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IAEA SAFETY STANDARDS

for protecting people and the environment

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International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources

Draft Safety Requirements
DS379

Cosponsors

Food and Agriculture Organization of the United Nations
International Atomic Energy Agency
International Labour Organization
Nuclear Energy Agency of the Organisation for Economic Co-operation and Development
Pan American Health Organization
World Health Organization

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FOREWORD

PREFACE BY THE JOINT SPONSORING ORGANIZATIONS

[to be written by the joint sponsoring organizations]

THE IAEA SAFETY STANDARDS
[standard text to be inserted]

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1. INTRODUCTION

1.1. This section explains the context of the Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (hereinafter referred to as 'these Standards'). As such, it does not constitute a part of the requirements, which appear from section 2 onwards.

BACKGROUND

1.2. Radioactivity is a natural phenomenon and natural sources of radiation are features of the environment. Radiation and radioactive material may also be of human origin and have many beneficial applications, including uses in medicine, industry, agriculture, research as well as nuclear power generation. The radiation risks to people and the environment that may arise from the uses of radiation and radioactive material must be assessed and, where necessary, controlled through the application of standards of safety.

1.3. Exposure of tissues or organs to radiation can induce cell death, extensive enough to impair the function of the irradiated tissue or organ. Effects of this type are called 'deterministic' and they are clinically observable only if the radiation dose reaches a certain threshold level of dose. In an individual, the severity of a deterministic effect increases with increasing dose.

1.4. Exposure to radiation can also induce the non-lethal transformation of cells, which may still maintain their capacity to divide. The body's immunological system for detecting and destroying abnormal cells is very effective. However, there remains a certain probability that the non-lethal transformation of a cell may lead to cancer in the exposed individual after a latency period, if it occurs in a somatic cell; or to heritable effects, if it affects a germ cell. These effects are called 'stochastic' effects. For the purposes of these Standards, it is assumed that the probability of occurrence of stochastic effects is proportional to the dose received, with no dose threshold. There is no threshold level of radiation exposure below which it is certain that cancer or genetic effects will not occur. The detriment-adjusted nominal risk co-efficient, which includes all cancers and heritable effects, is approximately 5% per Sv [1]. This risk coefficient may need to be adjusted as new scientific knowledge becomes available.

1.5. The requirements established in these Standards are governed by the objectives, concepts and principles of the Fundamental Safety Principles [2]. These

Standards draw upon information derived from experiences of States in applying the requirements of the previous Basic Safety Standards (BSS), and from experience in many countries in the use of radiation and nuclear techniques. They also draw upon extensive research and development work by national and international scientific and engineering organizations on the health effects of radiation and on techniques for the safe design and operation of sources. These Standards also take account of the applicable recommendations of the ICRP [1]. As scientific considerations are only part of the basis for decisions on protection and safety, these Standards also address the use of value judgements related to the management of risks.

The system of protection and safety

1.6. As stated in the Fundamental Safety Principles [2], "The fundamental safety objective is to protect people and the environment from harmful effects of ionizing radiation". This objective must be achieved without unduly limiting the operation of facilities or the conduct of activities that give rise to radiation risks. Therefore, the system of protection and safety aims to assess, manage and control exposures to ionizing radiation so that radiation risks, including possible health effects and impact on the environment, are reduced to the extent reasonably achievable.

1.7. These Standards are based on the following principles in the Fundamental Safety Principles [2]:

Safety Principle 1: Responsibility for safety: The prime responsibility for safety must rest with the person or organization responsible for facilities and activities[1] that give rise to radiation risks.

Safety Principle 2: Role of government: An effective legal and governmental framework for safety, including an independent regulatory body, must be established and sustained.

[1] The term 'facilities and activities' is a general term encompassing any human activity that may cause people to be exposed to radiation risks arising from naturally occurring or artificial sources. 'Facilities' includes: nuclear facilities; irradiation installations; some mining and raw material processing facilities such as uranium mines; radioactive waste management facilities; and any other places where radioactive materials are produced, processed, used, handled, stored or disposed of — or where radiation generators are installed — on such a scale that consideration of protection and safety is required. 'Activities' includes: the production, use, import and export of radiation sources for industrial, research and medical purposes; the transport of radioactive material; the decommissioning of facilities; radioactive waste management activities such as the discharge of effluents; and some aspects of the remediation of sites affected by residues from past activities.

Safety Principle 3: Leadership and management for safety: Effective leadership and management for safety must be established and sustained in organizations concerned with, and facilities and activities that give rise to, radiation risks.

Safety Principle 4: Justification of facilities and activities: Facilities and activities that give rise to radiation risks must yield an overall benefit.

Safety Principle 5: Optimization of protection: Protection must be optimized to provide the highest level of safety that can reasonably be achieved.

Safety Principle 6: Limitation of risks to individuals: Measures for controlling radiation risks must ensure that no individual bears an unacceptable risk of harm.

Safety Principle 7: Protection of present and future generations: People and the environment, present and future, must be protected against radiation risks.

Safety Principle 8: Prevention of accidents: All practical efforts must be made to prevent and mitigate nuclear or radiation accidents.

Safety Principle 9: Emergency preparedness and response: Arrangements must be made for emergency preparedness and response for nuclear or radiation incidents.

Safety Principle 10: Protective actions to reduce existing or unregulated radiation risks: Protective actions to reduce existing or unregulated radiation risks must be justified and optimized.

The three general principles of radiation protection, which are justification, optimization of protection and limitation of exposure, are expressed in Safety Principles 4, 5, 6, and 10.

1.8. The prime responsibility for safety rests with the person or organization responsible for any facility or activity that gives rise to radiation risks. Other parties also bear certain responsibilities. For instance, suppliers of radiation generators and radioactive sources bear responsibilities relating to the design, manufacture and operating instructions for the safe use of such devices. In the case of medical

exposures, because of the medical setting in which such exposures occur, primary responsibility for protection and safety of patients lies with the health professional responsible for administration of the radiation dose, referred to in these Standards as the 'radiological medical practitioner'. Many other health professionals may be involved in the preparations for, and the conduct of, radiological procedures, and all have specific responsibilities, as set out in these Standards.

1.9. A properly established legal and governmental framework provides for the regulation of facilities and activities that give rise to radiation risks. There is a hierarchy of responsibilities within this framework, from governments to regulatory bodies to the people engaged in activities involving exposure to radiation. The government is responsible for the adoption within its national legal system of such legislation, regulations, and other standards and measures as may be necessary to fulfil all its national and international obligations effectively, and for the establishment of an independent regulatory body. In some cases, more than one government organization may have the functions of a regulatory body for activities within their jurisdiction related to control of radiation and radioactive materials.

1.10. Both the government and the regulatory body have an important responsibility in establishing standards and establishing the regulatory framework for protecting people and the environment against radiation risks. These standards require the government to ensure coordination across government departments and agencies that have responsibilities for protection and safety, e.g. health, environment, labour, regulatory body, mining, science, agriculture, education. Standards should be developed through consultation with those who may be required to apply them. The government is also responsible for ensuring, as necessary, that provisions are in place for supporting services such as education and training, technical services and other functions. If such services are not available within the country, other mechanisms to provide such services may have to be considered. The regulatory body has responsibility for carrying out its regulatory functions such as the establishment of standards and guidelines, the authorization and inspection of facilities and activities, and the enforcement of regulations.

1.11. Leadership in safety matters has to be demonstrated at the highest levels in an organization, and safety has to be achieved and maintained by means of an effective management system. This system has to integrate all elements of

management so that requirements for safety are established and applied coherently with other requirements, including those for health, environment and security, together with economic considerations. The management system also has to ensure the promotion of a safety culture, the regular assessment of safety performance and the application of lessons learned. Safety culture includes individual and collective commitment to safety on the part of the leadership, the management and personnel at all levels. The term management system reflects and includes the initial concept of 'quality control', (controlling the quality of products) and its evolution through 'quality assurance' (the system to ensure the quality of products) and 'quality management' (the system to manage quality).

1.12. The conduct of activities or the operation of facilities that alter the radiation exposure situation by introducing a new source of radiation, change exposure or change the likelihood of exposure must be justified in the sense that the detriment that may be caused is outweighed by the associated individual and societal benefits. In addition to protection and safety, the concept of comparing health detriments and benefits also involves consideration of economic, societal and environmental factors and often goes beyond protection and safety considerations.

1.13. The application of the justification principle to medical exposures requires a special approach. As an overarching justification of medical exposures, it is accepted that the use of radiation in medicine does more good than harm. However at the next level, there is a need for generic justification of a given radiological procedure, carried out by the health authority in conjunction with appropriate professional bodies. This applies to new technologies and/or techniques as they evolve**.** The final level of justification considers the application of the radiological procedure to a given individual and must take into account the specific objectives of the exposure and the clinical circumstances and the characteristics of the individual involved, through referral criteria developed by professional bodies and the health authority.

1.14. The optimization of protection and safety, when applied to the exposure of workers, members of the public and carers and comforters of patients undergoing radiological procedures, is a process for ensuring that the magnitudes and likelihood of exposures and the numbers of individuals exposed are as low as reasonably achievable, taking economic, societal and environmental factors into account. This means that the level of protection would be the best under the prevailing

circumstances. Optimization is a forward-looking iterative process requiring both qualitative and quantitative judgements. As in the case of justification, the application of the optimization principle to medical exposures of patients and volunteers in biomedical research requires a special approach. Too little radiation can be as bad as too much radiation, in that the cancer may not be cured or the images may not be of suitable diagnostic quality. It is paramount that the medical exposure leads to the required outcome.

1.15. For planned exposure situations, exposures and risks are subject to control to ensure that the specified dose limits for occupational exposure and public exposure are not exceeded, and optimization is applied to achieve the desired level of protection and safety.

1.16. All practical efforts must be made to prevent and mitigate nuclear or radiological accidents. The most harmful consequences arising from facilities and activities have come from the loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source or other source of radiation. Consequently, to ensure that the likelihood of an accident having harmful consequences is extremely low, measures have to be taken to prevent the occurrence of failures or abnormal conditions that could lead to such a loss of control; to prevent the escalation of any such failures or abnormal conditions that do occur; and to prevent the loss of, or the loss of control over, a radioactive source or other source of radiation.

1.17. Arrangements must be made for emergency preparedness and response for nuclear or radiation incidents. The primary goals of preparedness and response for a nuclear or radiological emergency are:

(i) to ensure that arrangements are in place for an effective response at the scene and, as appropriate, at the local, regional, national and international levels;

(ii) to ensure that, for reasonably foreseeable incidents, radiation risks would be minor;

(iii) to take practical measures to mitigate any consequences for human life and health and the environment for any incidents that do occur.

Types of exposure situation

1.18. For the purpose of establishing practical requirements for protection and safety, these Standards distinguish between three types of exposure situations: planned exposure situations, emergency exposure situations and existing exposure situations [1]. Together, these cover all exposure situations to which these Standards apply:

(i) A planned exposure situation is a situation of exposure that arises from the planned operation of a source or from a planned activity that results in an exposure from a source. Since provisions for protection and safety can be made before embarking on the activity concerned, the associated exposures and their probability of occurrence can be restricted from the outset. The primary means of controlling exposure in planned exposure situations is by good design of installations, equipment and operating procedures. In planned exposure situations, a certain level of exposure is reasonably expected to occur. If exposure is not expected to be delivered with certainty but may result from an accident or an event or sequence of events that are not certain to occur, it is referred to as potential exposure.

(ii) An emergency exposure situation is a situation of exposure that arises as a result of an accident, a malicious act, or any other unexpected event, and requires prompt action in order to avoid or reduce adverse consequences. Although preventive and mitigation measures need to be considered before an emergency exposure situation arises, once it actually occurs exposures can be reduced only by implementing protective actions.

(iii) An existing exposure situation is a situation of exposure which already exists when a decision on the need for control needs to be taken. Existing exposure situations include exposure to natural background radiation and to residual radioactive material from past practices that were never subject to regulatory control or from a nuclear or radiological emergency after an emergency exposure situation has been declared ended.

If an event or sequence of events considered during the assessment of potential exposure actually takes place, it may be treated either as a planned exposure situation or as an emergency exposure situation, depending on whether an emergency has been declared.

1.19. The descriptions of the three types of exposure situation in para. 1.18 are, on their own, not always sufficient to determine unequivocally which type of exposure situation is applicable in particular circumstances. For instance, the transition from an emergency exposure situation to an existing exposure situation may occur progressively over time, while some exposures to natural sources may have characteristics of both planned exposure situations and existing exposure situations. In these Standards, the most appropriate type of exposure situation has been assigned taking practical considerations into account. For the purposes of these Standards, controls on the exposure of aircrew from cosmic radiation are considered within existing exposure situations in Section 5. The exposure of space crew presents exceptional circumstances and these are addressed separately in Section 5.

Dose constraints and reference levels

1.20. Dose constraints and reference levels are used for optimization,, the intended outcome of which is that all exposures reach levels that are as low as reasonably achievable, economic, societal and environmental factors being taken into account. Dose constraints are applied to occupational and public exposure in planned exposure situations. Dose constraints are set separately for each controlled source and serve as a boundary in defining the range of options for optimization. Dose constraints are not dose limits and exceeding a dose constraint does not represent a regulatory infraction, but could result in the implementation of follow-up actions. While the objectives of the use of dose constraints for controlling occupational and public exposure are similar, they are applied in different ways. For occupational exposure, the dose constraint is a tool to be established and used by the person or organization responsible for any facility or activity in the optimization of protection and safety. For public exposure in planned exposure situations, the government or regulatory body establishes or approves dose constraints, taking into account the characteristics of the site and the facility, the exposure scenarios and the views of interested parties. After the exposures have occurred, the dose constraint may be used as a benchmark when assessing the suitability of the optimized protection strategy that has been implemented and for making adjustments as judged necessary. The setting of the dose constraint needs to be considered together with other health and safety provisions and the available technology.

1.21. Reference levels are used for optimization in emergency exposure situations and existing exposure situations. These are established or approved by the government, regulatory body or other relevant authority. For occupational and public exposure in emergency exposure situations and existing exposure situations, a reference level serves as the boundary in defining the range of options in optimization for implementing protection actions. The reference level represents the level of dose or risk above which it is judged to be inappropriate to plan to allow exposures to occur, and below which optimization of protection is implemented. The chosen value for a reference level will depend upon the prevailing circumstances of the exposure under consideration. The optimized protection strategies should keep exposure levels below the reference level. Once an emergency exposure situation has occurred or an existing exposure situation has been identified, actual exposures may be above or below the reference level, which would then be used as a benchmark to judge whether further protective measures are necessary and to assist in prioritizing their application. Optimization is to be applied in emergency and existing exposure situations, even if the initial doses are below the defined reference levels.

1.22. The ICRP recommends a range of doses spanning two orders of magnitude within which the value of a dose constraint or reference level usually should be chosen [1]. At the lower end of this range, the dose constraint or reference level represents an increase, up to about 1 mSv, above the dose received in a year from natural background radiation[2], and would be used when individuals are exposed to a source that gives them little or no individual benefit, but for which there may be benefits to society in general. This would be the case, for instance, when establishing dose constraints for public exposure in planned exposure situations. Dose constraints or reference levels of 1–20 mSv would be used when individuals usually receive benefit from the exposure situation, but not necessarily from the exposure itself. This would be the case, for instance, when establishing dose constraints for occupational exposure in planned exposure situations or reference levels for exposure of the public in existing exposure situations. Reference levels of 20–100 mSv would be used when individuals are exposed to sources that are not under control or where actions to

[2] According to UNSCEAR [3], the worldwide annual average radiation dose from radiation sources of natural origin, including radon, is 2.4 mSv. In any large population, about 65% would be expected to have annual effective doses between 1 and 3 mSv. About 25% of the population would have annual effective doses less than 1 mSv and 10% would have annual effective doses greater than 3 mSv.

reduce doses would be disproportionately disruptive. This would be the case, for instance, when establishing reference levels for the residual dose from a radiological emergency. Any situation resulting in a dose above 100 mSv incurred acutely or in a year would be considered unacceptable except under circumstances addressed specifically in these Standards relating to the exposure of emergency workers. The selection of the value of the dose constraint or reference level would be based on the characteristics of the exposure situation, including:

(i) The nature of the exposure and the practicability of reducing or preventing the exposure;

(ii) The benefits from the exposure to individuals and society or the benefit of avoiding preventive or protective actions that would be detrimental to living conditions, as well as other societal criteria related to the management of the exposure situation;

(iii) National or regional factors, together with a consideration of international guidance and good practice elsewhere.

1.23. The system of protection and safety in these standards includes protection against exposure to radon which is based on the average level of risk to a population with typical but various smoking habits. Because of the synergistic effects of smoking and exposure to radon, the absolute risk of lung cancer from unit exposure to radon for smokers is more than twenty times greater than for those who never smoked [4, 5, 6] Information provided on the risk of exposure to radon needs to highlight the enhanced risk for smokers.

1.24. Dose constraints are also used in the optimization of protection of carers and comforters and of persons exposed in biomedical research. Dose constraints are not applicable to the exposure of patients to radiation for diagnosis or treatment.

1.25. In X ray medical imaging, image guided interventional procedures and diagnostic nuclear medicine, a diagnostic reference level (DRL) is used as a trigger for investigation. Periodic assessments of typical doses and/or administered activities are to be performed in a medical facility and, if the comparison with established DRLs shows that the typical doses and/or administered activities are either too high or unusually low, a local review is to be initiated to ascertain whether protection has been adequately optimized and whether corrective action is required.

Protection of the environment

1.26. In a global and long term perspective, protection of people and the environment against radiation risks associated with the operation of facilities and the conduct of activities — risks that may transcend national borders and may persist for long periods of time — is important to achieving equitable and sustainable development.

1.27. The system of protection and safety in these Standards generally provides appropriate protection of the environment against harmful effects of radiation exposure. Nevertheless, international trends in this field show an increasing awareness of the vulnerability of the environment. Trends also indicate the need to be able to demonstrate (rather than to assume) that the environment is protected against effects of industrial pollutants, including radionuclides, in a wider range of environmental situations, irrespective of any human connection with them. This is normally accomplished through an environmental assessment, which identifies the target(s), defines the appropriate criteria for protection, assesses the impacts and compares the results of the available protection options. The methods and criteria for these radiological assessments are being developed and will continue to evolve.

1.28. Radiological impacts within a particular environment constitute only one type of impact and in most cases, may not be the dominant impact of a particular facility or activity. Further, the assessment of impacts on the environment should be viewed in an integrated manner with the other features of the system of protection to establish the conditions applicable to a particular source. Because there are complex interrelations, the approach to the protection of people and the environment is not limited to the prevention of radiological effects on human health and on flora and fauna. When establishing regulations, an integrated perspective has to be adopted to ensure the sustainability of agriculture, forestry, fisheries and tourism and of the use of natural resources, now and in the future. Such an integrated perspective also has to take into account the need to prevent unauthorized acts with possible consequences for the environment, including, for example, the illicit dumping of radioactive material and the abandonment of sources of radiation. Consideration also needs to be given to the potential for build-up and accumulation of long-lived radionuclides released to the environment.

1.29. These Standards are designed to clearly identify protection of the environment as an issue to be assessed, while leaving flexibility to incorporate the results into the appropriate decision making processes.

Interfaces between safety and security

1.30. Safety measures and security measures have in common the aim of protecting human life and health and the environment. In addition, safety measures and security measures must be designed and implemented in an integrated manner so that security measures do not compromise safety and safety measures do not compromise security.

1.31. Security infrastructure and safety infrastructure needs to be developed, as far as possible, in a well-coordinated manner. All organizations involved need to be made aware of the commonalities and differences between safety and security to be able to factor both into development plans. The synergies between safety and security have to be developed and encouraged; safety and security have to complement and enhance one another. For guidance on Nuclear Security refer to Nuclear Security Series.

OBJECTIVE

1.32. These Standards establish basic requirements for protection of people and the environment from harmful effects of ionizing radiation and for the safety of sources.

1.33. These Standards are primarily intended for use by governments and regulatory bodies. Requirements also apply to principal parties and other parties as specified in section 2, health authorities, professional bodies, and service providers such as technical support organizations.

SCOPE

1.34. These Standards apply only to ionizing radiation, which includes gamma rays, X rays and particles such as protons, alpha particles, beta particles and neutrons. While these Standards do not specifically address the control of non-radiological aspects of health, safety and the environment, these aspects may need to be considered. Non-ionizing radiation is outside the scope of these Standards.

1.35. These Standards do not deal with security measures. Nuclear security recommendations complementary to safety requirements are addressed in the IAEA Nuclear Security Series.

1.36. These Standards apply to all situations involving exposures that are amenable to control. Exposures deemed to be unamenable to control are excluded from the scope of these Standards[3].

1.37. These Standards comprise basic requirements to be fulfilled in all facilities and activities involving radiation exposure. For certain facilities and activities, such as nuclear installations, radioactive waste management facilities and the transport of radioactive material, other Safety Requirements, complementary to these Standards, also apply. To assist with implementation of these Standards, as well as other relevant Safety Requirements, specific Safety Guides are developed and published.

1.38. These Standards apply to the following three categories of exposure: occupational exposure, public exposure and medical exposure.

1.39. These Standards apply to human activities involving exposure to radiation:

(i) Carried out in a State that chooses to adopt these Standards or requests any of the Sponsoring Organizations to provide for the application of these Standards;
(ii) Undertaken by States with the assistance of FAO, IAEA, ILO, PAHO, or WHO, in the light of relevant national rules and regulations;
(iii) Carried out by the IAEA or involving the use of materials, services, equipment, facilities and non-published information made available by the IAEA or at its request or under its control or supervision; or
(iv) Carried out under any bilateral or multilateral arrangement whereby the parties request the IAEA to provide for the application of these Standards.

1.40. Quantities and units used in these Standards are in accordance with the recommendations of the International Commission on Radiation Units and Measurements (ICRU) [7].

STRUCTURE

[3] For example, it is generally accepted that it is not feasible to control ^{40}K in the body and cosmic radiation at the surface of the earth.

1.41. The requirements of these Standards are grouped into requirements applicable to all types of exposure situations and requirements for planned exposure situations, emergency exposure situations and existing exposure situations. For each exposure situation, the requirements are further grouped into requirements for occupational exposure, public exposure and, in the case of planned exposure situations, medical exposure.

1.42. Section 2 sets out the requirements that generally apply to all categories of exposure and types of exposure situations. These requirements include the assignment of responsibilities to government, the regulatory body and principal and other parties with respect to the implementation of a protection and safety programme and management system, the promotion of a safety culture and the consideration of human factors.

1.43. Section 3 sets out the requirements, in addition to those of Section 2, for planned exposure situations. Section 3 includes generic requirements applicable to all categories of exposure, requirements for the safety of sources and more specific requirements for occupational exposure, public exposure and medical exposure.

1.44. Section 4 sets out the requirements, in addition to those of Section 2, for emergency exposure situations. This section includes requirements for public exposure and for exposure of emergency workers in emergency exposure situations. It also includes requirements on the transition from an emergency exposure situation to an existing exposure situation.

1.45. Section 5 sets out the requirements, in addition to those of Section 2, for existing exposure situations. This section includes requirements for public exposure and occupational exposure in existing exposure situations. It includes specific requirements for remediation of contaminated sites and living in areas with residual activity, for radon in homes and workplaces, for exposure of aircrew and space crew, and for radionuclides in commodities.

