Pa-233	1 × 10 ²	1 × 10 ⁷
Po-207	1 × 10 ¹	1 × 10 ⁶	U-230	1 × 10 ¹	1 × 10 ⁵
Po-210	1 × 10 ¹	1 × 10 ⁴	U-231	1 × 10 ²	1 × 10 ⁷
At-211	1 × 10 ³	1 × 10 ⁷	U-232 ^b	1 × 10 ⁰	1 × 10 ³
Rn-220 ^b	1 × 10 ⁴	1 × 10 ⁷	U-233	1 × 10 ¹	1 × 10 ⁴
Rn-222 ^b	1 × 10 ¹	1 × 10 ⁸	U-234	1 × 10 ¹	1 × 10 ⁴
Ra-223 ^b	1 × 10 ²	1 × 10 ⁵	U-235 ^b	1 × 10 ¹	1 × 10 ⁴
Ra-224 ^b	1 × 10 ¹	1 × 10 ⁵	U-236	1 × 10 ¹	1 × 10 ⁴
Ra-225	1 × 10 ²	1 × 10 ⁵	U-237	1 × 10 ²	1 × 10 ⁶
Ra-226 ^b	1 × 10 ¹	1 × 10 ⁴	U-238 ^b	1 × 10 ¹	1 × 10 ⁴
Ra-227	1 × 10 ²	1 × 10 ⁶	U-239	1 × 10 ²	1 × 10 ⁶
Ra-228 ^b	1 × 10 ¹	1 × 10 ⁵	U-240	1 × 10 ³	1 × 10 ⁷
Ac-228	1 × 10 ¹	1 × 10 ⁶	U-240 ^b	1 × 10 ¹	1 × 10 ⁶
Th-226 ^b	1 × 10 ³	1 × 10 ⁷	Np-237 ^b	1 × 10 ⁰	1 × 10 ³
Th-227	1 × 10 ¹	1 × 10 ⁴	Np-239	1 × 10 ²	1 × 10 ⁷
Th-228 ^b	1 × 10 ⁰	1 × 10 ⁴	Np-240	1 × 10 ¹	1 × 10 ⁶
Th-229 ^b	1 × 10 ⁰	1 × 10 ³	Pu-234	1 × 10 ²	1 × 10 ⁷

Radionuclide	Activity concentration (Bq g ⁻¹)	Activity (Bq)	Radionuclide	Activity concentration (Bq g ⁻¹)	Activity (Bq)
Pu-235	1 × 10 ²	1 × 10 ⁷	Cf-246	1 × 10 ³	1 × 10 ⁶
Pu-236	1 × 10 ¹	1 × 10 ⁴	Cf-248	1 × 10 ¹	1 × 10 ⁴
Pu-237	1 × 10 ³	1 × 10 ⁷	Cf-249	1 × 10 ⁰	1 × 10 ³
Pu-238	1 × 10 ⁰	1 × 10 ⁴	Cf-250	1 × 10 ¹	1 × 10 ⁴
Pu-239	1 × 10 ⁰	1 × 10 ⁴	Cf-251	1 × 10 ⁰	1 × 10 ³
Pu-240	1 × 10 ⁰	1 × 10 ³	Cf-252	1 × 10 ¹	1 × 10 ⁴
Pu-241	1 × 10 ²	1 × 10 ⁵	Cf-253	1 × 10 ²	1 × 10 ⁵
Pu-242	1 × 10 ⁰	1 × 10 ⁴	Cf-254	1 × 10 ⁰	1 × 10 ³
Pu-243	1 × 10 ³	1 × 10 ⁷	Es-253	1 × 10 ²	1 × 10 ⁵
Pu-244	1 × 10 ⁰	1 × 10 ⁴	Es-254	1 × 10 ¹	1 × 10 ⁴
Am-241	1 × 10 ⁰	1 × 10 ⁴	Es-254m	1 × 10 ²	1 × 10 ⁶
Am-242	1 × 10 ³	1 × 10 ⁶	Fm-254	1 × 10 ⁴	1 × 10 ⁷
Am-242m ^b	1 × 10 ⁰	1 × 10 ⁴	Fm-255	1 × 10 ³	1 × 10 ⁶
Am-243 ^b	1 × 10 ⁰	1 × 10 ³			
Cm-242	1 × 10 ²	1 × 10 ⁵			
Cm-243	1 × 10 ⁰	1 × 10 ⁴			
Cm-244	1 × 10 ¹	1 × 10 ⁴			
Cm-245	1 × 10 ⁰	1 × 10 ³			
Cm-246	1 × 10 ⁰	1 × 10 ³			
Cm-247	1 × 10 ⁰	1 × 10 ⁴			
Cm-248	1 × 10 ⁰	1 × 10 ³			
Bk-249	1 × 10 ³	1 × 10 ⁶			

b Parent radionuclides, and their progeny whose dose contributions are taken into account in the dose calculation (thus requiring only the exemption level of the parent radionuclide to be considered), are listed in the following:

Sr-90	Y-90
Zr-93	Nb-93m
Zr-97	Nb-97
Ru-106	Rh-106
Ag-108m	Ag-108
Cs-137	Ba-137m
Ba-140	La-140
Ce-144	Pr-144
Pb-210	Bi-210, Po-210
Pb-212	Bi-212, Tl-208 (0.36), Po-212 (0.64)
Bi-212	Tl-208 (0.36), Po-212 (0.64)
Rn-220	Po-216
Rn-222	Po-218, Pb-214, Bi-214, Po-214
Ra-223	Rn-219, Po-215, Pb-211, Bi-211, Tl-207
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Ra-226	Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Ra-228	Ac-228
Th-226	Ra-222, Rn-218, Po-214
Th-228	Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-229	Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-209
Th-234	Pa-234m

U-230	Th-226, Ra-222, Rn-218, Po-214
U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
U-235	Th-231
U-238	Th-234, Pa-234m
U-240	Np-240m
Np237	Pa-233
Am-242m	Am-242
Am-243	Np-239

ANNEX VII

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

For the purposes of Article 75(2), for identified types of building materials, the activity concentrations of primordial radionuclides Ra-226, Th-232 (or its decay product Ra-228) and K-40 shall be determined.

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

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

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

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

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

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

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

ANNEX VIII

Data system for individual radiological monitoring

General Provisions

The data system for individual radiological monitoring established by a Member State may be realised either as a centralised national network or as a national dose register. These networks or registers may be supplemented by the issuance of individual radiological monitoring documents for every outside worker.

1. Any data system of the Member States for individual radiological monitoring of exposed workers shall comprise the following sections:

- (a) particulars concerning the worker's identity;
- (b) particulars concerning the medical surveillance of the worker;
- (c) particulars concerning the undertaking of the worker and, in the case of an outside worker, the employer of the worker;
- (d) the results of the individual monitoring of the exposed worker.

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

A: Data to be included in the data system for individual radiological monitoring

3. Data on the worker's identity shall include the worker's

- (a) surname;
- (b) first name;
- (c) sex;
- (d) date of birth;
- (e) nationality; and
- (f) unique identification number.

4. Data on the medical surveillance of the worker shall include

- (a) the medical classification of the worker in accordance with Article 45 (fit; fit, subject to certain conditions; unfit);
- (b) information on any restrictions on working with radiation;
- (c) the date of the last periodic health review;
- (d) the responsible occupational health service; and

(e) the period of validity of the result.

5. Data on the undertaking shall include the name, address and unique identification number of the undertaking.

6. Data on the employment of the worker shall include:

(a) the name, address and unique identification number of the employer;

(b) the starting date of employment; and

(c) the categorisation of the worker in accordance with Article 38.

7. The results of the individual monitoring of the exposed worker shall include:

(a) the official dose record for the last 5 calendar years (year; effective dose in mSv; in the event of non-uniform exposure, dose-equivalent in the different parts of the body in mSv; and in the event of internal contamination, the committed dose in mSv); and

(b) the official dose record for the current year (period; effective dose in mSv; in the event of non-uniform exposure, dose-equivalent in the different parts of the body in mSv; and in the event of internal contamination, the committed dose in mSv).