1.46. The locations, within these Standards, of requirements for the relevant categories of exposure within each type of exposure situation are as shown in Table 1. Requirements for protection of the environment are given in Section 2, and for different exposure situations in Sections 3 and 4. Thus, for any particular facility or

activity, more than one section of these Standards must be considered, as illustrated by the following examples:

(i) The requirements for the regulatory body given in Section 2 are applicable to all exposure situations and exposure categories. They provide the basic regulatory framework within which persons or organizations responsible for facilities and activities must comply with the requirements placed on them. These requirements thus establish the general regulatory activities to be performed by the regulatory body. Any further requirements for the regulatory body that apply only to a particular exposure situation or exposure category are given in Sections 3, 4 and 5, as appropriate. These requirements are additional to the requirements given in Section 2.

(ii) Persons or organizations responsible for a medical facility using radiation generators or radioactive sources are subject to the requirements in Section 2 and to the requirements that are common to all planned exposure situations given in Section 3. In addition, they are subject to the requirements in Section 3 for occupational exposure (such as exposure of medical staff operating medical devices that emit radiation), public exposure (such as exposure in rooms adjacent to those that contain equipment that generate radiation) and medical exposure (protection of patients).

TABLE 1. LOCATION OF REQUIREMENTS WITHIN THESE STANDARDS.

	Occupational exposure	Public exposure	Medical exposure
Planned exposure situation	Section 2 Section 3: Paras 3.5 to 3.67, and Paras 3.68 to 3.116	Section 2 Section 3: Paras 3.5 to 3.67 and Paras 3.117 to 3.143	Section 2 Section 3: Paras 3.5 to 3.67 and Paras 3.144 to 3.184
Emergency exposure situation	Section 2 Section 4	Section 2 Section 4	Not applicable.
Existing exposure situation	Section 2 Section 5	Section 2 Section 5	Not applicable.

1.47. Four schedules provide the numerical values needed to support the requirements, covering exemption and clearance, categorization of sealed sources, dose limits for planned exposure situations and criteria for use in emergency preparedness and response.

1.48. A Glossary is included in these Standards.

2. GENERAL REQUIREMENTS FOR PROTECTION AND SAFETY

DEFINITIONS

2.1. Terms have the meanings given in the Glossary.

INTERPRETATION

2.2. Except as specifically authorized by the statutory governing body of a relevant sponsoring organization, no interpretation of these Standards by any officer or employee of the sponsoring organization other than a written interpretation by the Director General of the sponsoring organization will be binding on the sponsoring organization.

RESOLUTION OF CONFLICTS

2.3. The requirements of these Standards are in addition to and not in place of other applicable requirements, such as those of relevant binding conventions and national regulations.

2.4. In cases of conflict between the requirements of these Standards and other applicable requirements, the government or the regulatory body, as appropriate, shall determine which requirement is to be enforced.

2.5. Nothing in these Standards shall be construed as restricting any actions that may otherwise be necessary for protection and safety.

ENTRY INTO FORCE

2.6. The Standards shall come into force one year after the date of their adoption or acknowledgement, as appropriate, by the relevant Sponsoring Organization.

2.7. Should a State choose to adopt these Standards, these Standards shall come into force at the time indicated in the formal adoption by that State.

IMPLEMENTATION OF RADIATION PROTECTION PRINCIPLES

Requirement 1: Application of the principles of radiation protection

Parties with responsibilities for protection and safety shall ensure that the principles of radiation protection are applied in all exposure situations.

2.8. In planned exposure situations, each party with responsibilities for protection and safety shall ensure, when relevant requirements apply to that party, that no practice is undertaken unless justified.

2.9. In emergency exposure situations or existing exposure situations, each party with responsibilities for protection and safety shall ensure, when relevant requirements apply to that party, that protective or remedial actions are justified and undertaken in such a way as to achieve the objectives set out in the strategy for protection.

2.10. In all exposure situations, each party with responsibilities for protection and safety shall ensure, when relevant requirements apply to that party, that protection and safety is optimized[4].

2.11. In planned exposure situations except for medical exposure, each party with responsibilities for protection and safety shall ensure that, when relevant requirements apply to that party, specified dose limits are not exceeded.

2.12. The application of the requirements of the system of protection and safety shall be commensurate with the radiation risks associated with the exposure situation.

RESPONSIBILITIES OF THE GOVERNMENT[5]

Requirement 2: Establishment of a legal and regulatory framework

The government shall establish and maintain a legal, regulatory and organizational framework for protection and safety and shall establish an effectively independent regulatory body with defined responsibilities and functions.

2.13. The government shall establish and maintain an appropriate and effective legal, regulatory and organizational framework for protection and safety in all exposure situations [8]. This framework shall encompass both the assignment and the discharge of governmental responsibilities and the regulatory control of facilities and

[4] Optimized means that optimization of protection and safety has been applied and the result of that process has been implemented.

[5] Member States have different legal structures, and therefore the term 'Government' in this document is to be understood in a wide sense and is accordingly interchangeable with the term 'State'.

activities that give rise to radiation risks, and shall allow for the fulfilment of international obligations.

2.14. The government shall ensure that adequate arrangements are in place for the protection of people and the environment, both now and in the future, against harmful effects of ionizing radiation without unduly limiting the operation of facilities or the conduct of activities that give rise to radiation risks. This shall include the protection of populations remote from facilities and activities and populations beyond national borders, and present and future generations, against possible consequences of current actions.

2.15. The government shall establish legislation that, inter alia:

(a) Provides the statutory basis for requirements for protection and safety in all exposure situations;
(b) Specifies that the prime responsibility for protection and safety rests with the person or organization responsible for facilities and activities that give rise to radiation risks;
(c) Specifies the scope of its applicability;
(d) Establishes, and provides for the maintenance of a regulatory body with clearly defined functions and responsibilities for regulating protection and safety;
(e) Provides for coordination between authorities with responsibilities relevant for protection and safety in all exposure situations.

2.16. The government shall ensure that the regulatory body is effectively independent, in protection and safety related decisions, of persons and organizations using or otherwise promoting the use of radiation and radioactive material, so that it is free from any undue pressure from interested parties and any conflict of interest.

2.17. The government shall ensure that the regulatory body has the legal authority, competence and resources necessary to fulfill its statutory obligations.

2.18. The government shall ensure a graded approach to the control of radiation exposure, so that the stringency of regulatory requirements applied to any exposure situation is commensurate with the associated radiation risks.

2.19. The government shall establish mechanisms to ensure that:

(a) The activities of the regulatory body are coordinated with those of other governmental authorities, in accordance with para. 2.15 (e), and with national or international organizations with related responsibilities;
(b) Interested parties are involved in decision making or decision aiding processes, as appropriate.

2.20. The government shall ensure that appropriate arrangements are in place for making national decisions related to protection and safety that fall outside the authority of the regulatory body.

2.21. The government shall ensure that the appropriate requirements are established for:

(a) education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety;
(b) the formal recognition[6] of qualified experts;
(c) the competence of organizations that have responsibilities related to protection and safety.

2.22. The government shall ensure that arrangements are in place for the provision of the required educational and training services for building and maintaining the competence of organizations and persons that have responsibilities related to protection and safety.

2.23. The government shall ensure that arrangements are in place for the provision of technical services related to protection and safety, such as personal dosimetry, environmental monitoring and calibration of monitoring and measuring equipment.

2.24. The government shall ensure that adequate arrangements are made for the safe decommissioning of facilities [9] and safe management of radioactive waste arising from facilities and activities [10, 11], and for the safe management of spent fuel.

[6] Formal recognition means the documented acknowledgment by the relevant authority that a person has the qualifications and expertise required for the responsibilities he or she will bear in the conduct of the authorized activity.

2.25. The government shall ensure that the transport of radioactive material is regulated in accordance with the IAEA Regulations for the Safe Transport of Radioactive Material [12] and any applicable international conventions, taking into consideration other internationally endorsed standards and recommendations derived from these IAEA Regulations.[7]

2.26. The government shall ensure that arrangements are in place for regaining control over radioactive sources that have been abandoned, lost, misplaced, stolen or otherwise transferred without proper authorization.

2.27. The government shall ensure that adequate infrastructure arrangements for interface between safety, security and accounting and control of sources are clearly established.

2.28. In establishing the legal and regulatory framework, the government shall

(a) fulfil its respective international obligations;
(b) allow for participation in relevant international arrangements, including international peer reviews;
(c) promote international cooperation to enhance safety globally.

RESPONSIBILITIES OF THE REGULATORY BODY

Requirement 3: Responsibilities of the regulatory body

The regulatory body shall establish or adopt regulations and guides for protection and safety and shall establish a system to ensure their implementation.

2.29. The regulatory body shall establish appropriate requirements for the implementation of radiation protection principles specified in para. 2.8 to 2.11 for each exposure situation and shall establish or adopt regulations and guides addressing protection and safety.

2.30. The regulatory body shall establish a system for protection and safety that includes [8]:

[7] Additional measures are taken to provide appropriate security in the transport of radioactive material. Security in transport is covered in the Nuclear Security Series.

(a) Notification and authorization;

(b) Review and assessment of facilities and activities;

(c) Inspection of facilities and activities;

(d) Enforcement of regulatory requirements;

(e) The regulatory functions relevant to emergency exposure situations and existing exposure situations, as necessary;

(f) Provision of information to, and consultation with, parties affected by its decisions and, as appropriate, the public and other interested parties.

2.31. The regulatory body shall employ a graded approach to the implementation of the system, applying requirements that are commensurate with the radiation risks associated with the exposure situation.

2.32. The regulatory body shall ensure the implementation of the requirements for education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety.

2.33. The regulatory body shall ensure that mechanisms are in place for the timely dissemination of information to relevant parties, such as suppliers and users of sources, of protection and safety information concerning lessons learned from regulatory and operating experience and from incidents and accidents and related findings. The mechanisms established shall, as appropriate, be used to provide relevant information to other organizations at the national or international level that may have a role in achieving protection and safety.

2.34. The regulatory body, in conjunction with other competent authorities, shall adopt specific acceptance and performance criteria, through regulation or by the application of published standards, for any manufactured or constructed source, device, equipment or facility which, in use, has protection and safety implications.

2.35. The regulatory body shall make arrangements to establish, maintain and make retrievable adequate records related to facilities and activities, inter alia, a register of radiation generators and sealed sources[8]; records of occupational doses; records relating to the safety of facilities and activities; records needed for

[8] The regulatory body specifies which sources are to be included in the registers and inventories with due consideration to the associated risk.

decommissioning or closure of facilities; records of events including non-routine releases of radioactive material to the environment; and inventories of radioactive waste and spent fuel.

2.36. The regulatory body shall establish mechanisms of communication and discussion with the relevant parties for all safety related issues, involving professional and constructive interactions.

2.37. The regulatory body, in consultation with the health authority, shall ensure that provisions are in place to ensure protection and safety in the handling of deceased persons or human remains which are known to contain sealed or unsealed radioactive sources either as a result of patient treatment or as a consequence of an emergency exposure situation.

2.38. The regulatory body shall establish, implement, assess and strive to continually improve an effective management system that is aligned with its goals and contributes to the achievement of those goals.

RESPONSIBILITIES FOR PROTECTION AND SAFETY

Requirement 4: Responsibility for protection and safety

The person or organization responsible for facilities and activities that give rise to radiation risks shall have the prime responsibility for protection and safety. Other parties shall have specified responsibilities for protection and safety.-.

2.39. The person or organization responsible for facilities and activities that give rise to radiation risks shall have the prime responsibility for protection and safety, which cannot be delegated.

2.40. The principal parties responsible for protection and safety are:

(a) Registrants or licensees, or the persons or organizations responsible for facilities and activities for which notification only is required;
(b) Employers in the case of occupational exposure;
(c) Radiological medical practitioners in the case of medical exposure;
(d) Designated persons or organizations to deal with emergency exposure situations or existing exposure situations;

2.41. Other parties shall also have specified responsibilities for protection and safety. These parties include:

(a) Suppliers of sources, equipment and software or providers of consumer products;
(b) Radiation protection officers;
(c) Referring medical practitioners;
(d) Medical physicists;
(e) Medical radiation technologists;
(f) Qualified experts or any other party to whom a principal party has delegated specific responsibilities;
(g) Workers other than those listed in (a)–(f);
(h) Ethics committees.

2.42. The relevant principal parties shall establish and implement a protection and safety programme appropriate for the exposure situation. The protection and safety programme shall:

(a) Adopt protection and safety objectives in conformity with the requirements of these Standards;
(b) Apply protection and safety measures commensurate with the radiation risks associated with the exposure situation and sufficient to ensure compliance with the requirements of these Standards.

2.43. The relevant principal parties shall ensure that, in the implementation of the protection and safety programme:

(a) The measures and resources needed to achieve the protection and safety objectives are determined and duly provided;
(b) The protection and safety programme is periodically reviewed to assess its effectiveness and continued fitness for the purpose;
(c) Any failures or shortcomings in protection and safety are identified and rectified, and steps taken to prevent their recurrence;
(d) Arrangements are made to consult with relevant interested parties;
(e) Appropriate records are kept.

2.44. The relevant principal parties and other parties with related responsibilities shall ensure that all personnel engaged in activities relevant to protection and safety are appropriately educated, trained and qualified so that they understand their responsibilities and perform their duties competently with appropriate judgement and according to defined procedures.

2.45. The relevant principal parties shall permit access by duly authorized representatives of the regulatory body to carry out inspections of their facilities and activities and of their protection and safety records, and shall cooperate in the conduct of the inspections.

2.46. The relevant principal parties shall ensure that qualified experts are identified and consulted, as necessary, on the proper observance of these Standards.

MANAGEMENT REQUIREMENTS

Requirement 5: Management for protection and safety

The principal parties shall ensure that protection and safety are effectively integrated into the overall management system of the organization for which they are responsible.

Protection and safety aspects of the management system

2.47. The principal parties shall demonstrate commitment to protection and safety at the highest levels within the organization for which they are responsible.

2.48. The principal parties shall ensure that the management system [13] is designed and implemented to enhance protection and safety by:

(a) Applying the requirements for protection and safety coherently with other requirements, including those for operational performance, and guidelines for security;
(b) Describing the planned and systematic actions necessary to provide adequate confidence that the requirements for protection and safety are satisfied;
(c) Ensuring that protection and safety are not compromised by other requirements or demands;
(d) Providing for the regular assessment of protection and safety performance and

the application of lessons learned from experience;

(e) Promoting a safety culture.

2.49. The principal parties shall ensure that protection and safety aspects of the management system are commensurate with the complexity and the radiation risks of the activity.

2.50. The principal parties shall be able to demonstrate the effective fulfilment of the management system requirements for protection and safety.

Safety culture

2.51. The principal parties shall foster and maintain a safety culture by:

(a) Promoting individual and collective commitment to protection and safety at all levels of the organization;

(b) Ensuring a common understanding of the key aspects of safety culture within the organization;

(c) Providing the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, taking into account the interaction between individuals, technology and the organization;

(d) Encouraging the participation of workers and their representatives and other relevant persons in the development and implementation of policies, rules and procedures dealing with protection and safety;

(e) Ensuring accountability of the organization and of individuals at all levels for protection and safety;

(f) Encouraging open communication with regard to protection and safety within the organization and with other relevant parties, as appropriate;

(g) Encouraging a questioning and learning attitude and discouraging complacency with regard to protection and safety;

(h) Providing the means by which the organization continually seeks to develop and improve its safety culture.

Human factors

2.52. The relevant principal parties, and other parties with related responsibilities, as appropriate, shall take into account human factors and support good performance and good practices to prevent human and organizational failures, by ensuring that, inter alia:

(a) Sound ergonomic principles are followed in designing equipment and developing operating procedures, so as to facilitate the safe operation or use of equipment, to minimize the possibility that operator errors will lead to accidents, and to reduce the possibility that indications of normal and abnormal conditions will be misinterpreted;

(b) Appropriate equipment, safety systems, and procedural requirements are provided and other necessary provisions are made:

    (i) To reduce, as far as practicable, the possibility that human error or inadvertent action could give rise to accidents or other events causing exposure of any person;

    (ii) To provide means for detecting human errors and for correcting or compensating for them;

    (iii) To facilitate corrective actions in the event of failure of safety systems or of other protective measures.

3. PLANNED EXPOSURE SITUATIONS

SCOPE

3.1. The requirements for planned exposure situations apply to the following practices:

(a) The production, supply and transport of radioactive material and of devices that contain radioactive material, including sealed sources, unsealed sources and consumer products into which radionuclides are incorporated for their radioactive properties or properties as chemical elements;
(b) The production and supply of devices that generate radiation, including linear accelerators, cyclotrons, and fixed and mobile radiography equipment;
(c) The generation of nuclear power and any other activities within the nuclear fuel cycle that involve or could involve exposure due to radiation or radioactive material;
(d) The use of radiation or radioactive material for medical, industrial, veterinary, legal, security or agricultural purposes and the use of associated equipment, software and devices where such use may affect exposure to radiation;
(e) The use of radiation or radioactive material for education, training or research, including any activities related to such use which involve or could involve exposure due to radiation or radioactive material;
(f) The mining and processing of raw materials that involve exposure due to radioactive material;
(g) Any other practice specified by the regulatory body.

3.2. The requirements for planned exposure situations apply to exposure due to sources within practices, as follows:

(a) Facilities that contain radioactive material and facilities that contain radiation generators, including nuclear installations, medical radiation facilities, veterinary radiation facilities, radioactive waste management facilities, installations processing radioactive material, irradiation facilities, and mineral extraction and mineral processing facilities that involve or could involve exposure to radiation or exposure due to radioactive material;

(b) Individual sources of radiation, including sources within facilities referred to in (a), as appropriate, in accordance with the requirements of the regulatory body.

3.3. The requirements for planned exposure situations apply to any occupational exposure, medical exposure or public exposure due to any practice or source within a practice specified in para. 3.1 and 3.2.

3.4. Exposure due to natural sources is in general considered an existing exposure situation and subject to the requirements in Section 5. However, the requirements for planned exposure situations in Section 3 apply to the following exposures due to natural sources:

(a) Exposure due to material[9] in any relevant practice specified in para. 3.1 where the activity concentration in the material of any radionuclide in the uranium and thorium decay chains is greater than 1 Bq/g or the activity concentration of ^{40}K is greater than 10 Bq/g;
(b) Public exposure delivered by discharges or in the management of radioactive waste arising from a practice involving material specified in (a);
(c) Exposure to radon, thoron and their progeny, in workplaces in which occupational exposure to other radionuclides in the ^{238}U and ^{232}Th decay chains is controlled as a planned exposure situation;
(d) Exposure to radon and radon progeny in an existing exposure situation where the annual average activity concentration of radon in air in the workplace remains above the reference level established in accordance with para. 5.27 after the implementation of remedial action in accordance with para. 5.28.

GENERIC REQUIREMENTS

3.5. No person or organization shall adopt, introduce, conduct, discontinue or cease a practice or shall, as applicable, mine, extract, process, design, manufacture, construct, assemble, install, acquire, import, export, distribute, loan, hire, receive, site, locate, commission, possess, use, operate, maintain, repair, transfer, decommission, disassemble, transport, store or dispose of a source within a practice except in accordance with the appropriate requirements of these Standards.

[9] Exposure due to radionuclides of natural origin in food, feed, drinking water, agricultural fertilizer and soil amendments, construction material and existing residues in the environment is treated as an existing exposure situation regardless of the activity concentration.

Requirement 6: Graded approach

The application of the requirements of these Standards in planned exposure situations shall be commensurate with the characteristics of the practice or source within a practice and with the magnitude and likelihood of the exposures.

3.6. The application of the requirements of these Standards shall conform to any requirements specified by the regulatory body, noting that not all the requirements are relevant for every practice or source, nor for all the actions specified in para. 3.5.

Requirement 7: Notification and authorization

Any person or organization intending to operate a facility or conduct an activity shall submit a notification and an application for authorization, as appropriate, to the regulatory body.

Notification

3.7. Any person or organization intending to carry out any of the actions specified in para. 3.5 shall submit a notification to the regulatory body of such an intention[10]. Notification alone is sufficient provided that the exposures associated with the practice or action are unlikely to exceed a small fraction, specified by the regulatory body, of the relevant limits, and that the likelihood and expected amount of potential exposure and any other potentially detrimental consequence are negligible. Notification for consumer products is required only with respect to manufacture, assembly, maintenance, import, distribution and, in some cases, disposal.

Authorization: registration or licensing

3.8. Any person or organization intending to carry out any of the actions specified in para. 3.5 shall, unless notification alone is sufficient, apply to the regulatory body for an authorization[10] which shall take the form of either a registration[11] or a licence.

[10] For material being transported in accordance with the IAEA Regulations for the Safe Transport of Radioactive Material [12], the requirements for notification and authorization are fulfilled by compliance with those regulations.

[11] Typical practices that are amenable to registration are those for which: (a) safety can largely be ensured by the design of the facilities and equipment; (b) the operating procedures are simple to follow; (c) the safety training requirements are minimal; and (d) there is a history of few problems with safety in operations. Registration is best suited for those practices for which operations do not vary

3.9. Any person or organization applying for an authorization shall:

(a) Submit to the regulatory body the relevant information necessary to support the application;

(b) Refrain from carrying out any of the actions described in para. 3.5 until the registration or licence, as appropriate, has been granted;

(c) Assess the nature, magnitude and likelihood of the exposures attributed to the source and take all necessary steps for protection and safety;

(d) If there is a possibility for an exposure to be greater than a level as specified by the regulatory body, have a safety assessment made and submitted to the regulatory body as part of the application;

(e) As required by the regulatory body, have an appropriate assessment made of the potential radiological environmental impacts, commensurate with the hazards posed by the facility or activity.

Requirement 8: Exemption and clearance

The government or the regulatory body shall determine which practices or sources within practices are to be exempted from some or all of the requirements of these Standards. The regulatory body shall approve which sources, including materials and objects, within notified or authorized practices may be cleared from regulatory control.

Exemption

3.10. The government or the regulatory body shall determine which practices or sources within practices are to be exempted from some or all of the requirements of these Standards, including the requirements for notification, registration or licensing, using as the basis for such determination the criteria for exemption specified in Schedule I or any exemption levels defined by the regulatory body on the basis of the criteria.

3.11. Exemption shall not be granted for practices deemed not to be justified.

Clearance

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significantly.

3.12. The regulatory body shall approve which sources, including materials and objects, within notified or authorized practices may be cleared from further regulatory control using as the basis for such approval the criteria for clearance specified in Schedule I or any clearance levels defined by the regulatory body on the basis of such criteria. This approval shall ensure that sources that have been cleared do not again become subject to requirements for notification, registration or licensing, unless so specified by the regulatory body.

Requirement 9: Responsibilities of registrants and licensees in planned exposure situations

Registrants and licensees shall be responsible for protection and safety in planned exposure situations.

3.13. Registrants and licensees shall bear the responsibility for setting up and implementing the necessary technical and organizational measures that are needed for ensuring protection and safety of the practices and sources for which they are authorized. Registrants and licensees may appoint other suitably qualified persons to carry out actions and tasks related to these responsibilities, but shall retain the prime responsibility themselves. Registrants and licensees shall document the names and responsibilities of persons appointed to ensure compliance with these Standards.

3.14. Registrants and licensees shall notify the regulatory body of their intentions to introduce modifications to any practice or source for which they are authorized, whenever the modifications could have significant implications for protection and safety, and shall not carry out any such modification unless specifically authorized by the regulatory body.

3.15. Registrants and licensees shall:

(a) Establish clear lines of responsibility and accountability for protection and safety of the sources for which they are authorized, and establish organizational arrangements for protection and safety as appropriate;
(b) Ensure that any delegation of responsibilities by a principal party is documented;
(c) For the sources for which they are authorized, and for which a specific safety

assessment is required in para. 3.9 (d), carry out that assessment, and keep it up to date in accordance with para. 3.35;

(d) For the sources for which they are authorized, and for which the regulatory body requires an assessment to be made of the potential radiological environmental impacts, carry out and keep up to date that assessment.

(e) Assess the likely consequences of potential exposures, their magnitude and probability of occurrence, and the number of persons who may be affected by them;

(f) Have in place operating procedures and arrangements to maintain safety that are subject to periodic review and updating under an adequate management system;

(g) Establish procedures for reporting and learning from accidents and incidents;

(h) Establish arrangements for the periodic review of the overall effectiveness of the protection and safety measures;

(i) Ensure that adequate maintenance, testing, inspection and servicing is carried out as needed so that sources remain capable of meeting their design requirements for protection and safety throughout their lifetime;

(j) Ensure safe control and management of all radioactive waste that is generated, and dispose of such waste in accordance with the applicable regulatory requirements.

Requirement 10: Justification of practices

The government or the regulatory body shall ensure that only justified practices are authorized.

3.16. The government or regulatory body, as appropriate, shall ensure that provisions[12] are in place for the justification of any type of practice[13] and the review of the justification, as necessary, and shall ensure that only justified practices are authorized.

[12] Such provisions may involve several government entities, such as ministries of health, justice, immigration and security, not necessarily having direct responsibility for the safe use of radiation.

[13] This includes practices for which notification alone is sufficient.

3.17. Except for justified practices involving medical exposures[14], the following practices that result in an increase, by deliberate addition of radioactive substances or by activation[15], in the activity of the associated commodities or products, are deemed to be not justified:

(a) Practices involving food, feed, beverages, cosmetics or any other commodity or product intended for ingestion, inhalation or percutaneous intake by, or application to, a human being;

(b) Practices involving the frivolous use of radiation or radioactive substances in commodities or products such as toys and personal jewellery or adornments.

3.18. Human imaging using radiation performed for occupational, legal or health insurance purposes, and undertaken without reference to clinical indication, shall normally be deemed to be not justified. If, in exceptional circumstances, the government or regulatory body decides that the justification of such imaging for specific practices is to be considered, the requirements of paras 3.61 to 3.64 shall apply.

3.19. Human imaging using radiation for theft detection purposes shall be deemed to be not justified.

3.20. Human imaging using radiation for the detection of concealed objects for anti-smuggling purposes shall normally be deemed to be not justified. If, in exceptional circumstances, the government or regulatory body decides that the justification of such imaging is to be considered, the requirements of paras 3.61 to 3.64 shall apply.

3.21. Human imaging using radiation for the detection of concealed objects which can be used for terrorism or pose a national security threat shall only be justified by the government. If the government decides that justification of such imaging is to be considered, the requirements in paras 3.61 to 3.64 shall apply.

Requirement 11: Optimization of protection and safety

[14] Particular requirements for justification of medical exposure are specified in paras 3.154 to 3.160.

[15] This requirement is not intended to prohibit those practices that may involve the short term activation of commodities or products, and where there is no residual activity in the finally supplied commodity or product.

The regulatory body shall establish requirements for optimization of protection and safety, and registrants and licensees shall ensure that protection and safety is optimized.

3.22. The regulatory body shall establish requirements for optimization of protection and safety, require documentation addressing optimization of protection and safety, and establish or approve constraints, as appropriate, for dose and risk, or the process for establishing constraints, that are used for optimization of protection and safety.

3.23. Registrants and licensees shall ensure that protection and safety is optimized.

3.24. For occupational and public exposure[16], registrants and licensees shall ensure that all relevant factors are taken into account in the process of optimization of protection and safety in a coherent way so as to contribute to achieving the following objectives:

(a) To determine optimized protection and safety measures for the prevailing circumstances, with account taken of the available protection and safety options as well as the nature, magnitude and likelihood of exposures;

(b) To establish criteria, on the basis of the results of the optimization, for the restriction of the magnitudes of exposures and of their probabilities by means of measures for preventing accidents and mitigating their consequences.

3.25. For occupational and public exposure, registrants and licensees shall ensure, as appropriate, that relevant constraints are used in the optimization of protection and safety associated with any particular source within a practice.

Requirement 12: Dose limitation

The government or the regulatory body shall establish dose limits for occupational exposure and public exposure and registrants and licensees shall apply these limits.

3.26. The government or the regulatory body shall establish and the regulatory body shall enforce dose limits specified in Schedule III for occupational and public exposures resulting from planned exposure situations.

[16] Requirements for the optimization of medical exposures are specified in paras 3.161 to 3.176.

3.27. The government or the regulatory body shall determine what additional restrictions, if any, must be complied with by registrants and licensees to ensure that the dose limits specified in Schedule III are not exceeded by possible combinations of exposures from different authorized practices.

3.28. Registrants and licensees shall ensure that the exposure of individuals from the practice for which they are authorized is restricted so that neither the effective dose nor the equivalent dose to relevant organs or tissues exceeds any relevant dose limit specified in Schedule III. Dose limits do not apply to medical exposures.

Requirement 13: Safety assessment

The regulatory body shall establish requirements for safety assessment, and the person or organization responsible for a facility or activity that gives rise to radiation risks shall conduct an appropriate safety assessment of this facility or activity.

3.29. The regulatory body shall establish requirements for persons or organizations to carry out an appropriate safety assessment [14]. Prior to the granting of an authorization, the person or organization shall be required to submit a safety assessment, which shall be reviewed and assessed by the regulatory body.

3.30. The person or organization, if required under para. 3.9 (d), or registrants and licensees, as appropriate, shall conduct a safety assessment, either generic or specific to the practice or source for which they are responsible[17].

3.31. Safety assessments shall be made at different stages, including siting, design, manufacture, construction, assembly, commissioning, operation, maintenance and decommissioning, as appropriate, in order to:

(a) Identify the ways in which exposures could be incurred, account being taken of the effect of external events as well as events directly involving the sources and their associated equipment;

[17] Generic safety assessments are usually sufficient for types of source with a high degree of uniformity in design. Specific safety assessments are usually required in other cases but the specific safety assessment need not reconsider those aspects covered by a generic safety assessment, if such an assessment has been conducted for the source.

(b) Determine the expected magnitudes and likelihood of exposures in normal operations; and, to the extent reasonable and practicable, make an assessment of potential exposures;

(c) Assess the quality and extent of the protection and safety provisions.

3.32. The safety assessment shall include, as appropriate, a systematic critical review of:

(a) The operational limits and conditions for the operation of a facility;

(b) The ways in which structures, systems and components, and software and procedures related to protection and safety might fail, singly or in combination, or might otherwise give rise to exposures, and the consequences of such events;

(c) The ways in which external factors could affect protection and safety;

(d) The ways in which operating procedures related to protection and safety might be erroneous, and the consequences of such errors;

(e) The protection and safety implications of any modifications;

(f) The protection and safety implications of security measures or of any of their modifications;

(g) Any uncertainties or assumptions and their implications for safety.

3.33. The registrant or licensee shall, as appropriate, take into account in the safety assessment:

(a) Factors which could precipitate a substantial release of any radioactive material and the measures available to prevent or control such a release, and the maximum activity of any radioactive material which, in the event of a major failure of the containment, might be released to the environment;

(b) Factors which could precipitate a smaller but continuing release of any radioactive material and the measures available to identify and to prevent or control such a release;

(c) Factors which could give rise to the unintended operation of any radiation beam or the loss of shielding, and the measures available to identify and to prevent and control such occurrences;

(d) The extent to which redundant and diverse safety features, being independent of each other so that failure of one does not result in failure of any other, are appropriate in order to restrict the probability and magnitude of potential exposures.

3.34. Registrants and licensees shall ensure that the safety assessment is documented and, if appropriate, independently reviewed within the relevant management system.

3.35. Registrants and licensees shall perform additional reviews of the safety assessment as necessary for ensuring that the technical specifications or conditions of use continue to be met whenever:

(a) Significant modifications to the facility or its operating or maintenance procedures are envisaged;
(b) Significant changes are discovered on the site that could affect the safety of the facility or activity on that site;
(c) Operating experience, or other information about accidents and incidents that could lead to potential exposures, indicates that the current assessment might be invalid;
(d) Any significant changes in activities are envisaged;
(e) Any relevant changes in guidelines or standards are envisaged or have been made.

3.36. If as a result of a safety assessment, or for any other reason, opportunities for improving protection and safety seem to be available and desirable, any consequential modifications shall be made cautiously and only after a favourable assessment of all the implications for protection and safety. The implementation of all improvements shall be prioritized so as to optimize protection and safety.

Requirement 14: Monitoring for verification of compliance

Registrants and licensees and employers shall conduct monitoring to verify compliance with the requirements for protection and safety.

3.37. The regulatory body shall establish requirements that monitoring and measurements are performed to verify compliance with the requirements for protection and safety. The regulatory body shall be responsible for the review of

monitoring programmes of registrants and licensees.

3.38. Registrants and licensees and employers shall ensure that:

(a) Monitoring and measurements are performed of the parameters necessary for verification of compliance with the requirements of these Standards;
(b) Suitable equipment is provided and verification procedures implemented;
(c) The equipment is properly maintained, tested and calibrated at appropriate intervals with reference to standards traceable to national or international standards;
(d) Records are maintained of the results of monitoring and verification of compliance, as required by the regulatory body, including records of the tests and calibrations carried out in accordance with these Standards.
(e) The results of the monitoring and verification of compliance are shared with the regulatory body when requested.

Requirement 15: Prevention and mitigation of accidents

Registrants and licensees shall apply good engineering practice and shall take all practicable measures to prevent accidents and to mitigate the consequences of those that do occur.

Good engineering practice

3.39. The registrant or licensee, in cooperation with other responsible parties, shall ensure, as applicable, that the siting, location, design, construction, assembly, commissioning, operation, maintenance and decommissioning of facilities or parts thereof are based on good engineering practice which shall, as appropriate:

(a) Take account of international and national codes and standards;
(b) Be supported by reliable managerial and organizational features, with the aim of ensuring protection and safety throughout the life of the facility;
(c) Include sufficient safety margins for the design and construction of the facility, and for operations involving the facility, such as to ensure reliable performance during normal operation, taking into account quality, redundancy and inspectability, with emphasis on preventing accidents, mitigating their consequences and restricting any future exposures;

(d) Take account of relevant developments in technical criteria, as well as the results of any relevant research on protection and safety and lessons from experience.

Defence in depth

3.40. Registrants and licensees shall ensure that a multilevel (defence in depth) system of sequential, independent provisions for protection and safety, commensurate with the magnitude and likelihood of the potential exposures involved, is applied to sources for which they are authorized, such that if one level of protection were to fail, the subsequent independent level of protection would be available, for the purposes of:

(a) Preventing accidents;
(b) Mitigating the consequences of any such accident that does occur;
(c) Restoring the sources to safe conditions after any such accident.

Accident prevention

3.41. Registrants and licensees shall ensure that systems and components, including software, of facilities and activities that are related to protection and safety are designed, constructed, commissioned, operated and maintained so as to prevent accidents as far as reasonably possible.

3.42. The registrant or licensee of any facility or activity shall make suitable arrangements:

(a) To prevent reasonably foreseeable accidents (including very low probability accidents) in connection with the facility or activity;
(b) To mitigate the consequences of any accident that does occur;
(c) To provide workers with the information, training, and equipment necessary to restrict potential exposures;
(d) To ensure that there are adequate procedures for the control of the facility and of any reasonably foreseeable accidents (including very low probability accidents);
(e) To ensure that safety significant systems and components, including software,

and other equipment can be inspected and tested regularly for any degradation that could lead to abnormal conditions or inadequate performance;

(f) To ensure that maintenance, inspection and testing appropriate to the preservation of the protection and safety provisions can be carried out without undue occupational exposure;

(g) To provide, wherever appropriate, automatic systems for safely shutting off or reducing radiation output from facilities in the event that operating conditions exceed the operating ranges;

(h) To ensure that abnormal operating conditions that could significantly affect protection or safety are detected by systems that respond quickly enough to allow for timely corrective action to be taken;

(i) To ensure that all relevant safety documentation is available in the appropriate languages.

Emergency preparedness and response

3.43. If the safety assessment indicates that there is a reasonable likelihood of an emergency affecting either workers or members of the public, the registrant or licensee shall prepare an emergency plan for protection of people and the environment. As part of this plan, the registrant or licensee shall include arrangements for the prompt identification of an emergency, and for determining the appropriate level of their response [15]. In relation to the arrangements for the registrant or licensee response at the scene, the plan shall include, in particular:

(a) Provision for individual and area monitoring, and arrangements for medical treatment;

(b) Arrangements for assessing and mitigating consequences of the emergency.

3.44. Registrants and licensees shall be responsible for the implementation of their emergency plans and shall be prepared to take any necessary action for effective response. To prevent the occurrence of situations that could lead to a loss of control over a source or the escalation of such situations, registrants and licensees shall, as appropriate:

(a) Develop, maintain and implement procedures to provide the means for

preventing loss of control and regaining control over the source as necessary;

(b) Make available equipment, instrumentation and diagnostic aids that may be needed;

(c) Train personnel and periodically retrain them in the procedures to be followed, and in the exercising of the procedures.

Requirement 16: Investigations and feedback of information on operating experience

Registrants and licensees shall conduct formal investigations of abnormal circumstances arising in the operation of facilities or the conduct of activities, and shall disseminate information that is significant to protection and safety.

3.45. Registrants and licensees shall ensure that information on both normal operations and abnormal circumstances significant to protection and safety, is disseminated or made available, as appropriate, to the regulatory body and other relevant parties, as specified by the regulatory body. This information would cover, for example, doses associated with given activities, maintenance data, descriptions of events and corrective actions.

3.46. Registrants and licensees shall conduct an investigation as specified by the regulatory body in the event that:

(a) A quantity or operating parameter related to protection and safety exceeds an investigation level or is outside the stipulated range of operating conditions; or

(b) Any equipment failure, accident, error, mishap or other unusual event or circumstance occurs which has the potential for causing a quantity to exceed any relevant limit or operating restriction.

3.47. The registrant or licensee shall conduct an investigation as soon as possible after the event and prepare a written report on its cause, or suspected causes, with a verification or determination of any doses received or committed and recommendations for preventing the recurrence of the event and the occurrence of similar events.

3.48. The registrant or licensee shall communicate to the regulatory body and to any other relevant parties as appropriate, a written report of any formal investigation

relating to events prescribed by the regulatory body, including exposures greater than a dose limit. The registrant or licensee also shall immediately report any event where a dose limit is exceeded.

Requirement 17: Radiation generators and radioactive sources

Registrants and licensees shall ensure the safety of radiation generators and radioactive sources.

3.49. Registrants and licensees shall ensure that the following responsibilities are discharged by manufacturers and other suppliers, as applicable:

(a) To provide a well designed, manufactured and constructed radiation generator or radioactive source and device in which the radiation generator or radioactive source is used, as applicable, that:
    (i) Provides for protection and safety in compliance with these Standards;
    (ii) Meets engineering, performance and functional specifications;
    (iii) Meets quality standards commensurate with the protection and safety significance of systems and components, including software;
    (iv) Provides clear displays, dials and instructions on operating consoles in a language understandable and acceptable to the user.
(b) To ensure that radiation generators and radioactive sources are tested to demonstrate compliance with the appropriate specifications;
(c) To make available information, in a language that is understandable and acceptable to the user, concerning the proper installation and use of the radiation generator or radioactive source and its associated risks, including performance specifications, operating and maintenance instructions, and protection and safety instructions;
(d) To ensure that shielding and other protective devices are optimized.

3.50. Where applicable, registrants and licensees shall make suitable arrangements with suppliers of radiation generators and radioactive sources, the regulatory body, and other relevant parties:

(a) To obtain information on conditions of use and operating experience that may be important for protection and safety;

(b) To provide feedback and information that may have implications for protection and safety affecting other users, or that may have implications for future improvements in protection and safety of radiation generators and radioactive sources.

3.51. When choosing a location to use or store a radiation generator or radioactive source, registrants and licensees shall take into account:

(a) Factors that could affect the safety and security of the radiation generator or radioactive source;
(b) Factors that could affect the occupational exposure and public exposure caused by the radiation generator or radioactive source;
(c) The feasibility in engineering design of taking into account the foregoing factors.

3.52. When selecting a site for a facility that will hold a large amount of radioactive material and has the potential for releases of significant amounts of such radioactive material, registrants and licensees shall take into account any features that might affect protection and safety, features that might affect the integrity or function of the facility, and the feasibility of carrying out off-site protective actions if they become necessary.

3.53. Registrants and licensees shall keep radiation generators and radioactive sources under control so as to prevent loss or damage and to prevent any unauthorized person from carrying out any of the activities specified in para. 3.5 by ensuring that:

(a) Control of a radiation generator or radioactive source is not relinquished without compliance with all relevant requirements specified in the registration or licence;
(b) The regulatory body is promptly notified of information regarding any uncontrolled, lost or missing radiation generator or radioactive source;
(c) A radiation generator or radioactive source is not transferred unless the receiver possesses the necessary authorization;
(d) A periodic inventory of radiation generators or radioactive sources is conducted at appropriate intervals to confirm that they are in their assigned locations and are under control.

3.54. Registrants and licensees shall maintain an inventory that includes records of:

(a) The location and description of each radiation generator or radioactive source for which they are responsible;
(b) The activity and form of each radioactive source for which they are responsible.

3.55. Registrants and licensees shall provide appropriate information from their radiation generator or radioactive source inventory records with the regulatory body when requested.

3.56. Registrants and licensees shall ensure that sealed sources are categorized in accordance with the categorization scheme set out in Schedule II, and in accordance with the requirements of the regulatory body.

3.57. The manufacturer of a radioactive source or a device containing a radioactive source shall ensure that, where practicable, the source itself and its container are marked with the symbol recommended by the International Organization for Standardization (ISO) [16][18].

3.58. Registrants and licensees shall, in cooperation with manufacturers, ensure that, where practicable, sealed sources are identifiable and traceable.

3.59. Registrants and licensees shall ensure that when radioactive sources are not in use they are stored in an appropriate manner such that protection and safety is maintained.

3.60. Registrants and licensees shall ensure that arrangements are made promptly for the safe management and disposition of radiation generators and radioactive sources, including financial provisions where appropriate, once it has been decided to take them out of use.

[18] For category 1, 2 and 3 sealed sources as defined in Schedule II, the manufacturer may consider placement near the source, preferably on the shield or near the point of potential access to the source, of the supplementary symbol specified in Ref. [17]. The supplementary symbol is not to be placed on the external surfaces of transport packages, freight containers or conveyances or on building access doors.

Requirement 18: Human imaging for purposes other than medical diagnosis, medical treatment or biomedical research

The government shall ensure that the use of ionizing radiation for human imaging for purposes other than medical diagnosis, medical treatment or biomedical research shall be subject to the system of protection and safety.

3.61. The government, if so decided in accordance with paras 3.18-3.21, shall ensure that the provisions as required in para. 3.16 for the justification of practices are applied to any type of imaging procedure that exposes humans to radiation not intended for medical diagnosis, medical treatment or biomedical research purposes. The justification process shall consider, inter alia,

(a) The benefits and detriments of implementing the type of imaging procedure;
(b) The benefits and detriments of not implementing the type of imaging procedure;
(c) Any legal or ethical issues associated with the introduction of the type of imaging procedure;
(d) The effectiveness and suitability of the proposed type of imaging procedure including the appropriateness of the radiation equipment for the proposed use;
(e) The availability of sufficient resources to safely conduct the imaging procedure throughout the intended period of the practice;

3.62. If it has been determined through the process specified in para. 3.61 that a particular practice of human imaging is justified, then, such a practice shall be subject to regulatory control.

3.63. The regulatory body, in cooperation with other relevant authorities, agencies and professional bodies as appropriate, shall establish the requirements for regulatory control of the practice, and for review of the justification.

3.64. For human imaging conducted by medical personnel using medical radiological equipment, which exposes humans to radiation for occupational, legal or health insurance[19] purposes without reference to clinical indications:

[19] Such purposes include assessment of fitness for employment (pre or periodic), assessment of physiological suitability for a career or sport, athlete assessment before a transfer or appointment, age

(a) The government shall ensure, as a result of consultation between other relevant authorities, professional bodies and the regulatory body, the establishment of dose constraints for such human imaging procedures.

(b) The registrant or licensee shall ensure that the appropriate optimization requirements for medical exposures specified in paras 3.161 to 3.176 (see footnote 16) are applied, with the exception that dose constraints as set in (a) are to be used instead of diagnostic reference levels.

3.65. Inspection procedures, using inspection imaging devices, which intentionally expose humans for the purpose of detection of concealed weapons, contraband or other objects on or within the body shall be considered as giving rise to public exposure, and registrants and licensees shall ensure that the requirements for public exposure in planned exposure situations are met and, in particular, that optimization of protection and safety is subject to any dose constraints set by the government or regulatory body.

3.66. Registrants and licensees shall ensure that all persons that are about to be exposed to radiation for inspection procedures, are informed about the possibility of choosing an alternative technique that does not use ionizing radiation, where available.

3.67. The registrant or licensee shall ensure that, whether imported into or manufactured in the country where it is used, any inspection imaging device used for the detection of concealed objects and for security purposes conforms to applicable standards of the International Electrotechnical Commission (IEC), the International Organization for Standardization (ISO) or to equivalent national standards.

determination for legal status, obtaining legal evidence, detection of drugs concealed within the body, immigration or emigration requirements, pre-insurance checks, and obtaining evidence for compensation.

OCCUPATIONAL EXPOSURE

SCOPE

3.68. The requirements for occupational exposure in planned exposure situations (paras 3.68 to 3.116) apply to occupational exposure due to a practice or source within a practice, as referred to in paras 3.1 to 3.3, and as required in section 4 on emergency exposure situations and section 5 on existing exposure situations. In the case of exposure to natural sources, such requirements apply, as appropriate, only to the occupational exposures specified in para. 3.4 (a), (c) and (d).

Requirement 19: Responsibilities of the regulatory body specific to occupational exposure

The regulatory body shall establish and enforce requirements to ensure that protection and safety is optimized, and that doses from occupational exposure comply with dose limits.

3.69. The regulatory body shall establish the responsibilities of employers, registrants and licensees regarding the application of the requirements for occupational exposure in planned exposure situations.

3.70. The regulatory body shall establish and enforce requirements to ensure that protection and safety is optimized for occupational exposure.

3.71. The regulatory body shall establish and enforce appropriate requirements to ensure that occupational exposure from all authorized practices is limited as specified in Schedule III.

3.72. Before authorization of a new or modified practice, the regulatory body shall require, as appropriate, and review, supporting documents from the responsible parties that address:

(a) design criteria and design features related to the exposure and potential exposure of workers in all anticipated operational states and conditions;
(b) design criteria and design features of the appropriate systems and programmes of worker monitoring for occupational exposure in all anticipated operational states and conditions.

Requirement 20: Requirements for monitoring and recording of exposure

The regulatory body shall establish and enforce requirements for the monitoring and recording of occupational exposure in planned exposure situations.