B: Data on outside workers to be supplied via the data system for individual radiological monitoring

1. Before the start of any activity, the employer of the outside worker shall supply the following data to the undertaking via the data system for individual radiological monitoring:

(a) data on the employer of the outside worker in accordance with Section A, point 6;

(b) data on the medical surveillance of the outside worker in accordance with Section A, point 4;

(c) the results of the outside worker's individual exposure monitoring in accordance with Section A, point 7.

2. The following data shall be recorded or have been recorded by the undertaking in the data system for individual radiological monitoring after the end of any activity:

(a) the period covered by the activity;

(b) an estimate of any effective dose received by the outside worker (operational dose for the period covered by the activity);

(c) in the event of non-uniform exposure, an estimate of the dose-equivalent in the different parts of the body;

(d) in the event of internal contamination, an estimate of the intake or the committed dose.

C. Provisions concerning the individual radiological monitoring document

1. Member States may decide to issue an individual radiological monitoring document for every outside worker.

2. The document shall be non-transferable.
3. Member States shall take the measures necessary to prevent a worker from being issued with more than one valid individual monitoring document at the same time.
4. In addition to the information required in Part A and Part B, the document shall include the name and address of the issuing body and the issuing date.

ANNEX IX

A. Elements to be included in an emergency management system

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

B. Elements to be included in an emergency response plan

For emergency preparedness:

1. Reference levels, taking into account the criteria laid down in Annex I;
2. Optimised protection strategies for members of the public who may be exposed, for different postulated events and related scenarios;
3. Predefined generic criteria for particular protective measures, expressed in terms of projected and received doses;
4. Default triggers or operational criteria such as observables and indicators of on-scene conditions;
5. Arrangements for prompt coordination with the emergency response organisation in a neighbouring Member State or non-Member State, for facilities in the vicinity of a national border;

6. Arrangements for the emergency response plan to be reviewed and revised to take account of changes or lessons learned from exercises and events.

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

For emergency response:

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

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

ANNEX X

A. Prior information to the members of the public likely to be affected by an emergency:

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

B. Information to be provided to the affected members of the public in the event of an emergency

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

3. This information and advice shall be supplemented, if time permits, by a reminder of the basic facts about radioactivity and its effects on human beings and on the environment.

ANNEX XI

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

1. Natural materials
 - (a) Alum-shale.
 - (b) Building materials or additives of natural igneous origin, such as:
 - granite,
 - gneiss;
 - porphyries;
 - syenite;
 - basalt;
 - tuff;
 - pozzolana;
 - lava.
2. Materials incorporating residues from industries processing naturally occurring radioactive material, such as:
 - fly ash;
 - phosphogypsum;
 - phosphorus slag;
 - tin slag;
 - copper slag;
 - red mud (residue from aluminium production);
 - residues from steel production.

ANNEX XII

Information to be provided in the records for high activity sealed sources

HASS)