3.73. The regulatory body shall be responsible, as appropriate, for:

(a) Review of monitoring programmes of registrants and licensees, which shall be sufficient to ensure that the requirements of these Standards regarding occupational exposure in planned exposure situations are satisfied;
(b) Authorization or approval of individual monitoring and calibration service providers;
(c) Review of periodic reports on occupational exposure (including results of monitoring programmes and dose assessments), submitted by employers, registrants and licensees;
(d) Provisions for maintaining records and results of assessment of occupational exposure;
(e) Verification and enforcement of compliance of an authorized practice with requirements of the Standards on control of occupational exposure.

Requirement 21: Responsibilities of employers, registrants and licensees for the protection of workers

Employers, registrants and licensees shall be responsible for the protection of workers against occupational exposure. They shall ensure that protection and safety is optimized and the dose limits for occupational exposure are not exceeded.

3.74. Registrants and licensees and employers of workers who are engaged in activities involving exposure or could involve potential exposure in planned exposure situations shall be responsible for:

(a) The protection of workers from occupational exposure;
(b) Compliance with any other relevant requirements of these Standards.

3.75. Employers who are also registrants or licensees shall have the responsibilities of both employers and registrants or licensees.

3.76. Employers, registrants and licensees shall ensure, for all workers engaged in activities that involve or could involve occupational exposure, that:

(a) Occupational exposures are so controlled that the relevant dose limits for occupational exposure specified in Schedule III are not exceeded;
(b) Occupational protection and safety are optimized in accordance with the relevant requirements of these Standards;
(c) Decisions regarding measures for occupational protection and safety are recorded and made available to the relevant parties, through their representatives where appropriate, as specified by the regulatory body;
(d) Policies, procedures and organizational arrangements for protection and safety are established for implementing the relevant requirements of these Standards, with priority given to design and technical measures for controlling occupational exposures;
(e) Suitable and adequate facilities, equipment and services for protection and safety are provided, the nature and extent of which are commensurate with the expected magnitude and likelihood of the occupational exposure;
(f) Necessary health surveillance and health services for workers are provided;
(g) Appropriate protective devices and monitoring equipment are provided and arrangements made for their proper use, calibration, testing and maintenance;
(h) Suitable and adequate human resources and appropriate training in protection, and safety are provided, as well as periodic retraining and updating as required in order to ensure the necessary level of competence;
(i) Adequate records are maintained as required by these Standards;
(j) Arrangements are made to facilitate consultation and cooperation with workers with respect to protection and safety, through their representatives where appropriate, about all measures necessary to achieve the effective implementation of these Standards;
(k) Necessary conditions to promote a safety culture are provided.

3.77. Employers, registrants and licensees shall:

(a) Involve workers, through their representatives if appropriate, in optimization of protection and safety;

(b) Establish and use, as appropriate, constraints as part of optimization of protection and safety.

3.78. Employers, registrants and licensees shall ensure that workers exposed to radiation from sources within practices that are not required by or directly related to their work receive the same level of protection as if they were members of the public.

3.79. Employers, registrants and licensees shall take such administrative actions as are necessary to ensure that workers are informed that protection and safety are integral parts of a general occupational health and safety programme in which they have certain obligations and responsibilities for their own protection and the protection of others against radiation and for the safety of sources.

3.80. Employers, registrants and licensees shall record any report received from a worker that identifies circumstances which could affect compliance with these Standards, and shall take appropriate action.

3.81. Nothing in these Standards shall be construed as relieving employers from complying with applicable national and local laws and regulations governing workplace hazards.

Requirement 22: Compliance by workers

Workers shall fulfil their obligations and duties for protection and safety.

3.82. Employers, registrants and licensees shall facilitate compliance by workers with the requirements of the Standards.

3.83. Workers shall:

(a) Follow any applicable rules and procedures for protection and safety as specified by the employer, registrant or licensee;
(b) Use properly the monitoring devices and the protective equipment and clothing provided;
(c) Cooperate with the employer, registrant or licensee with respect to protection and safety and the operation of workers health surveillance and dose assessment programmes;

(d) Provide to the employer, registrant or licensee such information on their past and current work as is relevant to ensure effective and comprehensive protection and safety for themselves and others;

(e) Abstain from any wilful action that could put themselves or others in situations that contravene the requirements of these Standards;

(f) Accept such information, instruction and training concerning protection and safety as will enable them to conduct their work in accordance with the requirements of these Standards.

3.84. If a worker identifies circumstances that could adversely affect protection and safety, the worker shall, as soon as feasible, report such circumstances to the employer, registrant or licensee.

Requirement 23: Cooperation between employers and registrants and licensees

Employers and registrants and licensees shall cooperate to the extent necessary for compliance with the requirements of protection and safety by all responsible parties.

3.85. If workers are engaged in work that involves or could involve a source that is not under the control of their employer, the registrant or licensee responsible for the source and the employer shall cooperate to the extent necessary for compliance with these Standards by both parties.

3.86. The cooperation between the registrant or licensee and the employer shall include, where appropriate:

(a) The development and use of specific exposure restrictions and other means in order to ensure that the protective measures and safety provisions for such workers are at least as good as those provided for employees of the registrant or licensee;

(b) Specific assessments of the doses received by such workers;

(c) A clear allocation and documentation of the respective responsibilities of the employer and the registrant or licensee for occupational protection and safety.

3.87. As part of the cooperation between parties, the registrant or licensee responsible for the source or the exposure shall, as appropriate:

(a) Obtain from the employers, including self-employed individuals, the previous occupational exposure history of such workers and any other necessary information;
(b) Provide appropriate information to the employer, including any available information relevant for compliance with these Standards that the employer may request;
(c) Provide both the worker and the employer with the relevant exposure records.

Requirement 24: Arrangements under the radiation protection programme

Employers, registrants and licensees shall establish and maintain organizational, procedural and technical arrangements in the radiation protection programme for occupational exposure.

Classification of areas - controlled areas

3.88. Registrants and licensees shall designate as a controlled area any area[20] in which specific protective measures or safety provisions are or could be required for:

(a) Controlling exposures or preventing the spread of contamination during normal working conditions;
(b) Preventing or limiting the extent of potential exposures.

3.89. In determining the boundaries of any controlled area, registrants and licensees shall take account of the magnitudes of the expected exposures, the likelihood and magnitude of potential exposures and the nature and extent of the required protection and safety procedures.

3.90. Registrants and licensees shall:

(a) Delineate controlled areas by physical means or, where this is not reasonably practicable, by some other suitable means;
(b) Where a source is only intermittently brought into operation or energized, or is moved from place to place, delineate an appropriate controlled area by means

[20]The transport of radioactive material is regulated in accordance with the IAEA Regulations for the Safe Transport of Radioactive Material [12].

that are appropriate under the prevailing circumstances and specify exposure times;

(c) Display the symbol recommended by the International Organization for Standardization (ISO) [16] and appropriate instructions at access points and other appropriate locations within controlled areas;

(d) Establish occupational protection and safety measures including, as appropriate, physical measures to control the spread of contamination and local rules and procedures for controlled areas;

(e) Restrict access to controlled areas by means of administrative procedures, such as the use of work permits, and by physical barriers, which could include locks or interlocks, the degree of restriction being commensurate with the magnitude and likelihood of the expected exposures;

(f) Provide, as appropriate, at entrances to controlled areas:
   (i) Protective clothing and equipment;
   (ii) Individual and workplace monitoring equipment;
   (iii) Suitable storage for personal clothing;

(g) Provide, as appropriate, at exits from controlled areas:
   (i) Equipment for monitoring for contamination of skin and clothing;
   (ii) Equipment for monitoring for contamination of any object or substance being removed from the area;
   (iii) Washing or showering facilities, and other appropriate personal decontamination facilities;
   (iv) Suitable storage for contaminated protective clothing and equipment;

(h) Periodically review conditions to determine the possible need to revise the protective measures or safety provisions or the boundaries of controlled areas;

(i) Provide appropriate information and training for persons working in controlled areas.

Classification of areas - supervised areas

3.91. Registrants and licensees shall designate as a supervised area any area not already designated as a controlled area but where occupational exposure conditions need to be kept under review even though specific protective measures and safety provisions are not normally needed.

3.92. Registrants and licensees shall, taking into account the nature, likelihood and extent of radiation hazards in the supervised areas:

(a) Delineate the supervised areas by appropriate means;
(b) Display approved signs, if appropriate, at access points to supervised areas;
(c) Periodically review the conditions to determine any need for protective measures and safety provisions or changes to the boundaries of supervised areas.

Local rules and personal protective equipment

3.93. Employers, registrants and licensees shall minimize the need to rely on administrative controls and personal protective equipment for achieving protection and safety by maximizing the provision of well engineered controls and satisfactory working conditions, in accordance with the following hierarchy of prevention principles:

1. Engineered controls,
2. Administrative controls,
3. Personal protective equipment.

3.94. Employers, registrants and licensees shall, if appropriate in consultation with workers or through their representatives:

(a) Establish in writing such local rules and procedures as are necessary to ensure adequate levels of protection and safety for workers and other persons;
(b) Include in the local rules and procedures the values of any relevant investigation level or authorized level, and the procedure to be followed in the event that any such value is exceeded;
(c) Make the local rules and procedures and the protective measures and safety provisions known to those workers to whom they apply and to other persons who may be affected by them;
(d) Ensure that any work involving occupational exposure is adequately supervised and take all reasonable steps to ensure that the rules, procedures, protective measures and safety provisions are observed;

(e) Designate, as appropriate, a radiation protection officer according to criteria established by the regulatory body.

3.95. Employers, registrants and licensees shall ensure that:

(a) Workers are provided with suitable and adequate personal protective equipment which meets relevant standards or specifications, including as appropriate:
    (i) Protective clothing;
    (ii) Respiratory protective equipment for which the protection characteristics are made known to the users;
    (iii) Protective aprons and gloves and organ shields;
(b) When appropriate, workers receive adequate instruction in the proper use of respiratory protective equipment, including testing for good fit;
(c) Tasks requiring the use of certain personal protective equipment are assigned only to workers who on the basis of medical advice are capable of safely sustaining the extra effort necessary;
(d) All personal protective equipment, including equipment for use in an emergency, is maintained in proper condition and, if appropriate, is tested at regular intervals;
(e) If the use of personal protective equipment is considered for any given task, account is taken of any additional exposure that could result owing to the additional time or inconvenience, and of any additional non-radiological risks that might be associated with performing the task while using protective equipment.

Monitoring of the workplace

3.96. Registrants and licensees, in cooperation with employers if appropriate, shall establish, maintain and keep under review a programme for the monitoring of the workplace under the supervision of a radiation protection officer or qualified expert as appropriate.

3.97. The nature and frequency of monitoring of workplaces shall:

(a) Be sufficient to enable:
    (i) Evaluation of the radiological conditions in all workplaces;

(ii) Exposure assessment in controlled areas and supervised areas;

(iii) Review of the classification of controlled and supervised areas;

(b) Be based on the dose rate, activity concentration in air and on the surface contamination, including their expected fluctuations and the likelihood and magnitude of potential exposures.

3.98. Registrants and licensees, in cooperation with employers if appropriate, shall keep records, as appropriate, of the findings of the workplace monitoring programme which shall be made available to workers, where appropriate through their representatives.

Requirement 25: Assessment of the occupational exposure and health surveillance of workers

Employers, registrants and licensees shall be responsible for making arrangements for assessment and recording of the occupational exposure of workers and for their health surveillance.

Exposure assessment

3.99. Employers, as well as self-employed individuals, and registrants and licensees shall be responsible for making arrangements for the assessment of the occupational exposure of workers, on the basis of individual monitoring where appropriate, and shall ensure that adequate arrangements are made with authorized or approved dosimetry service providers that operate under an adequate quality management system.

3.100. For any worker who normally works in a controlled area, or who occasionally works in a controlled area and may receive significant occupational exposure, individual monitoring shall be undertaken where appropriate, adequate and feasible. In cases where individual monitoring is inappropriate, inadequate or not feasible, the occupational exposure of the worker shall be assessed on the basis of the results of monitoring of the workplace and on information on the locations and durations of exposure of the worker[21].

[21] The distinction between workers in paras 3.100 and 3.101 for the purposes of monitoring has similarities to the distinction between Category A and Category B workers in European Union legislation [18].

3.101. For any worker who regularly works in a supervised area or who enters a controlled area only occasionally, the occupational exposure of the worker shall be assessed on the basis of the results of monitoring of the workplace or individual monitoring, as appropriate.

3.102. Employers shall ensure that workers who may be exposed to contamination, including workers who use respiratory protective equipment, are identified and shall arrange for appropriate monitoring to the extent necessary to demonstrate the effectiveness of the protection provided and to assess the intake of radionuclides and the committed effective doses, as appropriate.

Exposure records

3.103. Employers, registrants and licensees shall maintain exposure records[22] for each worker for whom assessment of occupational exposure is required in terms of paras 3.99 to 3.102.

3.104. Exposure records for each worker shall be preserved during the worker's working life and afterwards at least until the former worker attains or would have attained the age of 75 years, and for not less than 30 years after the termination of the work involving occupational exposure.

3.105. The exposure records shall include:

(a) Information on the general nature of the work involving occupational exposure;
(b) Information on doses, exposures and intakes at or above the relevant recording levels and the data upon which the dose assessments have been based;
(c) When a worker is or has been occupationally exposed while in the employ of more than one employer, information on the dates of employment with each employer and the doses, exposures and intakes in each such employment;
(d) Records of any doses, exposures and intakes due to actions taken in an emergency or due to accidents, which shall be distinguished from doses, exposures or intakes during normal work and which shall include references to reports of any relevant investigations.

[22] 'Exposure records' are often referred to as 'dose records'.

3.106. Employers, registrants and licensees shall:

(a) Provide workers with access to information on their own exposure records;
(b) Provide access to the exposure records for the supervisor of the workers' health surveillance programme, by the regulatory body and by the relevant employer;
(c) Facilitate the provision of copies of workers' exposure records to new employers when workers change employment;
(d) Make arrangements for the retention of exposure records of former workers by the employer, registrant or licensee, as appropriate;
(e) In complying with (a)–(d), give due care and attention to the maintenance of appropriate confidentiality of records.

3.107. If employers, registrants or licensees cease activities that involve occupational exposure of workers, they shall make arrangements for the retention of workers' exposure records by the regulatory body or State registry, or by a relevant employer, registrant or licensee, as appropriate.

Health surveillance

3.108. Workers' health surveillance programmes provided under para. 3.76(f) shall be:

(a) Based on the general principles of occupational health [19];
(b) Designed to assess the initial and continuing fitness of workers for their intended tasks.

3.109. If one or more workers are to be engaged in work that involves or could involve exposure from a source that is not under the control of their employer, the registrant or licensee responsible for the source shall, as a precondition for such engagement, make any special arrangements for workers' health surveillance with the employer which are needed to comply with the rules established by the regulatory body.

Requirement 26: Information, instruction and training

Employers, registrants and licensees shall provide workers with adequate information, instruction and training on protection and safety.

3.110. Employers, in cooperation with registrants and licensees, shall:

(a) Provide to all workers adequate information on the health risks due to their occupational exposure or due to possible accidents, adequate instruction and training and periodic retraining on protection and safety and adequate information on the significance for protection and safety of their actions;
(b) Provide appropriate information, adequate instruction and training and periodic retraining on protection and safety to those workers who could be affected by or involved in the response to an emergency;
(c) Keep records of the training provided to individual workers.

Requirement 27: Conditions of service

Employers, registrants and licensees shall not offer benefits as substitutes for protection and safety measures.

3.111. The conditions of service of workers shall be independent of the existence or the possibility of occupational exposure. Special compensatory arrangements or preferential treatment with respect to salary or special insurance coverage, working hours, length of vacation, additional holidays or retirement benefits shall neither be granted nor be used as substitutes for the provision of proper protection and safety measures to ensure compliance with the requirements of these Standards.

3.112. Employers shall make every reasonable effort to provide workers with suitable alternative employment in circumstances where it has been determined, either by the regulatory body or in the framework of the workers' health surveillance programme required by these Standards, that the worker, for health reasons, may no longer continue in employment involving occupational exposure.

Requirement 28: Special arrangements

Employers, registrants and licensees shall make special arrangements for female workers, as necessary, for the protection of embryos and foetuses, and infants being breast-fed, and for the protection of persons undergoing training under 18 years of age, from exposure to radiation.

3.113. Employers, in cooperation with registrants and licensees, shall provide to female workers who are liable to enter controlled or supervised areas or who may undertake emergency duties, appropriate information on:

(a) The risk to the embryo or foetus due to exposure of a pregnant woman;
(b) The importance for a female worker of notifying her employer as soon as she suspects that she is pregnant[23] or if she is breast feeding;
(c) The risk to an infant ingesting radioactive substances by breast feeding.

3.114. The notification of pregnancy or breast feeding shall not be considered a reason to exclude a female worker from work; the employer of a female worker who has been notified of pregnancy or breast feeding shall adapt the working conditions in respect of occupational exposure so as to ensure that the embryo, foetus or infant is afforded the same broad level of protection as that required for members of the public.

3.115. Employers, registrants and licensees shall ensure that no person under the age of 16 years is subjected to occupational exposure.

3.116. Employers, registrants and licensees shall ensure that no person under the age of 18 years is allowed to work in a controlled area unless under supervision and then only for the purpose of training for employment involving exposure to radiation or for students who are required to use sources in the course of their studies.

[23] Notification of pregnancy or breast feeding cannot be a requirement on a female worker in terms of these Standards. However, it is important that all female employees understand the importance of making such notification in order that their working conditions may be modified accordingly.

PUBLIC EXPOSURE

SCOPE

3.117. The requirements for public exposure in planned exposure situations (paras 3.117 to 3.143) apply to public exposure due to a practice or source within a practice, as referred to in paras 3.1 to 3.3. In the case of exposure to natural sources, such requirements apply only to the public exposure specified in para. 3.4 (a) and (b).

Requirement 29: Responsibilities of the government and the regulatory body specific to public exposure

The government or the regulatory body shall establish the responsibilities of relevant parties specific to public exposure and shall establish and enforce requirements for optimization and dose limitation. .

3.118. The government or the regulatory body shall establish the responsibilities of registrants, licensees, suppliers, and providers of consumer products[24], regarding the implementation and application of requirements for public exposure in planned exposure situations.

3.119. The government or the regulatory body shall establish and enforce requirements that protection and safety be optimized for situations involving public exposure.

3.120. The government or the regulatory body shall establish or approve constraints for dose and risk to be used for optimization of the protection of the public. When establishing or approving constraints for a source within a practice, the government or regulatory body shall take into account, as appropriate:

(a) The characteristics of the source and the practice relevant to public exposure;
(b) Good practice in the operation of similar sources;
(c) Dose contributions from other authorized or anticipated[25] practices so that the prospectively assessed total exposure of members of the public at the design

[24] Providers of consumer products include designers, manufacturers, producers, constructors, assemblers, installers, distributors, sellers or importers of consumer products.

[25] Realistically assessed possible future sources and practices.

and planning stage is not expected to exceed the dose limit at any time after the start of operation of the source under consideration;

(d) The views of interested parties.

3.121. The government or the regulatory body shall establish and enforce appropriate requirements to ensure that public exposure from all authorized sources in planned exposure situations is limited as specified in Schedule III.

3.122. Before authorization of a new or modified practice the regulatory body shall require, and review, the safety assessments (see paras 3.29-3.36) and other design documents from the responsible parties that address: the optimization of protection, the design criteria and the design features related to the exposure and potential exposure of the public.

3.123. The regulatory body shall establish or approve operational limits and conditions related to public exposure, including authorized limits on discharges. These operational limits and conditions shall:

(a) Be used by registrants and licensees as the criteria for demonstration of compliance after the start of operation of a source;
(b) Correspond to doses below the dose limits and take into account the results of the optimization of protection and safety;
(c) Reflect good practice in the operation of similar facilities or activities;
(d) Allow for operational flexibility;
(e) Take into account the results of the assessment of the potential radiological environmental impacts undertaken in accordance with national requirements.

3.124. When a source within a practice could cause public exposure in a country other than the country where the source is located, the government or the regulatory body shall:

(a) ensure that the assessment of the radiological impact includes those impacts outside the country;
(b) to the extent possible, establish commensurate requirements for control of discharges; and

(c) arrange with the affected country the means for exchange of information and consultations, as appropriate.

Requirement 30: Responsibilities of relevant parties specific to public exposure

The relevant parties shall apply the system of protection and safety to protect the public from exposure to radiation

General considerations

3.125. Registrants and licensees in cooperation with suppliers, and providers of consumer products, shall apply and demonstrate compliance with the requirements of these Standards as specified by the regulatory body regarding any public exposure delivered by a source for which they are responsible.

3.126. Registrants and licensees in cooperation with suppliers, in applying the principle of optimization of protection and safety during design, planning, operation, and decommissioning of a source (or for the closure and post-closure period of waste disposal facilities), shall take into account, as appropriate:

(a) Potential changes in any condition that could affect public exposure, such as changes in the characteristics and operation of the source, changes in environmental dispersion conditions, changes in exposure pathways, or changes in parameters used for the determination of the representative person;
(b) Current good practice in the operation of similar sources or practices;
(c) Build-up and accumulation of discharged radioactive material in the environment during the operational lifetime of a source;
(d) Uncertainties in the assessment of exposures, especially in contributions to the exposures if the source and the representative person are separated in distance or time.

3.127. Registrants and licensees shall, with respect to the sources under their responsibility, establish, implement and maintain:

(a) Protection and safety policies, procedures and organizational arrangements in relation to public exposure in fulfilment of the requirements of these Standards;

(b) Measures for ensuring:

(i) The optimization of protection;

(ii) The limitation of the exposure of members of the public, which results from such sources, in accordance with the authorization;

(c) Measures for ensuring the safety of such sources;

(d) Suitable and adequate resources (such as facilities, equipment and services for the protection of the public) commensurate with the magnitude and likelihood of the exposure;

(e) Appropriate training to the personnel having functions relevant to the protection of the public, as well as periodic retraining and updating, in order to ensure the necessary level of competence;

(f) Appropriate monitoring equipment, surveillance programmes and methods to assess public exposure;

(g) Adequate records of surveillance and monitoring;

(h) Emergency plans, procedures and arrangements, commensurate with the nature and magnitude of the risk involved.

Visitors

3.128. Registrants and licensees, in co-operation with employers when appropriate, shall:

(a) Apply the relevant requirements of these Standards regarding public exposure to visitors to a controlled area or supervised area;

(b) Ensure that visitors are accompanied in any controlled area by a person knowledgeable about the protection and safety measures for that area;

(c) Provide adequate information and instruction to visitors before they enter a controlled area or a supervised area so as to provide for appropriate protection of the visitors and of other individuals who could be affected by their actions;

(d) Ensure that adequate control over entry of visitors to a controlled area or supervised area is maintained, including the appropriate use of signs for such areas.

External exposure and contamination in areas accessible by the public

3.129. Registrants and licensees, shall ensure that, if a source of external exposure can cause exposure to the public:

(a) The floor plans and equipment arrangements for all new installations, utilizing such sources of external exposure, as well as all significant modifications to existing installations, are subject to review and approval by the regulatory body prior to commissioning, as appropriate;

(b) Shielding and other protective measures including access control are provided as appropriate for restricting public exposure, in particular at open sites such as for some applications of industrial radiography.

3.130. Registrants and licensees shall ensure, as appropriate, that:

(a) Specific confinement provisions are established for the design and operation of a source that could cause spread of contamination in areas accessible to the public;

(b) Protective measures are implemented for restricting public exposure due to contamination in areas accessible to the public within a facility.

Requirement 31: Radioactive waste and discharges

The relevant parties shall ensure that radioactive waste and discharges of radioactive material to the environment are managed in accordance with the authorization.

Radioactive waste

3.131. Registrants and licensees, in cooperation with suppliers, as appropriate, shall:

(a) Ensure that, in terms of both activity and volume, any radioactive waste generated is kept to the minimum practicable, when optimizing protection and safety, and that the waste is managed in accordance with the requirements of these Standards and any other applicable IAEA standards, and in accordance with their authorization;

(b) Ensure, if appropriate, separate processing of different types of radioactive waste where warranted by differences in factors such as radionuclide content, half-life, concentration, volume and physical and chemical properties, taking into account the available options for waste storage and disposal, without precluding the mixing of waste for purposes of protection and safety;

(c) Ensure that radioactive waste predisposal and disposal activities are in accordance with applicable standards, and in accordance with their authorization;
(d) Maintain an inventory of all radioactive waste (generated, stored, transferred or disposed);
(e) Develop and implement a radioactive waste management plan and include appropriate evidence that protection and safety is optimized.

Discharges

3.132. Registrants and licensees, in cooperation with suppliers, in applying for an authorization for discharges, shall, as appropriate:

(a) Determine the characteristics and activity of the material to be discharged, and the potential points and methods of discharge;
(b) Determine by an appropriate pre-operational study all significant exposure pathways by which discharged radionuclides can deliver public exposure;
(c) Assess the doses to the representative person due to the planned discharges;
(d) Consider the potential radiological environmental impacts in an integrated manner with other features of the system of protection and safety, as required by the regulatory body;
(e) Submit the information in (a) to (d) to the regulatory body as an input to the establishment by the regulatory body of authorized limits on discharge and conditions for their implementation.

3.133. Registrants and licensees shall ensure that operational limits and conditions related to public exposure are met in accordance with para. 3.123.

3.134. Registrants and licensees shall, as appropriate and in agreement with the regulatory body, review and adjust their discharge control measures taking into account:

(a) Operating experience,
(b) Any changes in exposure pathways and the characteristics of the representative person that could affect the assessment of doses due to the discharges.

Requirement 32: Monitoring and reporting

The regulatory body and the relevant parties shall ensure that environmental monitoring programmes are in place, and that the results are recorded and made available.

3.135. The regulatory body shall be responsible, as appropriate, for:

(a) Review and approval of monitoring programmes of registrants and licensees, which shall be sufficient:
    (i) To ensure that the requirements of these Standards regarding public exposure in planned exposure situations are satisfied, and
    (ii) To assess doses to the public;
(b) Review of periodic reports on public exposure (including results of monitoring programmes and dose assessments), submitted by registrants and licensees;
(c) Making provision for an independent monitoring programme;
(d) Assessment of the total exposure of the public from authorized sources and practices in the country based on the monitoring data provided by registrants and licensees and with the use of the independent monitoring data and assessments;
(e) Making provision for maintaining records of radioactive discharges, results of monitoring programmes, and results of assessment of public exposure;
(f) Verification of compliance of an authorized practice with requirements of the Standards on control of public exposure.

3.136. The regulatory body shall publish or make available on request, as appropriate, results of source and environmental monitoring programmes and assessments of public exposure.

3.137. Registrants and licensees shall, as appropriate:

(a) Establish and implement a monitoring programme to ensure that public exposure in relation to sources under their responsibility is adequately assessed, and sufficient to demonstrate compliance with the authorization. This programme shall include the following, as appropriate:
    - external exposure from the sources;

- discharges;
- radioactivity in the environment;
- other parameters important for the assessment of public exposure.

(b) Keep appropriate records of the results of the monitoring programmes and estimated exposures;

(c) Report, or make available, the results of the monitoring programme to the regulatory body at approved intervals, including, as applicable, the levels and composition of discharges, dose rates at the site boundary and in premises open to members of the public, results of environmental monitoring, results of retrospective assessments of doses to the representative person;

(d) Report promptly to the regulatory body any levels exceeding the operational limits and conditions related to public exposure including authorized limits on discharges in accordance with reporting criteria established by the regulatory body;

(e) Report promptly to the regulatory body any significant increase in dose rate or content of radionuclides in the environment that could be attributed to their authorized practice in accordance with reporting criteria established by the regulatory body;

(f) Establish and maintain a capability to carry out emergency monitoring, in case of unexpected increases in radiation levels or content of radionuclides in the environment due to accidental or other unusual events attributed to their authorized source or facility;

(g) Verify the adequacy of the assumptions made for the assessment of public exposure and radiological environmental impact;

(h) Publish or make available on request, as appropriate, results of source and environmental monitoring programmes and assessments of public exposure.

Requirement 33: Consumer products

Providers of consumer products shall not make them available to the public unless their use by members of the public has been justified, and their use has been either exempted or their provision to the public has been authorized.

3.138. Providers of consumer products shall ensure that such products are not made available to the public unless their use by members of the public has been justified by

the regulatory body, and their use has been exempted on the basis of the criteria specified in Schedule I.

3.139. Upon receipt of a request for authorization of providing to the public a consumer product capable of causing public exposure, the regulatory body shall:

(a) Require the provider of the consumer product to provide documents that demonstrate compliance with the requirements of paras 3.140 to 3.143;
(b) Verify the assessments and parameters presented in the request for authorization;
(c) Determine if the end use of the product can be exempted;
(d) Authorize the supply of the consumer product, where appropriate, subject to specific conditions of authorization.

3.140. Providers of consumer products shall comply with the conditions of the authorization to provide such products, ensure that such products comply with the requirements of these Standards, and anticipate appropriate arrangements for the service, maintenance, recycling or disposal of such products. The design and construction of such products, in relation to features that could affect exposure during normal handling, transport and use, as well as in the event of mishandling, misuse, accident or disposal, shall be subject to optimization of protection and safety. In this regard, designers, manufacturers and providers of consumer products shall take into account:

(a) The various radionuclides that could be used and their radiation types, energies, activities and half-lives;
(b) The chemical and physical forms of the radionuclides that could be used and their influence on protection and safety in normal and abnormal circumstances;
(c) The containment and shielding of the radioactive material in the consumer product and the access to this material in normal and abnormal circumstances;
(d) The need for servicing or repair and the ways in which this could be done;
(e) Relevant experience with similar consumer products.

3.141. Providers of consumer products shall ensure that:

(a) Where practicable, a legible label is firmly affixed to a visible surface of each consumer product:

(i) Stating that the product contains a radioactive source, and identifying the radionuclides and their activity;

(ii) Stating that the sale of the product to the public has been authorized by the relevant regulatory body;

(iii) Providing information about required or recommended options for recycling or disposal;

(b) The information specified in (a) is also displayed legibly on the retail packaging in which the consumer product is provided.

3.142. Providers of consumer products shall provide clear and appropriate information and instructions with each consumer product on:

(a) The correct installation, use and maintenance of the product;

(b) Servicing and repair;

(c) The radionuclides involved and their activities at a specified date;

(d) Radiation dose rates during normal operation and during servicing and repair operations;

(e) Required or recommended options for recycling or disposal.

3.143. Providers of consumer products shall provide appropriate safety information, including transport and storage instructions, to the product retailers.

MEDICAL EXPOSURE

SCOPE

3.144. The requirements for medical exposure in planned exposure situations (paras 3.144 to 3.184) apply to all medical exposures[26], including intended, unintended and accidental exposures.

3.145. Dose limits are not to be applied to medical exposures.

Requirement 34: Responsibilities of government specific to medical exposure

The government shall ensure that the relevant parties are authorized to assume their roles and responsibilities and that diagnostic reference levels, dose constraints, and criteria and guidelines for the release of patients are established.

3.146. The government, in accordance with the responsibilities identified in paras 2.13 to 2.28, shall, with respect to medical exposures, ensure that as a result of consultation between the health authority, relevant professional bodies and the regulatory body, the relevant parties identified in paras 2.39 and 2.40 are authorized to assume their roles and responsibilities and are notified of their duties regarding protection and safety of the individuals undergoing medical exposures.

3.147. The government shall ensure, as part of the responsibilities given in para. 2.15, that as a result of consultation between the health authority, relevant professional bodies and the regulatory body, a set of diagnostic reference levels for medical exposures incurred in medical imaging, including image-guided interventional procedures, is established, taking into account the need for adequate image quality, to enable the requirements of para. 3.168 to be fulfilled. Such diagnostic reference levels shall be based, as far as possible, on wide-scale surveys or on published values appropriate to the local circumstances.

3.148. The government shall ensure, as a result of consultation between the health authority, relevant professional bodies and the regulatory body, the establishment of:

(a) Dose constraints, to enable the requirements of paras 3.172 and 3.173 to be fulfilled for, respectively:

[26] Requirements for the imaging of humans for purposes other than medical diagnosis or treatment (and hence not within the scope of medical exposure) are given in paras. 3.61 to 3.67.

(i) Exposures of carers and comforters of patients undergoing radiological procedures[27;]

(ii) Exposures from diagnostic investigations of volunteers participating in biomedical research projects;

(b) Criteria and guidelines for the release of patients who have undergone therapeutic procedures using unsealed sources or those who still retain implanted sealed sources.

Requirement 35: Responsibilities of the regulatory body specific to medical exposure

The regulatory body shall require that health professionals with responsibilities for medical exposure are specialized in the appropriate area and meet the requirements for education, training and competence in the relevant specialty.

3.149. The regulatory body shall ensure that the authorization for medical exposures to be performed at a particular medical radiation facility allows personnel (including radiological medical practitioners, medical physicists, medical radiation technologists, and any other health professionals with specific duties in patient protection) to take on the responsibilities specified in these Standards only if they:

(a) are specialized[28] in the appropriate area[29];

(b) meet the respective education, training and competence requirements in the radiation protection, in accordance with para. 2.32;

(c) are named in an up-to-date list maintained by the registrant or licensee.

Requirement 36: Responsibilities of registrants and licensees specific to medical exposure

[27] The selection of constraints for carers and comforters is a complex process, which must take into account a number of factors, such as the age of the individual, and the possibility for the individual to be pregnant.

[28] As acknowledged by the relevant professional body, health authority or appropriate organization.

[29] The appropriate area means, in the first instance, diagnostic radiology, image-guided interventional procedures, radiotherapy or nuclear medicine (diagnostic, therapeutic or both). But often, particularly with regard to the radiological medical practitioner, the area of specialization is likely to be narrower, such as dental, chiropractic, or podiatric, for example, in the case of diagnostic radiology, and cardiology, urology, or neurology, for example, in the case of image-guided interventional procedures.

Registrants and licensees shall ensure that no person receives a medical exposure unless there has been appropriate referral, protection and safety is assured, and the person to be exposed has been informed as appropriate.

3.150. Registrants and licensees shall ensure that no patient, whether symptomatic or not, receives a medical exposure unless:

(a) The examination or treatment has been requested by a referring medical practitioner and information on the clinical context has been provided, or is part of an approved health screening programme;
(b) The medical exposure has been justified through consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate, or is part of an approved health screening programme;
(c) A radiological medical practitioner has taken responsibility as specified in para. 3.153(a);
(d) The patient or a legal authorized representative has been informed, as appropriate, of the potential benefit of the radiological procedure as well as the radiation risks.

3.151. Registrants and licensees shall ensure that no individual receives a medical exposure as part of a biomedical research programme unless it has been approved by an ethics committee (or other institutional body assigned similar functions by the relevant authority) as required in para. 3.160, and a radiological medical practitioner has taken responsibility as specified in para. 3.153(a) and that the requirements specified in para. 3.173 are applied.

3.152. Registrants and licensees shall ensure that no individual receives a medical exposure as a carer or comforter unless he or she has received, and has indicated an understanding of, relevant information on radiation protection and radiation risks prior to providing support and comfort to an individual undergoing diagnosis or treatment, and that the requirements specified in para. 3.172 are applied.

3.153. Registrants and licensees shall ensure that:

(a) The radiological medical practitioner performing or overseeing the radiological procedure has assumed responsibility for ensuring overall patient protection

and safety during the planning and delivery of the medical exposure, including the justification of the procedure as required in paras 3.154 to 3.160 and the optimization of protection, in cooperation with the medical physicist and the medical radiation technologist, as required in paras 3.161 to 3.176;

(b) Radiological medical practitioners, medical physicists, medical radiation technologists and other health professionals with specific duties in patient protection involved in a given radiological procedure have the appropriate specialization;

(c) Sufficient medical and paramedical personnel are available as specified by the health authority;

(d) For therapeutic uses of radiation, the calibration, dosimetry and quality assurance (including medical radiological equipment acceptance and commissioning) requirements of these Standards, specified in paras 3.166, 3.167(c), 3.169 and 3.170 are conducted by or under the supervision of a medical physicist;

(e) For diagnostic and image-guided interventional uses of radiation, the imaging, calibration, dosimetry and quality assurance (including medical radiological equipment acceptance and commissioning) requirements of these Standards, listed in paras 3.166, 3.167(a), 3.167(b), 3.168, 3.169 and 3.170 are fulfilled by, or under the oversight of or with the documented advice of, a medical physicist, where the degree of involvement of the medical physicist is determined by the complexity of the particular use of radiation and the ensuing radiation risks;

(f) Any delegation of responsibilities by a principal party is documented.

Requirement 37: Justification of medical exposures

Relevant parties shall ensure that medical exposures are justified.

3.154. Medical exposures shall be justified by weighing the diagnostic or therapeutic benefits[30] they produce against the radiation detriment they might cause,

[30] The benefit may not be necessarily to the exposed person. Clearly for patients this is the case, but for exposures in biomedical research the benefit is expected to be for biomedical sciences and future healthcare. Similarly the benefit associated with carers and comforters might be, for example, the successful performance of a diagnostic procedure on a child.

taking into account the benefits and risks of available alternative techniques that do not involve medical exposure.

3.155. Generic justification of a radiological procedure shall be carried out by the health authority in conjunction with appropriate professional bodies, and shall be reviewed from time to time, taking into account new knowledge and new technical developments.

3.156. The justification of medical exposure for an individual patient shall be carried out through consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate, taking into account, particularly when the patient is pregnant, breast feeding or paediatric:

(a) The appropriateness of the request;
(b) The urgency for the procedure;
(c) The characteristics of the exposure;
(d) The characteristics of the individual patient;
(e) Relevant information from previous radiological procedures.

3.157. Relevant national or international referral guidelines shall be taken into account for the justification of the exposure of an individual patient for diagnostic, image-guided interventional or therapeutic purposes.

3.158. Justification for radiological procedures to be performed as part of a health screening programme of asymptomatic populations shall be carried out by the health authority in conjunction with appropriate professional bodies.

3.159. Any radiological procedure on an asymptomatic individual, intended to be performed for early detection of disease but not as part of an approved health screening programme, shall require specific justification for that individual by the radiological medical practitioner and the referring medical practitioner, following guidelines from relevant professional bodies or the health authority. As part of that process the individual shall have been informed about the estimated benefits, risks and limitations of the procedure.

3.160. The exposure of volunteers for biomedical research is deemed to be not justified unless it is:

(a) In accordance with the provisions of the Helsinki Declaration [20] and takes into account the guidelines published by the Council for International Organizations of Medical Sciences (CIOMS) [21], together with the recommendations of the International Commission on Radiological Protection (ICRP) [22];

(b) Subject to approval by an ethics committee (or other institutional body assigned similar functions by the relevant authority) to any dose constraints that may be specified (paras 3.148(a) (ii) and 3.173), and to applicable national and local regulations.

Requirement 38: Optimization of protection and safety

Registrants and licensees and radiological medical practitioners shall ensure that for each medical exposure protection and safety is optimized.

Design considerations

3.161. In addition to ensuring that the responsibilities under para. 3.49 are discharged, as applicable, registrants and licensees, in cooperation with suppliers, shall ensure that use is made only of medical radiological equipment and of software that can influence the delivery of the radiation, that conforms to applicable standards of the International Electrotechnical Commission (IEC) and the International Organization for Standardization (ISO) or to national standards adopted by the regulatory body.

Operational considerations

3.162. For diagnostic radiological procedures and image-guided interventional procedures, the radiological medical practitioner shall, in cooperation with the medical radiation technologist, the medical physicist, and the radiopharmacist or radiochemist, if appropriate, ensure that the following are used:

(a) Appropriate medical radiological equipment and software and, for nuclear medicine, also appropriate radiopharmaceuticals;

(b) Appropriate techniques and parameters to deliver a patient exposure that is the minimum necessary to achieve the clinical purpose of the procedure, taking

into account relevant norms of acceptable image quality established by appropriate professional bodies and relevant diagnostic reference levels established in accordance with paras 3.147 and 3.168.

3.163. For therapeutic radiological procedures, the radiological medical practitioner shall, in cooperation with the medical physicist and the medical radiation technologist, ensure that for each patient the exposure of volumes other than the planning target volume is kept as low as reasonably achievable consistent with delivering the prescribed dose to the planning target volume within the required tolerances.

3.164. For therapeutic radiological procedures involving administered radiopharmaceuticals, the radiological medical practitioner shall, in cooperation with the medical physicist, the medical radiation technologist, and the radiopharmacist or radiochemist, if appropriate, ensure that for each patient the appropriate radiopharmaceutical and activity are selected and administered so that the activity is primarily localised in the organ(s) of interest, while the activity in the rest of the body is kept as low as reasonably achievable.

3.165. Registrants and licensees shall ensure that the optimization process considers the unique aspects of medical exposures involving:

(a) Paediatric patients;
(b) Individuals as part of a health screening programme;
(c) Volunteers as part of a biomedical research project;
(d) Relatively high doses[31] to the patient;
(e) Exposure of an embryo or foetus, particularly for radiological procedures where the abdomen or pelvis of the woman who is pregnant is in the useful beam or may receive a significant dose;
(f) Exposure of a child as a result of a breast-feeding female undergoing a radiological procedure with radiopharmaceuticals.

Calibration

[31] The term 'relatively high' is intended to apply within a given context. Clearly therapeutic exposures are included, as are image-guided interventional procedures. Within diagnostic imaging, such exposures would include CT and the higher dose procedures in nuclear medicine.

3.166. In accordance with para. 3.153 (d) & (e), the medical physicist shall ensure that:

(a) All sources giving rise to medical exposure are calibrated in terms of appropriate quantities using internationally or nationally accepted protocols;
(b) Calibrations are carried out at the time of commissioning a unit prior to clinical use, after any maintenance procedure that may have an effect on the dosimetry and at intervals approved by the regulatory body;
(c) Prior to clinical use, calibrations of radiotherapy units are independently verified[32];
(d) The calibration of all dosimeters, used for patient dosimetry or for the calibration of sources, is traceable to a standards dosimetry laboratory.

Clinical dosimetry

3.167. Registrants and licensees shall ensure that appropriate clinical dosimetry is performed, and documented, by or under the supervision of a medical physicist, using calibrated dosimeters and following internationally or nationally accepted protocols, including:

(a) For diagnostic medical exposures, typical patient doses for common examinations;
(b) For image-guided interventional procedures, typical patient doses;
(c) For therapeutic medical exposures, individual patient absorbed doses to the tissues or organs determined relevant by the radiological medical practitioner.

Diagnostic reference levels

3.168. Registrants and licensees shall ensure that:

(a) Local assessments, based on the measurements required by para. 3.167, are made at approved intervals for those radiological procedures for which diagnostic reference levels have been established (see para. 3.147);

[32] Independent verification ideally means different medical physicist using different dosimetry equipment. However, other options such as only a second medical physicist or only a second set of equipment or even using a form of postal TLD verification may be acceptable. In checking for compliance, the regulator must be cognizant of local resources.

(b) A review is conducted to determine whether the optimization of protection of patients is adequate or whether corrective action is required if the typical doses or activities for a given radiological procedure:

(i) exceed the relevant diagnostic reference level; or

(ii) fall substantially below the relevant diagnostic reference level and the exposures do not provide useful diagnostic information or do not yield the expected medical benefit to the patient.

Quality assurance for medical exposures

3.169. Registrants and licensees, as part of applying the relevant management system requirements of these Standards, shall establish a comprehensive programme of quality assurance for medical exposures with the active participation of the medical physicists, radiological medical practitioners, medical radiation technologists and, for complex nuclear medicine facilities, radiopharmacists and radiochemists, and in conjunction with other health professionals as appropriate. Principles established by the World Health Organization (WHO), the Pan American Health Organization (PAHO) and relevant professional bodies shall be taken into account.

3.170. Registrants and licensees shall ensure that programmes of quality assurance for medical exposures include, as appropriate to the medical radiation facility:

(a) Measurements by, or under the oversight of, a medical physicist of the physical parameters of medical radiological equipment:

(i) At the time of acceptance and commissioning prior to clinical use on patients;

(ii) Periodically thereafter;

(iii) After any major maintenance that could affect patient protection;

(iv) After any installation of new or modification of existing software that could affect patient protection;

(b) Implementation of corrective actions if measured values of the physical parameters in (a) are outside established tolerance limits;

(c) Verification of the appropriate physical and clinical factors used in patient diagnosis or treatment;

(d) Records of relevant procedures and results;

(e) Periodic checks of the appropriate calibration and conditions of operation of dosimetry and monitoring equipment.

3.171. Registrants and licensees shall ensure that there are regular and independent audits of the programme of quality assurance for medical exposures; their frequency depending on the complexity of the radiological procedures performed and the risks involved.

Dose constraints

3.172. Registrants and licensees shall ensure that relevant dose constraints (see para. 3.148(a) (i)) are used in the optimization of protection in any procedure in which an individual acts as a carer or comforter, as appropriate.

3.173. Registrants and licensees shall ensure that dose constraints specified or approved by the ethics committee (or other institutional body assigned similar functions by the relevant authority) on a case-by-case basis as part of the proposal for the biomedical research (see para. 3.160), are used in the optimization of protection and safety for persons exposed in biomedical research.

Requirement 39: Pregnant or breast-feeding women

Registrants and licensees shall ensure that there are arrangements in place to afford appropriate radiation protection in cases where a woman is or might be pregnant or is breast-feeding.

3.174. Registrants and licensees shall ensure that there are signs in appropriate languages in public places, patient waiting rooms, cubicles and other appropriate places, and other communication methods as appropriate, requesting a female patient who is to undergo a radiological procedure to notify the radiological medical practitioner, medical radiation technologist or other personnel if:

(a) She is or might be pregnant
(b) She is breast-feeding and the scheduled radiological procedure involves the administration of a radiopharmaceutical.

3.175. Registrants and licensees shall ensure that there are procedures in place to ascertain the pregnancy status of a female of reproductive capacity before the

performance of any radiological procedure that may give a significant dose to the embryo or foetus, so that this information can be considered in the justification for the radiological procedure (see para. 3.154) and in its optimization (see para. 3.165).

3.176. Registrants and licensees shall ensure that there are arrangements in place to establish that a female is not breast-feeding before the performance of any radiological procedure involving the administration of a radiopharmaceutical that may give a significant dose to an infant being breast-fed, so that this information can be considered in the justification for the radiological procedure (see para. 3.154) and in its optimization (see para. 3.165).