1. HASS identification number	2. Identification of the authorised undertaking		3. Location of HASS (Use or storage) if not the same as in 2.	
	Name:		Name:	
<i>Manufacturer device number</i>	Address:		Address:	
	Country:		Country:	
<i>Field of use:</i>	Manufacturer <input type="checkbox"/>	Supplier <input type="checkbox"/>	User <input type="checkbox"/>	Fixed use <input type="checkbox"/> Storage <input type="checkbox"/> Mobile use <input type="checkbox"/>
4. Registration	5. Authorisation		6. Operational controls of HASS	
Date of start of registration:	Number:		Date:	
Date of transfer of registration to historic file:	Date of issue:		Date:	
	Date of expiry:		Date:	
7. HASS characteristic	8. Receipt of HASS		Date:	
<i>Year of manufacture:</i>			Date:	
Radionuclide:	Date of receipt:		Date:	
Activity at the date of manufacturing:	Receipt from		Date:	
			Date:	
Activity reference date:	Name:		Date:	
Manufacturer/Supplier*:	Address:		Date:	
Name:	Country:		Date:	
Address:	Manufacturer <input type="checkbox"/>	Supplier <input type="checkbox"/>	Another user <input type="checkbox"/>	Date:
Country:	9. Transfer of HASS		10. Further information	
Physical and chemical characteristics	Date of transfer:		Loss <input type="checkbox"/>	Date of loss:
<i>Source type identification:</i>	Transfer to		Theft <input type="checkbox"/>	Date of theft:
<i>Capsule identification:</i>			<i>Finding:</i>	Yes <input type="checkbox"/> No <input type="checkbox"/>
<i>ISO classificaton:</i>	Name:		Date:	
<i>ANSI classificaton:</i>	Address:		Place:	
<i>IAEA source category:</i>	Country:		<i>Other information:</i>	
	Authorisation number:			
<i>Neutron source: Yes <input type="checkbox"/> No <input type="checkbox"/></i>	Date of issue:			
<i>Neutron source target:</i>	Date of expiry:			
<i>Neutron flux:</i>	Manufacturer <input type="checkbox"/>	Supplier <input type="checkbox"/>	Another user <input type="checkbox"/>	
	Facility for long term storage and disposal <input type="checkbox"/>			
* Where the manufacturer of the source is established outside the Community, the name and address of the importer-supplier may be provided instead.				

ANNEX XIII

Provision of data on high-activity sealed sources

The undertaking shall provide the competent authority with an electronic or written copy of the records for high-activity sealed sources, referred to in Article 90 and covering the information set out in Annex XII, as follows:

1. without undue delay, at the time of the establishment of such records, which shall be as soon as possible after the source is acquired;
2. at intervals, to be determined by Member States, of not more than 12 months after the acquisition of the source;
3. if the situation indicated on the information sheet has changed;
4. without undue delay upon the closure of the records for a specific source when the undertaking no longer holds this source, whereby the name of the undertaking or waste disposal and storage facility to which the source is transferred shall be included;
5. without undue delay upon the closure of such records when the undertaking no longer holds any sources.

ANNEX XIV

Requirements for undertakings responsible for a high-activity sealed source

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

- (a) ensure that suitable tests, such as leak tests based on international standards, are undertaken regularly in order to check and maintain the integrity of each source;
- (b) regularly verify at specific intervals, which may be determined by Member States, that each source and, where relevant, the equipment containing the source are still present and in apparently good condition at their place of use or storage;
- (c) ensure that each fixed and mobile source is subject to adequate documented measures, such as written protocols and procedures, aimed at preventing unauthorised access to or loss or theft of the source or its damage by fire;
- (d) promptly notify the competent authority of any loss, theft or unauthorised use of a source, arrange for a check on the integrity of each source after any event, including fire, that may have damaged the source, and, if appropriate, inform the competent authority thereof and of the measures taken;
- (e) return each disused source to the supplier or place it in a facility for long term storage and disposal or transfer it to another authorised undertaking unless otherwise agreed by the competent authority, without undue delay after termination of the use;
- (f) ascertain that, before a transfer is made, the recipient holds appropriate authorisation.
- (g) Promptly notify the competent authority of any accident or incident resulting in unintentional exposure of a worker or a member of the public.

ANNEX XV

Identification and marking of high-activity sealed sources

1. The manufacturer or supplier shall ensure that:
 - (a) Each high-activity sealed source is identified by a unique number. This number shall be engraved or stamped on the source, where practicable.

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

- (b) The source container and, where practicable, the source are marked and labelled with an appropriate sign to warn people of the radiation hazard.
2. The manufacturer shall provide a photograph of each manufactured source design type and a photograph of the typical source container.
3. The undertaking shall ensure that each high-activity sealed source is accompanied by written information indicating that the source is identified and marked in compliance with point 1 and that the markings and labels referred to in point 1 remain legible. The information shall include photographs of the source, source container, transport packaging, device and equipment as appropriate.

ANNEX XVI

Indicative list of items to be covered in the national action plan to manage long term risks from radon exposures

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