Requirement 40: Release of patients after radionuclide therapy

Registrants and licensees shall ensure that there are arrangements in place to ensure appropriate radiation protection for members of the public and for family members before a patient is released following radionuclide therapy.

3.177. The radiological medical practitioner shall ensure that no patient who has undergone a therapeutic procedure with sealed or unsealed sources is discharged from a medical radiation facility until it has been established by either a medical physicist or by the facility's radiation protection officer that:

(a) The activity of radioactive material in the patient is such that the doses that may be received by members of the public and family members would meet the requirements set by the relevant authorities (see para. 3.148(b)): and

(b) The patient or legal guardian of the patient is provided with:

  (i) Written instructions with a view to keeping doses to persons in contact with or in the vicinity of the patient as low as reasonably achievable and to avoiding the spread of contamination;

  (ii) Information on the radiation risks.

Requirement 41: Unintended and accidental medical exposures

Registrants and licensees shall ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical exposures. They shall promptly investigate any such exposure and, if appropriate, shall implement corrective measures.

3.178. Registrants and licensees, through the application of the relevant requirements of paras 2.51, 3.41 to 3.44, and 3.50 shall ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical exposures arising from design flaws and operational failures of medical radiological equipment, failures of and errors in software, or as a result of human error.

Investigation of unintended and accidental medical exposures

3.179. Registrants and licensees shall promptly investigate any of the following unintended or accidental medical exposures:

(a) Any treatment delivered to the wrong individual or the wrong tissue of the patient, or using the wrong radiopharmaceutical, or with a dose or dose fractionation differing substantially (above or below) from the values prescribed by the radiological medical practitioner, or which may lead to unduly severe secondary effects;
(b) Any diagnostic or image-guided interventional procedure which irradiates the wrong individual or the wrong tissue of the patient;
(c) Any exposure for diagnostic purposes substantially greater than intended;
(d) Any exposure substantially greater than intended arising from an image-guided interventional procedure;
(e) Any inadvertent exposure of the embryo or foetus in the course of performing a radiological procedure;
(f) Any medical radiological equipment failure, software or other system failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure substantially different from that intended.

3.180. Registrants and licensees shall, with respect to any investigation required under para. 3.179:

(a) Calculate or estimate the doses received and their distribution within the patient;
(b) Indicate the corrective measures required to prevent recurrence of such an unintended or accidental medical exposure;
(c) Implement all the corrective measures that are under their own responsibility;

(d) Produce and keep as a record, as soon as possible after the investigation or as otherwise specified by the regulatory body, a written report which states the cause of the unintended or accidental medical exposure and includes the information specified in (a) to (c), as relevant, and any other information required by the regulatory body; and submit this report, as soon as possible, to the regulatory body, and to the relevant health authority if appropriate, for those unintended or accidental medical exposures involving significant exposure or as otherwise required by the regulatory body;

(e) Inform the referring medical practitioner and the patient or a legal authorized representative about the unintended or accidental medical exposure.

Requirement 42: Reviews and records

Registrants and licensees shall ensure that periodic radiological reviews are performed at medical radiation facilities and that records are kept.

Radiological reviews

3.181. Registrants and licensees shall ensure that periodic radiological reviews are performed by the radiological medical practitioners at the medical radiation facility, in cooperation with the medical radiation technologists and the medical physicists. The radiological review has to examine and critically review the current practical implementation of the radiation protection principles of justification and optimization for the radiological procedures that are being performed in the medical radiation facility.

Records

3.182. Registrants and licensees shall keep for a period specified by the regulatory body and shall make available, as required, the following records for personnel:

(a) Any delegation of responsibilities by principal parties (see para. 3.153(f));

(b) Training records of personnel in radiation protection (see para. 3.149).

3.183. Registrants and licensees shall keep for a period specified by the regulatory body and shall make available, as required, the following calibration, dosimetry, and quality assurance records:

(a) Results of the calibrations and periodic checks of the relevant physical and clinical parameters selected during treatments;
(b) Records of clinical dosimetry (para 3.167);
(c) Records of local assessments and reviews made with respect to diagnostic reference levels (para 3.168);
(d) Records associated with the programme of quality assurance (3.170(d)).

3.184. Registrants and licensees shall keep for a period specified by the regulatory body and shall make available, as required, the following records of medical exposure:

(a) In diagnostic radiology, necessary information to allow retrospective dose assessment, including the number of exposures and the duration of fluoroscopic examinations;
(b) In image-guided interventional procedures, necessary information to allow retrospective dose assessment, including the duration of the fluoroscopy component and the number of images acquired;
(c) In nuclear medicine, types of radiopharmaceuticals administered and their activities;
(d) In radiation therapy, a description of the planning target volume, the dose to the centre of the planning target volume and the maximum and minimum doses delivered to the planning target volume or alternative equivalent information on doses to the planning target volume, the doses to other relevant organs selected by the radiological medical practitioner, the dose fractionation, and the overall treatment time;
(e) The exposure of volunteers in biomedical research;
(f) Reports on investigations of unintended and accidental medical exposures (para 3.180(d)).

4. EMERGENCY EXPOSURE SITUATIONS

SCOPE

4.1. The requirements for emergency exposure situations given in this section apply to activities undertaken in preparedness for and in response to a nuclear or radiological emergency.

GENERIC REQUIREMENTS

Requirement 43: Emergency management system

The government shall ensure that an integrated and coordinated emergency management system is established and maintained.

4.2. The government shall ensure that an emergency management system is established and maintained on its territories and within its jurisdiction for an emergency response to protect human life, health and the environment in the event of a nuclear or radiological emergency.

4.3. The system shall be designed to be commensurate with the results of a hazard assessment [15] and to be able to respond effectively to reasonably foreseeable events (including very low probability events) in connection with facilities or activities.

4.4. The system shall be integrated, to the extent appropriate, into all-hazards emergency management systems.

4.5. The system shall provide for, inter alia, the following elements at the scene, local, national and international levels, as appropriate[15]:

(a) Hazard assessment;
(b) Development and testing of emergency plans and procedures;
(c) Clear allocation of the responsibilities of persons and organizations having a role in preparedness and response arrangements;
(d) Efficient and effective arrangements for cooperation and coordination among organizations;
(e) Reliable communication, including the provision of public information;

(f) Optimized protection strategies for the implementation and termination of measures to protect members of the public who may be exposed in an emergency, including considerations for protection of the environment;

(g) Arrangements for the protection of emergency workers;

(h) Education and training, including in radiation protection, of all persons involved in response and in exercising of emergency plans and procedures;

(i) Preparations for the transition from emergency exposure situation to an existing exposure situation;

(j) Arrangements for the medical and public health response in an emergency;

(k) Provision for monitoring and dose assessment;

(l) Involvement of relevant and interested parties.

4.6. The government shall ensure coordination of its emergency arrangements and capabilities with international emergency arrangements.

PUBLIC EXPOSURE

Requirement 44: Preparedness and response to an emergency

The government shall ensure that protection strategies are developed, justified and optimized at the planning stage, and that the response in an emergency is undertaken through their timely implementation.

4.7. The government shall ensure that protection strategies are developed, justified, and optimized at the planning stage using scenarios based on the hazard assessment for avoiding deterministic effects and reducing the risk of stochastic effects to the public.

4.8. Development of a protection strategy shall include, in the following order, but not be limited to, the following:

(a) A reference level, expressed in terms of residual dose, shall be set, typically between 20 mSv and 100 mSv effective dose, which includes dose contributions from all exposure pathways. The protection strategy shall plan that residual doses are as low as reasonable achievable below the reference level, and that protection is optimized.

(b) Based on the outcome of the optimization of the protection strategy, using the reference level, generic criteria for particular protective and other actions, expressed in terms of projected dose or dose that has been received, shall be developed. If the numerical values of the generic criteria[33] are exceeded, those actions either individually or in combination, shall be implemented.

(c) Once the protection strategy has been optimized and a set of generic criteria has been developed, pre-established default triggers for initiating the different parts of an emergency response plan primarily for the initial phase shall be derived from the generic criteria. Default triggers, such as on-scene conditions, operational intervention levels (OILs), and emergency action levels (EALs), shall be expressed in terms of parameters or observable circumstances. Arrangements shall be established in advance to revise these triggers, as appropriate, during an emergency exposure situation, taking into account the prevailing conditions as these evolve.

4.9. Each protective action shall be justified in the context of the protection strategy.

4.10. The government, recognizing that emergencies can result in dynamic situations, shall ensure that preparedness and response arrangements take into consideration that decisions taken early in the response may impact subsequent actions, and that different geographical areas may have different prevailing conditions and response requirements.

4.11. The government shall ensure that the response to emergency exposure situations is undertaken through the timely implementation of arrangements for emergency response, including but not limited to:

(a) Promptly implementing protective actions to avoid severe deterministic effects based on observed conditions and, if possible, before any exposure occurs. Dose levels to be used as generic criteria to prevent severe deterministic effects are given in Schedule IV, Table IV-1;

[33] Table A-1 in the Annex provides a set of generic criteria for use within the protection strategy and are based on reference levels within a range of 20-100 mSv and further details for specific actions in different timeframes.

(b) Assessing the effectiveness of implemented actions and adjusting them as appropriate;
(c) Comparing the expected residual doses against the applicable reference level, giving priority to those groups whose doses exceed the reference level;
(d) Implementing further protection strategies as necessary, based on the prevailing conditions and available information.

EXPOSURE OF EMERGENCY WORKERS

Requirement 45: Arrangements for controlling exposure of emergency workers

The government shall establish a programme for managing, controlling and recording doses received in an emergency by emergency workers, which shall be implemented by response organizations and employers.

4.12. The government shall establish a programme for managing, controlling and recording doses received in an emergency by emergency workers.

4.13. The response organization and employers responsible for ensuring compliance with the requirements set out in paras 4.14 to 4.19 shall be specified in the emergency plan.

4.14. In an emergency exposure situation, the relevant requirements for occupational exposure in planned exposure situations (paras 3.68 to 3.116) shall be applied to emergency workers using a graded approach, except as provided in para. 4.15.

4.15. Response organizations and employers shall ensure that no emergency worker is exposed in an emergency in excess of 50 mSv except:

(a) For the purpose of saving life or preventing serious injury;
(b) If undertaking actions to prevent severe deterministic health effects and to prevent the development of catastrophic conditions; or
(c) If undertaking actions intended to avert a large collective dose.

4.16. In the exceptional circumstances of para. 4.15 (a), (b) and (c), response organizations and employers shall make all reasonable efforts to keep doses to emergency workers, below the values set out in Schedule IV, Table IV-2. In addition,

emergency workers undertaking actions in which their doses may approach or exceed the values set out in Schedule IV, Table IV-2 shall do so only when the benefits to others clearly outweigh their own risk.

4.17. Response organizations and employers shall ensure that emergency workers who undertake actions in which the dose received might exceed the single year dose limit for occupational exposure specified in Schedule III do so voluntarily, and have been clearly and comprehensively informed in advance of the associated health risk, as well as of available protection measures, and are, to the extent feasible, trained in the actions that may be required.

4.18. Response organizations and employers shall take all reasonable steps to assess and record the doses received by emergency workers. The doses received and information concerning the consequent health risk shall be communicated to the workers involved.

4.19. Workers shall not normally be precluded from incurring further occupational exposure because of doses received in an emergency exposure situation. However, qualified medical advice shall be obtained before any further exposure, either if a worker has received a dose exceeding 200 mSv or if the worker requests it.

TRANSITION FROM AN EMERGENCY EXPOSURE SITUATION TO AN EXISTING EXPOSURE SITUATION

Requirement 46: Arrangements for transition from an emergency exposure situation to an existing exposure situation

The government shall ensure that arrangements are put in place, and implemented as appropriate, for the transition from an emergency exposure situation to an existing exposure situation.

4.20. As part of the overall emergency preparedness the government shall ensure that arrangements are in place for the transition from an emergency exposure situation to an existing exposure situation. The arrangements shall take into account that different geographic areas may undergo the transition at different times. The responsible authority shall make the decision to undergo the transition to an existing exposure situation. The transition shall be undertaken in a coordinated and orderly

manner, making any necessary transfer of responsibilities between organizations, and with the involvement of relevant authorities and interested parties.

4.21. Workers undertaking remedial work, such as repairs to plant and buildings, radioactive waste management or decontamination of the site and surrounding areas, shall be subject to the relevant requirements for occupational exposure in planned exposure situations given in Section 3.

5. EXISTING EXPOSURE SITUATIONS

SCOPE

5.1. The requirements for existing exposure situations in this section 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 that were regulated, but not in accordance with these Standards;
  (ii) A nuclear or radiological emergency, after an emergency exposure situation has been declared ended (see paras 4.20 and 4.21);

(b) Exposure due to commodities, including food, feed, drinking water, and construction material, incorporating radionuclides coming from contaminated areas specified in (a);

(c) Exposure due to natural sources, including:
  (i) Radon, thoron and their progeny in workplaces other than where exposure due to other radionuclides in the ^{238}U and ^{232}Th decay chains is controlled as a planned exposure situation, in dwellings and in other buildings with high occupancy factors for members of the public;
  (ii) Radionuclides of natural origin in commodities including food, feed, drinking water, agricultural fertilizer and soil amendments, and construction material and existing residues in the environment are treated as an existing exposure situation regardless of the activity concentration;
  (iii) Materials, other than those defined in (ii), in which the activity concentration of any radionuclide in the uranium and thorium decay chains does not exceed 1 Bq/g or the activity concentration of ^{40}K does not exceed 10 Bq/g;
  (iii) Exposure of aircrew and space crew to cosmic radiation.

GENERIC REQUIREMENTS

Requirement 47: Responsibilities of the government specific to existing exposure situations

The government shall ensure that existing exposure situations that have been identified are evaluated to determine which occupational and public exposures are of concern from the point of view of radiation protection.

5.2. The government shall ensure that when an existing exposure situation is identified, responsibilities for protection and safety are assigned, and appropriate reference levels are established.

5.3. The government shall include in the framework for protection and safety (see Section 2) provision for the management of existing exposure situations. The framework shall:

(a) Specify the types of situations that are included in its scope;[34]
(b) Specify the general principles underlying the strategies developed to reduce exposure when remedial and protective actions have been determined to be justified;[35]
(c) Assign responsibilities for the establishment and implementation of strategies for the management of exposures to the regulatory body and other relevant authorities[36] and, as appropriate, to registrants, licensees and other parties involved in the implementation of remedial and protective actions;
(d) Provide for the involvement of interested parties in decisions regarding the development and implementation of strategies for managing exposures, as appropriate.

5.4. The regulatory body or other relevant authority assigned to establish a strategy for managing an existing exposure situation shall ensure that it defines:

(a) The objectives pursued by the strategy;
(b) Appropriate reference levels.

[34] In the case of exposure to radon, these will include workplaces and workplace types where the exposure is not required by, or directly related to, the work and where annual average radon concentrations might be expected to exceed the reference level established in accordance with para. 5.27.

[35] These include remedial actions such as the removal or reduction of the source of exposure, as well as other long term protective actions such as restrictions on the use of construction materials, restriction of consumption of foodstuffs and restrictions on land use or on access to land or buildings.

[36] In existing exposure situations that do not fall under the jurisdiction of the regulatory body, another relevant authority, such as a health authority, may be empowered to implement measures for protection and safety.

5.5. The regulatory body or other relevant authority shall implement the strategy, including:

(a) Arranging for the evaluation of the available remedial and protective actions for the achievement of the objectives and of the efficiency of planned and implemented actions;

(b) Ensuring that information is available to exposed individuals on the potential health risks and on the available means for reducing their own exposure and associated risk.

PUBLIC EXPOSURE

SCOPE

5.6. The requirements for public exposure in existing exposure situations (paras 5.7 to 5.23) apply to any public exposure resulting from the situations specified in para. 5.1.

Requirement 48: Justification for protective actions and optimization of protection

The government and the regulatory body or other relevant authority shall ensure that remedial actions and protective actions are justified, and radiation protection is optimized.

5.7. The government and the regulatory body or other relevant authority shall ensure that the strategy for the control of existing exposure situations established in terms of paras 5.2 and 5.4 is commensurate with the risks associated with the existing exposure situation and that remedial or protective actions yield sufficient benefit to outweigh the detriments associated with taking them, including detriments in the form of radiation risks.[37]

5.8. The regulatory body or other relevant authority and other parties responsible for remedial or protective actions shall ensure that the form, scale and duration of such actions are optimized. While this optimization process is aimed at

[37] The implementation of remedial actions (remediation) does not imply the elimination of all radioactivity or all traces of radioactive material. The optimization process may lead to an extensive remediation but not necessarily to the restoration of pre-existing conditions.

providing optimized protection of all exposed individuals, priority shall be given to those groups of individuals whose residual dose exceeds the reference level and all reasonable steps shall be taken to avoid doses remaining above the reference levels. Reference levels shall typically be expressed as an annual effective dose to the representative person in the range 1–20 mSv or other equivalent quantity, the actual value depending on the feasibility of controlling the situation and past experience in managing similar situations.

5.9. The regulatory body or other relevant authority shall periodically review the reference levels to ensure that they remain appropriate in the light of prevailing circumstances.

Requirement 49: Responsibilities for remediation of areas with residual radioactive material

The government shall ensure that provision is made for identifying those responsible for areas with residual radioactive material, for establishing and implementing remediation programmes and post-remediation control measures, if appropriate, and for an appropriate waste management strategy to be put in place.

5.10. In the case of remediation of areas contaminated by residual radioactive material from past activities or from nuclear or radiological emergencies (see para. 5.1(a)), the government shall ensure that provision is made in the framework for protection and safety for:

(a) The identification of all persons or organizations responsible for the contamination and for financing the remediation programme and of appropriate arrangements for alternative sources of funding if such persons or organizations no longer exist or are unable to meet their liabilities;
(b) The identification of the persons or organizations responsible for planning, implementing and verifying the remedial actions;
(c) The establishment of any restrictions on the use of or access to the area before, during and, if necessary, after remediation;
(d) An appropriate system for archiving, retrieval and amendment of records that covers the nature and extent of contamination, the decisions made before,

during and after remediation and information on verification including the results of all monitoring and surveillance programmes after completion of the remedial work.

5.11. The government shall ensure that an appropriate waste management strategy is established to deal with any waste arising from the remedial work and that provision for such a strategy is made in the framework for protection and safety.

5.12. The persons or organizations responsible for the planning, implementation and verification of remedial actions shall, as appropriate, ensure that:

(a) A remedial action plan, supported by an appropriate safety assessment, is prepared and submitted to the regulatory body or other relevant authority for approval;

(b) The remedial actions are aimed at the timely and progressive reduction of the hazard and eventually, if possible, the removal of restrictions on the use of or access to the area;

(c) Any additional exposure received temporarily by members of the public as a result of the remedial work is justified on the basis of the resulting net benefit, including the final reduction of the annual dose;

(d) In the choice of the optimized remediation option:

  (i) The radiological impacts on health, safety and the environment are considered together with other, non-radiological impacts on health, safety and the environment, and technical, societal and economic factors;

  (ii) The cost of transportation and waste management, the radiation exposure of, and other risks to, the workers managing it and, subsequently, the exposure of the public associated with its disposal, are all taken into account;

(e) A mechanism for public information is in place and the interested parties affected by the existing exposure situation are involved in the planning, implementation and verification of the remedial actions, including any post-remediation monitoring and surveillance;

(f) A monitoring programme is defined and established;

(g) A system to keep adequate records related to the existing exposure situation and actions taken to improve protection and safety is in place;

(h) Procedures are in place for reporting any abnormal situation relevant to protection and safety to the regulatory body.

5.13. The regulatory body or other relevant authority shall carry out the duties in para. 2.29, and in particular, take responsibility for:

(a) Review of the safety assessment submitted by the person or organization, approval of the remedial action plan, and any subsequent changes to the remedial action plan, and granting of any necessary authorization;

(b) Establishment of criteria and methods for assessing safety;

(c) Review of work procedures, monitoring programmes and records;

(d) Review and approval of significant changes in procedures or equipment that may have a radiological environmental impact or may alter the exposure conditions of remediation workers or of members of the public;

(e) Where necessary, establishment of regulatory requirements for post-remediation control measures.

5.14. The person or organization responsible for carrying out the remedial work shall:

(a) Ensure that the work, including the management of the resulting radioactive waste, is conducted in accordance with the approved remedial action plan;

(b) Take responsibility for all aspects of safety including the performance of a safety assessment;

(c) Monitor and survey the area regularly during remediation so as to verify the levels of contamination, to ensure compliance with the requirements for waste management and to enable any unexpected levels of radiation to be detected and the remedial action plan to be modified accordingly, subject to approval by the regulatory body or other relevant authority;

(d) Perform a survey after completion of the remedial work to demonstrate that the end point conditions, as established in the remedial action plan, have been met;

(e) Prepare and retain a final remediation report, and submit a copy to the regulatory body or other relevant authority.

5.15. After the remedial work has been completed, the regulatory body or other relevant authority shall:

(a) Review, amend as necessary and formalize the nature, extent and duration of any post-remediation control measures already identified in the remedial action plan with due consideration of the residual risk;
(b) Identify the person or organization responsible for any post-remediation control measures;
(c) Where necessary, impose specific restrictions on the remediated area, to control:
    (i) Access by unauthorized individuals;
    (ii) The removal of radioactive material or the use of such material, including its use in commodities;
    (iii) Future use, including the use of water resources and use for the production of food or feed, and the consumption of food from the area;
(d) Periodically review the conditions in the remediated area and, if appropriate, amend or remove any restrictions.

5.16. The person or organization responsible for the post-remediation control measures shall establish and maintain for as long as required by the regulatory body or other relevant authority an appropriate programme, including any necessary provisions for monitoring and surveillance, to verify the long term effectiveness of the completed remedial actions for areas in which controls are required after remediation.

5.17. For those areas with long-lasting residual contamination in which the government has decided to allow habitation and the resumption of social and economic activities, the government shall ensure, in consultation with interested parties, that arrangements are in place, as necessary, for the ongoing control of exposure with the aim of establishing sustainable living conditions, including:

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

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

5.18. The conditions prevailing after the completion of the remedial actions, if the regulatory body or other relevant authority has imposed no restrictions or controls, shall be considered to constitute the background conditions for new facilities and activities or for habitation of the land.

Requirement 50: Public exposure to radon indoors

The government shall provide information on levels of radon indoors and the associated risks and, if appropriate, shall establish and implement an action plan for controlling public exposure to radon indoors.

5.19. As part of its responsibilities under para. 5.3, the government shall ensure that:

(a) Information on radon levels in dwellings and other buildings with high occupancy factors for members of the public[38] is gathered, through appropriate means such as representative radon surveys;

(b) Relevant information on radon exposure, and the associated risks, including the enhanced risk related to smoking, is provided to the public and other interested parties.

5.20. Where radon levels of public health concern are identified from the information gathered as required by para. 5.19 (a), the government shall ensure that an action plan comprising coordinated actions to reduce such levels in both existing and future buildings is established,[39] which include:

(a) The establishment of an appropriate reference level for dwellings and other buildings with high occupancy factors for members of the public, which takes into account the prevailing social and economic circumstances but which in general does not exceed an annual average radon concentration of 300 Bq/m^3 [40];

[38] Such buildings include kindergartens, schools and hospitals.

[39] Guidance on the preparation of radon action plans can be found, for example, in Ref. [6].

[40] Using an equilibrium factor of 0.4 and an annual occupancy rate of 7000 hours, the value of 300 Bq/m^3 corresponds to an annual effective dose of the order of 10 mSv.

(b) Making all reasonable efforts to reduce radon concentrations and exposures to a level where protection is optimized;

(c) Giving priority to reducing radon concentrations in those situations where such action is likely to be most effective[41];

(d) Inclusion of appropriate radon prevention and mitigation measures in building codes to prevent radon ingress and to facilitate potential remediation actions wherever necessary.

5.21. The government shall assign responsibility for:

(a) Establishing and implementing the action plan for controlling public exposure to radon indoors;

(b) Determining the circumstances under which remedial action is to be mandatory or voluntary, taking into account the prevailing legal and social circumstances.

Requirement 51: Exposure to radionuclides in commodities

The regulatory body or other relevant authority shall establish reference levels for radionuclides in commodities.

5.22. The regulatory body or other relevant authority shall establish specific reference levels for exposure to radionuclides in commodities such as construction material, food, feed and drinking water, each of which shall typically be expressed as, or based on, an annual effective dose to the representative person generally not exceeding a value of around 1 mSv.

5.23. The regulatory body or other relevant authority shall consider the guideline levels for radionuclides contained in foods destined for human consumption and traded internationally, which have been contaminated following a nuclear or radiological emergency, as published by the Joint FAO/WHO Codex Alimentarius Commission [23]. The regulatory body or other relevant authority shall consider the guidelines for drinking water that have been published by the WHO [24].

[41] Examples of such prioritization include (a) specifying levels of radon concentration in dwellings and other buildings with high occupancy factors at which protection against radon can be considered optimized; (b) identifying radon-prone areas; (c) identifying building characteristics that are likely to give rise to elevated radon concentrations; and (d) identifying and requiring preventive measures for future buildings which can be introduced at relatively low cost.

OCCUPATIONAL EXPOSURE

SCOPE

5.24. The requirements for occupational exposure in existing exposure situations (paras 5.25 to 5.31) shall apply to any occupational exposure resulting from the situations specified in para. 5.1.

Requirement 52: Exposure in workplaces

The regulatory body shall establish and enforce requirements for the protection of workers in existing exposure situations.

5.25. For the protection and safety of workers in existing exposure situations, other than in specific situations identified in paras 5.26 to 5.31, the requirements for public exposure set out in paras 5.7 to 5.9 shall apply.

Remediation of areas contaminated by residual radioactive material

5.26. The employer shall ensure that the exposure of workers undertaking remedial work is controlled in accordance with the relevant requirements for occupational exposure in planned exposure situations given in section 3.

Exposure to radon in workplaces

5.27. The regulatory body or other relevant authority shall establish a radon protection strategy for workplaces, including the establishment of an appropriate reference level, the value of which takes into account the prevailing social and economic circumstances but which does not exceed an annual average radon concentration of 1000 Bq/m^3.[42]

5.28. Employers shall ensure that:

(a) Protection is optimized by making all reasonable efforts to reduce radon concentrations and radon exposures;
(b) To the extent possible, radon concentrations in workplaces are reduced to below the reference level established in accordance with para. 5.27.

[42] Using an equilibrium factor of 0.4 and an annual occupancy rate of 2000 hours, the value of 1000 Bq/m^3 corresponds to an annual effective dose of the order of 10 mSv.

5.29. If, despite all reasonable efforts by the employer to reduce radon levels, the radon concentration in the workplace remains above the reference level established in accordance with para. 5.27, exposure to radon shall be subject to the relevant requirements for occupational exposure in planned exposure situations given in section 3, including the requirement for a graded approach to regulation.

Exposure to cosmic radiation

5.30. The regulatory body or other relevant authority shall determine whether the assessment of the exposure of aircrew[43] to cosmic radiation is warranted, and whether relevant requirements for occupational exposure in planned exposure situations given in section 3 apply, particularly for pregnant aircrew as in paras 3.113 and 3.114.

5.31. The regulatory body or other relevant authority shall establish, when appropriate, a framework for radiation protection that applies to humans in space-based activities that are appropriate for the exceptional circumstances of the space environment. While the dose limitation requirements of these Standards do not apply to humans in space-based activities, all reasonable efforts shall be made to optimize protection by restricting the radiation doses received by these individuals while not unduly limiting the extent of activities that they can undertake.

[43] The exposure of aircrew to cosmic radiation cannot be reasonably controlled for a specific flight, as it is determined by altitude, latitude and duration of the flight.

Schedule I
EXEMPTION AND CLEARANCE

CRITERIA FOR EXEMPTION

I-1. The general criteria for exemption are that:

(a) The radiation risks arising from the practice or source within the practice are sufficiently low as to not warrant regulatory control, with no appreciable likelihood of scenarios that could lead to a failure to meet this criterion; or

(b) Regulation of the practice or source would provide no net benefit, in that no reasonable control measures would achieve a worthwhile return in reduction of individual doses or risks.

I-2. A practice or a source within a practice may be exempted under para. I-1(a) without further consideration provided that in all reasonably foreseeable situations, the effective dose expected to be incurred by any member of the public due to the exempted practice or source is of the order of 10 μSv or less in a year. To take account of low probability scenarios, a different criterion can be used, namely that the effective dose due to such low probability scenarios does not exceed 1 mSv in a year.

I-3. Under the criteria in paras I-1 and I-2, the following sources within justified practices are automatically exempted without further consideration from the requirements of these Standards, including those for notification, registration or licensing:

(a) Radioactive material in a moderate amount[44] for which either the total activity of an individual radionuclide present on the premises at any one time or the activity concentration used in the practice, does not exceed the applicable exemption level given in Table I-1 of Schedule I;[45];

[44] The exemption values (activity concentrations) set forth in Table I-1 have been calculated on the basis of scenarios involving a moderate quantity of material: "The calculated values apply to practices involving small scale usage of activity where the quantities involved are at the most of the order of a tonne." (see Ref. [25]) The regulatory body will need to establish for which quantities the concentration values in Table I-1 may be applied, bearing in mind that for many radionuclides, in particular those for which there is no corresponding value in Table I-2, a restriction on the quantity is not meaningful.

[45] The exemption levels set out in Table I-1 and exemption and clearance levels set out in Table I-2 of Schedule I are subject to the following considerations: (a) They were derived using a conservative model based on (i) the criteria of paras. I-2 and I-11 respectively and (ii) a series of limiting (bounding) use and disposal scenarios (see Ref. [25] in the case of Table I-1 and Ref. [26] in the case of Table I-2). (b) In the case of more than one radionuclide, the derived exemption level or derived clearance level for the mixture is determined as specified in paras. I-7 and I-14 respectively.

(b) Radioactive material in a bulk amount[44] for which the activity concentration of a given radionuclide of artificial origin used in the practice does not exceed the relevant value given in Table I-2 of Schedule I[45];

(c) Radiation generators, of a type approved by the regulatory body, or in the form of an electronic tube, such as a cathode ray tube for the display of visual images, provided that:

(i) They do not cause in normal operating conditions an ambient dose equivalent rate or a directional dose equivalent rate, as appropriate, exceeding 1 μSv/h at a distance of 0.1 m from any accessible surface of the equipment; or

(ii) The maximum energy of the radiation generated is no greater than 5 keV.

I-4. For radionuclides of natural origin, exemption of bulk amounts of material is necessarily considered on a case by case basis[46] by using a dose criterion of the order of 1 mSv in a year, commensurate with typical natural background levels

I-5. The Regulations for the Safe Transport of Radioactive Material [12] (the Transport Regulations) do not apply to exempt material or exempt consignments — that is, material in transport for which either the activity concentration of the material or the total activity of radionuclides in the consignment, does not exceed the relevant 'basic radionuclide value' for exemption given in the Transport Regulations[47]. In general, such basic radionuclide values are numerically equal to the corresponding exempt activity concentrations or exempt activities given in Table I-1 of Schedule I.

I-6. Exemptions may be granted subject to conditions specified by the regulatory body, such as conditions relating to the physical or chemical form and to the use or disposal of the radioactive material. In particular, such an exemption may be granted for equipment containing radioactive material not otherwise exempted under para. I-3(a) provided that:

(a) The equipment is of a type approved by the regulatory body;

(b) The radioactive material

[46] Material containing radionuclides of natural origin at an activity concentration of less than 1 Bq/g of any radionuclide in the uranium and thorium decay chains and less than 10 Bq/g of ^{40}K is outside the scope of planned exposure situations (see para. 3.4(a)), so the concept of exemption for these activity concentrations does not apply.

[47] For purposes of material in transport, exemption means exemption from the requirements of the Transport Regulations [12].

(i) Is in the form of a sealed source that effectively prevents any contact with the radioactive material and prevents its leakage, or

(ii) Is an unsealed source of a small amount such as sources used for radioimmunoassay;

(c) In normal operating conditions it does not cause an ambient dose equivalent rate or a directional dose equivalent rate, as appropriate, exceeding 1 μSv/h at a distance of 0.1 m from any accessible surface of the apparatus;

(d) Necessary conditions for disposal have been specified by the regulatory body.

I-7. For exemption of radioactive material containing more than one radionuclide, using the levels given in Tables I-1 and I-2, the condition for exemption is that the sum of the individual radionuclide activities or activity concentrations, as appropriate, is less than the derived exemption level for the mixture (X_m), determined as follows:

$$X_m = \frac{1}{\sum_{i=1}^{n} \frac{f(i)}{X(i)}}$$

where *f(i)* is the fraction of activity or activity concentration, as appropriate, of radionuclide *i* in the mixture, *X(i)* is the applicable level for radionuclide *i* as given in Table I-1 or Table I-2, and *n* is the number of radionuclides present.

I-8. Residual radioactive material arising from authorized discharges is exempted from any future requirements for notification, registration or licensing unless otherwise specified by the regulatory body.

I-9. The values provided in Table I-1 and Table I-2 are not intended to be applied to the control of discharges or radioactive residues in the environment.

CRITERIA FOR CLEARANCE

I-10. The general criteria for clearance are that:

(a) The radiation risks arising from the cleared material are sufficiently low as to not warrant regulatory control, with no appreciable likelihood of scenarios that could lead to a failure to meet this criterion; or

(b) The continued regulatory control of the material would provide no net benefit, in that no reasonable control measures would achieve a worthwhile return in reduction of individual doses or risks.

I-11. Material may be cleared under para. I-10(a) without further consideration provided that, in all reasonably foreseeable situations, the effective dose expected to be incurred by any member of the public due to the cleared material is of the order of 10 μSv or less in a year. To take account of low probability scenarios, a different criterion can be used, namely that the effective dose due to such low probability scenarios does not exceed 1 mSv in a year.

I-12. Radioactive material within a notified or authorized practice may be cleared without further consideration provided that:

(a) The activity concentration of an individual radionuclide of artificial origin does not exceed the relevant level given in Table I-2 of Schedule I[45]; or
(b) The activity concentrations of radionuclides of natural origin do not exceed the relevant level given in Table I-3 of Schedule I[48]; or
(c) In the case of radionuclides of natural origin in residues which may be recycled into construction materials[49] or the disposal of which is liable to contaminate drinking water supplies, the activity concentration in the residues does not exceed specific values derived such as to meet dose criterion of the order of 1 mSv in a year commensurate with typical natural background levels.

I-13. Clearance may be granted by the regulatory body for specific situations, on the basis of criteria of I-7 and I-8, taking into account the physical or chemical form of the material, use or disposal of the material[50]. Such clearance levels may be defined in terms of activity concentration per unit mass or per unit surface area.

I-14. For clearance of radioactive material containing more than one radionuclide of artificial origin, using the levels given in Table I-2, the condition for clearance is that the sum

[48] These values may also be applied to clearance of materials arising from practices subject to the clearance criteria in I-8, pending the establishment of radionuclide-specific values for naturally occurring radionuclides in Table I-2.

[49] Control of construction materials is addressed as an existing exposure situation in Section 5.

[50] For example, specific clearance levels may be developed for metals, building rubble, and waste for landfill.

of the individual radionuclide activity concentrations is less than the derived clearance level for the mixture (X_m), determined as follows:

$$X_m = \frac{1}{\sum_{i=1}^{n} \frac{f(i)}{X(i)}}$$

where *f(i)* is the fraction of activity concentration of radionuclide *i* in the mixture, *X(i)* is the applicable level for radionuclide *i* as given in Table I-2, and *n* is the number of radionuclides present.

I-15. For clearance of bulk quantities of material containing a mixture of radionuclides of both natural and artificial origin, both conditions in paras I-12(b) and I-14 are both to be satisfied.

TABLE I-1: LEVELS FOR EXEMPTION OF MODERATE AMOUNTS OF MATERIAL WITHOUT FURTHER CONSIDERATION: EXEMPT ACTIVITY CONCENTRATIONS AND EXEMPT ACTIVITIES OF RADIONUCLIDES *(see footnotes 44 and 45)*

Radionuclide	Activity concentration (Bq/g)	Activity (Bq)
H-3	1×10^{6}	1×10^{9}
Be-7	1×10^{3}	1×10^{7}
Be-10	1×10^{4}	1×10^{6}
C-11	1×10^{1}	1×10^{6}
C-14	1×10^{4}	1×10^{7}
N-13	1×10^{2}	1×10^{9}
Ne-19	1×10^{2}	1×10^{9}
O-15	1×10^{2}	1×10^{9}
F-18	1×10^{1}	1×10^{6}
Na-22	1×10^{1}	1×10^{6}
Na-24	1×10^{1}	1×10^{5}
Mg-28	1×10^{1}	1×10^{5}
Al-26	1×10^{1}	1×10^{5}
Si-31	1×10^{3}	1×10^{6}
Si-32	1×10^{3}	1×10^{6}
P-32	1×10^{3}	1×10^{5}
P-33	1×10^{5}	1×10^{8}
S-35	1×10^{5}	1×10^{8}
Cl-36	1×10^{4}	1×10^{6}
Cl-38	1×10^{1}	1×10^{5}
Cl-39	1×10^{1}	1×10^{5}
Ar-37	1×10^{6}	1×10^{8}
Ar-39	1×10^{7}	1×10^{4}
Ar-41	1×10^{2}	1×10^{9}
K-40	1×10^{2}	1×10^{6}
K-42	1×10^{2}	1×10^{6}
K-43	1×10^{1}	1×10^{6}
K-44	1×10^{1}	1×10^{5}
K-45	1×10^{1}	1×10^{5}
Ca-41	1×10^{5}	1×10^{7}
Ca-45	1×10^{4}	1×10^{7}
Ca-47	1×10^{1}	1×10^{6}
Sc-43	1×10^{1}	1×10^{6}
Sc-44	1×10^{1}	1×10^{5}
Sc-45	1×10^{2}	1×10^{7}
Sc-46	1×10^{1}	1×10^{6}
Sc-47	1×10^{2}	1×10^{6}
Sc-48	1×10^{1}	1×10^{5}
Sc-49	1×10^{3}	1×10^{5}
Ti-44	1×10^{1}	1×10^{5}
Ti-45	1×10^{1}	1×10^{6}
V-47	1×10^{1}	1×10^{5}
V-48	1×10^{1}	1×10^{5}
V-49	1×10^{4}	1×10^{7}
Cr-48	1×10^{2}	1×10^{6}
Cr-49	1×10^{1}	1×10^{6}
Cr-51	1×10^{3}	1×10^{7}
Mn-51	1×10^{1}	1×10^{5}
Mn-52	1×10^{1}	1×10^{5}
Mn-52m	1×10^{1}	1×10^{5}
Mn-53	1×10^{4}	1×10^{9}
Mn-54	1×10^{1}	1×10^{6}
Mn-56	1×10^{1}	1×10^{5}
Fe-52	1×10^{1}	1×10^{6}
Fe-55	1×10^{4}	1×10^{6}
Fe-59	1×10^{1}	1×10^{6}
Fe-60	1×10^{2}	1×10^{5}
Co-55	1×10^{1}	1×10^{6}
Co-56	1×10^{1}	1×10^{5}
Co-57	1×10^{2}	1×10^{6}
Co-58	1×10^{1}	1×10^{6}
Co-58m	1×10^{4}	1×10^{7}
Co-60	1×10^{1}	1×10^{5}
Co-60m	1×10^{3}	1×10^{6}
Co-61	1×10^{2}	1×10^{6}
Co-62m	1×10^{1}	1×10^{5}
Ni-56	1×10^{1}	1×10^{6}
Ni-57	1×10^{1}	1×10^{6}
Ni-59	1×10^{4}	1×10^{8}
Ni-63	1×10^{5}	1×10^{8}

Radionuclide	Activity concentration (Bq/g)	Activity (Bq)
Ni-65	1×10^{1}	1×10^{6}
Ni-66	1×10^{4}	1×10^{7}
Cu-60	1×10^{1}	1×10^{5}
Cu-61	1×10^{1}	1×10^{6}
Cu-64	1×10^{2}	1×10^{6}
Cu-67	1×10^{2}	1×10^{6}
Zn-62	1×10^{2}	1×10^{6}
Zn-63	1×10^{1}	1×10^{5}
Zn-65	1×10^{1}	1×10^{6}
Zn-69	1×10^{4}	1×10^{6}
Zn-69m	1×10^{2}	1×10^{6}
Zn-71m	1×10^{1}	1×10^{6}
Zn-72	1×10^{2}	1×10^{6}
Ga-65	1×10^{1}	1×10^{5}
Ga-66	1×10^{1}	1×10^{5}
Ga-67	1×10^{2}	1×10^{6}
Ga-68	1×10^{1}	1×10^{5}
Ga-70	1×10^{2}	1×10^{6}
Ga-72	1×10^{1}	1×10^{5}
Ga-73	1×10^{2}	1×10^{6}
Ge-66	1×10^{1}	1×10^{6}
Ge-67	1×10^{1}	1×10^{5}
Ge-68[a]	1×10^{1}	1×10^{5}
Ge-69	1×10^{1}	1×10^{6}
Ge-71	1×10^{4}	1×10^{8}
Ge-75	1×10^{3}	1×10^{6}
Ge-77	1×10^{1}	1×10^{5}
Ge-78	1×10^{2}	1×10^{6}
As-69	1×10^{1}	1×10^{5}
As-70	1×10^{1}	1×10^{5}
As-71	1×10^{1}	1×10^{6}
As-72	1×10^{1}	1×10^{5}
As-73	1×10^{3}	1×10^{7}
As-74	1×10^{1}	1×10^{6}
As-76	1×10^{2}	1×10^{5}
As-77	1×10^{3}	1×10^{6}
As-78	1×10^{1}	1×10^{5}
Se-70	1×10^{1}	1×10^{6}
Se-73	1×10^{1}	1×10^{6}
Se-73m	1×10^{2}	1×10^{6}
Se-75	1×10^{2}	1×10^{6}
Se-79	1×10^{4}	1×10^{7}
Se-81	1×10^{3}	1×10^{6}
Se-81m	1×10^{3}	1×10^{7}
Se-83	1×10^{1}	1×10^{5}
Br-74	1×10^{1}	1×10^{5}
Br-74m	1×10^{1}	1×10^{5}
Br-75	1×10^{1}	1×10^{6}
Br-76	1×10^{1}	1×10^{5}
Br-77	1×10^{2}	1×10^{6}
Br-80	1×10^{2}	1×10^{5}
Br-80m	1×10^{3}	1×10^{7}
Br-82	1×10^{1}	1×10^{6}
Br-83	1×10^{3}	1×10^{6}
Br-84	1×10^{1}	1×10^{5}
Kr-74	1×10^{2}	1×10^{9}
Kr-76	1×10^{2}	1×10^{9}
Kr-77	1×10^{2}	1×10^{9}
Kr-79	1×10^{3}	1×10^{5}
Kr-81	1×10^{4}	1×10^{7}
Kr-81m	1×10^{3}	1×10^{10}
Kr-83m	1×10^{5}	1×10^{12}
Kr-85	1×10^{5}	1×10^{4}
Kr-85m	1×10^{3}	1×10^{10}
Kr-87	1×10^{2}	1×10^{9}
Kr-88	1×10^{2}	1×10^{9}
Rb-79	1×10^{1}	1×10^{5}
Rb-81	1×10^{1}	1×10^{6}
Rb-81m	1×10^{3}	1×10^{7}
Rb-82m	1×10^{1}	1×10^{6}
Rb-83[a]	1×10^{2}	1×10^{6}
Rb-84	1×10^{1}	1×10^{6}
Rb-86	1×10^{2}	1×10^{5}
Rb-87	1×10^{3}	1×10^{7}
Rb-88	1×10^{2}	1×10^{5}
Rb-89	1×10^{2}	1×10^{5}
Sr-80	1×10^{3}	1×10^{7}
Sr-81	1×10^{1}	1×10^{5}

Radionuclide	Activity concentration (Bq/g)	Activity (Bq)
Sr-82[a]	1×10^{1}	1×10^{5}
Sr-83	1×10^{1}	1×10^{6}
Sr-85	1×10^{2}	1×10^{6}
Sr-85m	1×10^{2}	1×10^{7}
Sr-87m	1×10^{2}	1×10^{6}
Sr-89	1×10^{3}	1×10^{6}
Sr-90[a]	1×10^{2}	1×10^{4}
Sr-91	1×10^{1}	1×10^{5}
Sr-92	1×10^{1}	1×10^{6}
Y-86	1×10^{1}	1×10^{5}
Y-86m	1×10^{2}	1×10^{7}
Y-87[a]	1×10^{1}	1×10^{6}
Y-88	1×10^{1}	1×10^{6}
Y-90	1×10^{3}	1×10^{5}
Y-90m	1×10^{1}	1×10^{6}
Y-91	1×10^{3}	1×10^{6}
Y-91m	1×10^{2}	1×10^{6}
Y-92	1×10^{2}	1×10^{5}
Y-93	1×10^{2}	1×10^{5}
Y-94	1×10^{1}	1×10^{5}
Y-95	1×10^{1}	1×10^{5}
Zr-86	1×10^{2}	1×10^{7}
Zr-88	1×10^{2}	1×10^{6}
Zr-89	1×10^{1}	1×10^{6}
Zr-93[a]	1×10^{3}	1×10^{7}
Zr-95	1×10^{1}	1×10^{6}
Zr-97[a]	1×10^{1}	1×10^{5}
Nb-88	1×10^{1}	1×10^{5}
Nb-89 (2.03 h)	1×10^{1}	1×10^{5}
Nb-89 (1.01 h)	1×10^{1}	1×10^{5}
Nb-90	1×10^{1}	1×10^{5}
Nb-93m	1×10^{4}	1×10^{7}
Nb-94	1×10^{1}	1×10^{6}
Nb-95	1×10^{1}	1×10^{6}
Nb-95m	1×10^{2}	1×10^{7}
Nb-96	1×10^{1}	1×10^{5}
Nb-97	1×10^{1}	1×10^{6}
Nb-98	1×10^{1}	1×10^{5}
Mo-90	1×10^{1}	1×10^{6}
Mo-93	1×10^{3}	1×10^{8}
Mo-93m	1×10^{1}	1×10^{6}
Mo-99	1×10^{2}	1×10^{6}
Mo-101	1×10^{1}	1×10^{6}
Tc-93	1×10^{1}	1×10^{6}
Tc-93m	1×10^{1}	1×10^{6}
Tc-94	1×10^{1}	1×10^{6}
Tc-94m	1×10^{1}	1×10^{5}
Tc-95	1×10^{1}	1×10^{6}
Tc-95m	1×10^{1}	1×10^{6}
Tc-96	1×10^{1}	1×10^{6}
Tc-96m	1×10^{3}	1×10^{7}
Tc-97	1×10^{3}	1×10^{8}
Tc-97m	1×10^{3}	1×10^{7}
Tc-98	1×10^{1}	1×10^{6}
Tc-99	1×10^{4}	1×10^{7}
Tc-99m	1×10^{2}	1×10^{7}
Tc-101	1×10^{2}	1×10^{6}
Tc-104	1×10^{1}	1×10^{5}
Ru-94	1×10^{2}	1×10^{6}
Ru-97	1×10^{2}	1×10^{7}
Ru-103	1×10^{2}	1×10^{6}
Ru-105	1×10^{1}	1×10^{6}
Ru-106[a]	1×10^{2}	1×10^{5}
Rh-99	1×10^{1}	1×10^{6}
Rh-99m	1×10^{1}	1×10^{6}
Rh-100	1×10^{1}	1×10^{6}
Rh-101	1×10^{2}	1×10^{7}
Rh-101m	1×10^{2}	1×10^{7}
Rh-102	1×10^{1}	1×10^{6}
Rh-102m	1×10^{2}	1×10^{6}
Rh-103m	1×10^{4}	1×10^{8}
Rh-105	1×10^{2}	1×10^{7}
Rh-106m	1×10^{1}	1×10^{5}
Rh-107	1×10^{2}	1×10^{6}
Pd-100	1×10^{2}	1×10^{7}
Pd-101	1×10^{2}	1×10^{6}
Pd-103	1×10^{3}	1×10^{8}
Pd-107	1×10^{5}	1×10^{8}

Radionuclide	Activity concentration (Bq/g)	Activity (Bq)
Pd-109	1×10^{3}	1×10^{6}
Ag-102	1×10^{1}	1×10^{5}
Ag-103	1×10^{1}	1×10^{6}
Ag-104	1×10^{1}	1×10^{6}
Ag-104m	1×10^{1}	1×10^{6}
Ag-105	1×10^{2}	1×10^{6}
Ag-106	1×10^{1}	1×10^{6}
Ag-106m	1×10^{1}	1×10^{6}
Ag-108m	1×10^{1}	1×10^{6}
Ag-110m	1×10^{1}	1×10^{6}
Ag-111	1×10^{3}	1×10^{6}
Ag-112	1×10^{1}	1×10^{5}
Ag-115	1×10^{1}	1×10^{5}
Cd-104	1×10^{2}	1×10^{7}
Cd-107	1×10^{3}	1×10^{7}
Cd-109	1×10^{4}	1×10^{6}
Cd-113	1×10^{3}	1×10^{6}
Cd-113m	1×10^{3}	1×10^{6}
Cd-115	1×10^{2}	1×10^{6}
Cd-115m	1×10^{3}	1×10^{6}
Cd-117	1×10^{1}	1×10^{6}
Cd-117m	1×10^{1}	1×10^{6}
In-109	1×10^{1}	1×10^{6}
In-110 (4.9h)	1×10^{1}	1×10^{6}
In-110 (69.1m)	1×10^{1}	1×10^{5}
In-111	1×10^{2}	1×10^{6}
In-112	1×10^{2}	1×10^{6}
In-113m	1×10^{2}	1×10^{6}
In-114	1×10^{3}	1×10^{5}
In-114m	1×10^{2}	1×10^{6}
In-115	1×10^{3}	1×10^{5}
In-115m	1×10^{2}	1×10^{6}
In-116m	1×10^{1}	1×10^{5}
In-117	1×10^{1}	1×10^{6}
In-117m	1×10^{2}	1×10^{6}
In-119m	1×10^{2}	1×10^{5}
Sn-110	1×10^{2}	1×10^{7}
Sn-111	1×10^{2}	1×10^{6}
Sn-113	1×10^{3}	1×10^{7}
Sn-117m	1×10^{2}	1×10^{6}
Sn-119m	1×10^{3}	1×10^{7}
Sn-121	1×10^{5}	1×10^{7}
Sn-121m[a]	1×10^{3}	1×10^{7}
Sn-123	1×10^{3}	1×10^{6}
Sn-123m	1×10^{2}	1×10^{6}
Sn-125	1×10^{2}	1×10^{5}
Sn-126[a]	1×10^{1}	1×10^{5}
Sn-127	1×10^{1}	1×10^{6}
Sn-128	1×10^{1}	1×10^{6}
Sb-115	1×10^{1}	1×10^{6}
Sb-116	1×10^{1}	1×10^{6}
Sb-116m	1×10^{1}	1×10^{5}
Sb-117	1×10^{2}	1×10^{7}
Sb-118m	1×10^{1}	1×10^{6}
Sb-119	1×10^{3}	1×10^{7}
Sb-120 (5.76d)	1×10^{1}	1×10^{6}
Sb-120 (15.89m)	1×10^{2}	1×10^{6}
Sb-122	1×10^{2}	1×10^{4}
Sb-124	1×10^{1}	1×10^{6}
Sb-124m	1×10^{2}	1×10^{6}
Sb-125	1×10^{2}	1×10^{6}
Sb-126	1×10^{1}	1×10^{5}
Sb-126m	1×10^{1}	1×10^{5}
Sb-127	1×10^{1}	1×10^{6}
Sb-128(9.01h)	1×10^{1}	1×10^{5}
Sb-128 (10.4m)	1×10^{1}	1×10^{5}
Sb-129	1×10^{1}	1×10^{6}
Sb-130	1×10^{1}	1×10^{5}
Sb-131	1×10^{1}	1×10^{6}
Te-116	1×10^{2}	1×10^{7}
Te-121	1×10^{1}	1×10^{6}
Te-121m	1×10^{2}	1×10^{6}
Te-123	1×10^{3}	1×10^{6}
Te-123m	1×10^{2}	1×10^{7}
Te-125m	1×10^{3}	1×10^{7}
Te-127	1×10^{3}	1×10^{6}
Te-127m	1×10^{3}	1×10^{7}
Te-129	1×10^{2}	1×10^{6}

Radionuclide	Activity concentration (Bq/g)	Activity (Bq)
Te-129m	1×10^{3}	1×10^{6}
Te-131	1×10^{2}	1×10^{5}
Te-131m	1×10^{1}	1×10^{6}
Te-132	1×10^{2}	1×10^{7}
Te-133	1×10^{1}	1×10^{5}
Te-133m	1×10^{1}	1×10^{5}
Te-134	1×10^{1}	1×10^{6}
I-120	1×10^{1}	1×10^{5}
I-120m	1×10^{1}	1×10^{5}
I-121	1×10^{2}	1×10^{6}
I-123	1×10^{2}	1×10^{7}
I-124	1×10^{1}	1×10^{6}
I-125	1×10^{3}	1×10^{6}
I-126	1×10^{2}	1×10^{6}
I-128	1×10^{2}	1×10^{5}
I-129	1×10^{2}	1×10^{5}
I-130	1×10^{1}	1×10^{6}
I-131	1×10^{2}	1×10^{6}
I-132	1×10^{1}	1×10^{5}
I-132m	1×10^{2}	1×10^{6}
I-133	1×10^{1}	1×10^{6}
I-134	1×10^{1}	1×10^{5}
I-135	1×10^{1}	1×10^{6}
Xe-120	1×10^{2}	1×10^{9}
Xe-121	1×10^{2}	1×10^{9}
Xe-122[a]	1×10^{2}	1×10^{9}
Xe-123	1×10^{2}	1×10^{9}
Xe-125	1×10^{3}	1×10^{9}
Xe-127	1×10^{3}	1×10^{5}
Xe-129m	1×10^{3}	1×10^{4}
Xe-131m	1×10^{4}	1×10^{4}
Xe-133m	1×10^{3}	1×10^{4}
Xe-133	1×10^{3}	1×10^{4}
Xe-135	1×10^{3}	1×10^{10}
Xe-135m	1×10^{2}	1×10^{9}
Xe-138	1×10^{2}	1×10^{9}
Cs-125	1×10^{1}	1×10^{4}
Cs-127	1×10^{2}	1×10^{5}
Cs-129	1×10^{2}	1×10^{5}

Radionuclide	Activity concentration (Bq/g)	Activity (Bq)
Cs-130	1×10^{2}	1×10^{6}
Cs-131	1×10^{3}	1×10^{6}
Cs-132	1×10^{1}	1×10^{5}
Cs-134m	1×10^{3}	1×10^{5}
Cs-134	1×10^{1}	1×10^{4}
Cs-135	1×10^{4}	1×10^{7}
Cs-135m	1×10^{1}	1×10^{6}
Cs-136	1×10^{1}	1×10^{5}
Cs-137[a]	1×10^{1}	1×10^{4}
Cs-138	1×10^{1}	1×10^{4}
Ba-126	1×10^{2}	1×10^{7}
Ba-128	1×10^{2}	1×10^{7}
Ba-131	1×10^{2}	1×10^{6}
Ba-131m	1×10^{2}	1×10^{7}
Ba-133	1×10^{2}	1×10^{6}
Ba-133m	1×10^{2}	1×10^{6}
Ba-135m	1×10^{2}	1×10^{6}
Ba-137m	1×10^{1}	1×10^{6}
Ba-139	1×10^{2}	1×10^{5}
Ba-140[a]	1×10^{1}	1×10^{5}
Ba-141	1×10^{2}	1×10^{5}
Ba-142	1×10^{2}	1×10^{6}
La-131	1×10^{1}	1×10^{6}
La-132	1×10^{1}	1×10^{6}
La-135	1×10^{3}	1×10^{7}
La-137	1×10^{3}	1×10^{7}
La-138	1×10^{1}	1×10^{6}
La-140	1×10^{1}	1×10^{5}
La-141	1×10^{2}	1×10^{5}
La-142	1×10^{1}	1×10^{5}
La-143	1×10^{2}	1×10^{5}
Ce-134	1×10^{3}	1×10^{7}
Ce-135	1×10^{1}	1×10^{6}
Ce-137	1×10^{3}	1×10^{7}
Ce-137m	1×10^{3}	1×10^{6}
Ce-139	1×10^{2}	1×10^{6}
Ce-141	1×10^{2}	1×10^{7}
Ce-143	1×10^{2}	1×10^{6}
Ce-144[a]	1×10^{2}	1×10^{5}

Radionuclide	Activity concentration (Bq/g)	Activity (Bq)
Pr-136	1×10^{1}	1×10^{5}
Pr-137	1×10^{2}	1×10^{6}
Pr-138m	1×10^{1}	1×10^{6}
Pr-139	1×10^{2}	1×10^{7}
Pr-142	1×10^{2}	1×10^{5}
Pr-142m	1×10^{7}	1×10^{9}
Pr-143	1×10^{4}	1×10^{6}
Pr-144	1×10^{2}	1×10^{5}
Pr-145	1×10^{3}	1×10^{5}
Pr-147	1×10^{1}	1×10^{5}
Nd-136	1×10^{2}	1×10^{6}
Nd-138	1×10^{3}	1×10^{7}
Nd-139	1×10^{2}	1×10^{6}
Nd-139m	1×10^{1}	1×10^{6}
Nd-141	1×10^{2}	1×10^{7}
Nd-147	1×10^{2}	1×10^{6}
Nd-149	1×10^{2}	1×10^{6}
Nd-151	1×10^{1}	1×10^{5}
Pm-141	1×10^{1}	1×10^{5}
Pm-143	1×10^{2}	1×10^{6}
Pm-144	1×10^{1}	1×10^{6}
Pm-145	1×10^{3}	1×10^{7}
Pm-146	1×10^{1}	1×10^{6}
Pm-147	1×10^{4}	1×10^{7}
Pm-148	1×10^{1}	1×10^{5}
Pm-148m	1×10^{1}	1×10^{6}
Pm-149	1×10^{3}	1×10^{6}
Pm-150	1×10^{1}	1×10^{5}
Pm-151	1×10^{2}	1×10^{6}
Sm-141	1×10^{1}	1×10^{5}
Sm-141m	1×10^{1}	1×10^{6}
Sm-142	1×10^{2}	1×10^{7}
Sm-145	1×10^{2}	1×10^{7}
Sm-146	1×10^{1}	1×10^{5}
Sm-147	1×10^{1}	1×10^{4}
Sm-151	1×10^{4}	1×10^{8}
Sm-153	1×10^{2}	1×10^{6}
Sm-155	1×10^{2}	1×10^{6}
Sm-156	1×10^{2}	1×10^{6}

Radionuclide	Activity concentration (Bq/g)	Activity (Bq)
Eu-145	1×10^{1}	1×10^{6}
Eu-146	1×10^{1}	1×10^{6}
Eu-147	1×10^{2}	1×10^{6}
Eu-148	1×10^{1}	1×10^{6}
Eu-149	1×10^{2}	1×10^{7}
Eu-150 (34.2y)	1×10^{1}	1×10^{6}
Eu-150 (12.6h)	1×10^{3}	1×10^{6}
Eu-152	1×10^{1}	1×10^{6}
Eu-152m	1×10^{2}	1×10^{6}
Eu-154	1×10^{1}	1×10^{6}
Eu-155	1×10^{2}	1×10^{7}
Eu-156	1×10^{1}	1×10^{6}
Eu157	1×10^{2}	1×10^{6}
Eu-158	1×10^{1}	1×10^{5}
Gd-145	1×10^{1}	1×10^{5}
Gd-146[a]	1×10^{1}	1×10^{6}
Gd-147	1×10^{1}	1×10^{6}
Gd-148	1×10^{1}	1×10^{4}
Gd-149	1×10^{2}	1×10^{6}
Gd-151	1×10^{2}	1×10^{7}
Gd-152	1×10^{1}	1×10^{4}
Gd-153	1×10^{2}	1×10^{7}
Gd-159	1×10^{3}	1×10^{6}
Tb-147	1×10^{1}	1×10^{6}
Tb-149	1×10^{1}	1×10^{6}
Tb-150	1×10^{1}	1×10^{6}
Tb-151	1×10^{1}	1×10^{6}
Tb-153	1×10^{2}	1×10^{7}
Tb-154	1×10^{1}	1×10^{6}
Tb-155	1×10^{2}	1×10^{7}
Tb-156	1×10^{1}	1×10^{6}
Tb-156m (24.4h)	1×10^{3}	1×10^{7}
Tb-156m (5h)	1×10^{4}	1×10^{7}
Tb-157	1×10^{4}	1×10^{7}
Tb-158	1×10^{1}	1×10^{6}
Tb-160	1×10^{1}	1×10^{6}
Tb-161	1×10^{3}	1×10^{6}
Dy-155	1×10^{1}	1×10^{6}
Dy-157	1×10^{2}	1×10^{6}

Radionuclide	Activity concentration (Bq/g)	Activity (Bq)
Dy-159	1×10^{3}	1×10^{7}
Dy-165	1×10^{3}	1×10^{6}
Dy-166	1×10^{3}	1×10^{6}
Ho-155	1×10^{2}	1×10^{6}
Ho-157	1×10^{2}	1×10^{6}
Ho-159	1×10^{2}	1×10^{6}
Ho-161	1×10^{2}	1×10^{7}
Ho-162	1×10^{2}	1×10^{7}
Ho-162m	1×10^{1}	1×10^{6}
Ho-164	1×10^{3}	1×10^{6}
Ho-164m	1×10^{3}	1×10^{7}
Ho-166	1×10^{3}	1×10^{5}
Ho-166m	1×10^{1}	1×10^{6}
Ho-167	1×10^{2}	1×10^{6}
Er-161	1×10^{1}	1×10^{6}
Er-165	1×10^{3}	1×10^{7}
Er-169	1×10^{4}	1×10^{7}
Er-171	1×10^{2}	1×10^{6}
Er-172	1×10^{2}	1×10^{6}
Tm-162	1×10^{1}	1×10^{6}
Tm-166	1×10^{1}	1×10^{6}
Tm-167	1×10^{2}	1×10^{6}
Tm-170	1×10^{3}	1×10^{6}
Tm-171	1×10^{4}	1×10^{8}
Tm-172	1×10^{2}	1×10^{6}
Tm-173	1×10^{2}	1×10^{6}
Tm-175	1×10^{1}	1×10^{6}
Yb-162	1×10^{2}	1×10^{7}
Yb-166	1×10^{2}	1×10^{7}
Yb-167	1×10^{2}	1×10^{6}
Yb-169	1×10^{2}	1×10^{7}
Yb-175	1×10^{3}	1×10^{7}
Yb-177	1×10^{2}	1×10^{6}
Yb-178	1×10^{3}	1×10^{6}
Lu-169	1×10^{1}	1×10^{6}
Lu-170	1×10^{1}	1×10^{6}
Lu-171	1×10^{1}	1×10^{6}
Lu-172	1×10^{1}	1×10^{6}
Lu-173	1×10^{2}	1×10^{7}
Lu-174	1×10^{2}	1×10^{7}
Lu-174m	1×10^{2}	1×10^{7}
Lu-176	1×10^{2}	1×10^{6}
Lu-176m	1×10^{3}	1×10^{6}
Lu-177	1×10^{3}	1×10^{7}
Lu-177m	1×10^{1}	1×10^{6}
Lu-178	1×10^{2}	1×10^{5}
Lu-178m	1×10^{1}	1×10^{5}
Lu-179	1×10^{3}	1×10^{6}
Hf-170	1×10^{2}	1×10^{6}
Hf-172[a]	1×10^{1}	1×10^{6}
Hf-173	1×10^{2}	1×10^{6}
Hf-175	1×10^{2}	1×10^{6}
Hf-177m	1×10^{1}	1×10^{5}
Hf-178m	1×10^{1}	1×10^{6}
Hf-179m	1×10^{1}	1×10^{6}
Hf-180m	1×10^{1}	1×10^{6}
Hf-181	1×10^{1}	1×10^{6}
Hf-182	1×10^{2}	1×10^{6}
Hf-182m	1×10^{1}	1×10^{6}
Hf-183	1×10^{1}	1×10^{6}
Hf-184	1×10^{2}	1×10^{6}
Ta-172	1×10^{1}	1×10^{6}
Ta -173	1×10^{1}	1×10^{6}
Ta-174	1×10^{1}	1×10^{6}
Ta-175	1×10^{1}	1×10^{6}
Ta-176	1×10^{1}	1×10^{6}
Ta-177	1×10^{2}	1×10^{7}
Ta-178	1×10^{1}	1×10^{6}
Ta-179	1×10^{3}	1×10^{7}
Ta-180	1×10^{1}	1×10^{6}
Ta-180m	1×10^{3}	1×10^{7}
Ta-182	1×10^{1}	1×10^{4}
Ta-182m	1×10^{2}	1×10^{6}
Ta-183	1×10^{2}	1×10^{6}
Ta-184	1×10^{1}	1×10^{6}
Ta-185	1×10^{2}	1×10^{5}
Ta-186	1×10^{1}	1×10^{5}
W-176	1×10^{2}	1×10^{6}

Radionuclide	Activity concentration (Bq/g)	Activity (Bq)
W-177	1×10^{1}	1×10^{6}
W-178[a]	1×10^{1}	1×10^{6}
W-179	1×10^{2}	1×10^{7}
W-181	1×10^{3}	1×10^{7}
W-185	1×10^{4}	1×10^{7}
W-187	1×10^{2}	1×10^{6}
W-188[a]	1×10^{2}	1×10^{5}
Re-177	1×10^{1}	1×10^{6}
Re-178	1×10^{1}	1×10^{6}
Re-181	1×10^{1}	1×10^{6}
Re-182 (64h)	1×10^{1}	1×10^{6}
Re-182 (12.7h)	1×10^{1}	1×10^{6}
Re-184	1×10^{1}	1×10^{6}
Re-184m	1×10^{2}	1×10^{6}
Re-186	1×10^{3}	1×10^{6}
Re-186m	1×10^{3}	1×10^{7}
Re-187	1×10^{6}	1×10^{9}
Re-188	1×10^{2}	1×10^{5}
Re-188m	1×10^{2}	1×10^{7}
Re-189[a]	1×10^{2}	1×10^{6}
Os-180	1×10^{2}	1×10^{7}
Os-181	1×10^{1}	1×10^{6}
Os-182	1×10^{2}	1×10^{6}
Os-185	1×10^{1}	1×10^{6}
Os-189m	1×10^{4}	1×10^{7}
Os-191	1×10^{2}	1×10^{7}
Os-191m	1×10^{3}	1×10^{7}
Os-193	1×10^{2}	1×10^{6}
Os-194[a]	1×10^{2}	1×10^{5}
Ir-182	1×10^{1}	1×10^{5}
Ir-184	1×10^{1}	1×10^{6}
Ir-185	1×10^{1}	1×10^{6}
Ir-186 (15.8h)	1×10^{1}	1×10^{6}
Ir-186 (1.75h)	1×10^{1}	1×10^{6}
Ir-187	1×10^{2}	1×10^{6}
Ir-188	1×10^{1}	1×10^{6}
Ir-189[a]	1×10^{2}	1×10^{7}
Ir-190	1×10^{1}	1×10^{6}
Ir-190m (3.1h)	1×10^{1}	1×10^{6}
Ir-190m (1.2h)	1×10^{4}	1×10^{7}
Ir-192	1×10^{1}	1×10^{4}
Ir-192m	1×10^{2}	1×10^{7}
Ir-193m	1×10^{4}	1×10^{7}
Ir-194	1×10^{2}	1×10^{5}
Ir-194m	1×10^{1}	1×10^{6}
Ir-195	1×10^{2}	1×10^{6}
Ir-195m	1×10^{2}	1×10^{6}
Pt-186	1×10^{1}	1×10^{6}
Pt-188[a]	1×10^{1}	1×10^{6}
Pt-189	1×10^{2}	1×10^{6}
Pt-191	1×10^{2}	1×10^{6}
Pt-193	1×10^{4}	1×10^{7}
Pt-193m	1×10^{3}	1×10^{7}
Pt-195m	1×10^{2}	1×10^{6}
Pt-197	1×10^{3}	1×10^{6}
Pt-197m	1×10^{2}	1×10^{6}
Pt-199	1×10^{2}	1×10^{6}
Pt-200	1×10^{2}	1×10^{6}
Au-193	1×10^{2}	1×10^{7}
Au-194	1×10^{1}	1×10^{6}
Au-195	1×10^{2}	1×10^{7}
Au-198	1×10^{2}	1×10^{6}
Au-198m	1×10^{1}	1×10^{6}
Au-199	1×10^{2}	1×10^{6}
Au-200	1×10^{2}	1×10^{5}
Au-200m	1×10^{1}	1×10^{6}
Au-201	1×10^{2}	1×10^{6}
Hg-193	1×10^{2}	1×10^{6}
Hg-193m	1×10^{1}	1×10^{6}
Hg-194[a]	1×10^{1}	1×10^{6}
Hg-195	1×10^{2}	1×10^{6}
Hg-195m[a]	1×10^{2}	1×10^{6}
Hg-197	1×10^{2}	1×10^{7}
Hg-197m	1×10^{2}	1×10^{6}
Hg-199m	1×10^{2}	1×10^{6}
Hg-203	1×10^{2}	1×10^{5}
Tl-194	1×10^{1}	1×10^{6}
Tl-194m	1×10^{1}	1×10^{6}

Radionuclide	Activity concentration (Bq/g)	Activity (Bq)
Tl-195	1×10^{1}	1×10^{6}
Tl-197	1×10^{2}	1×10^{6}
Tl-198	1×10^{1}	1×10^{6}
Tl-198m	1×10^{1}	1×10^{6}
Tl-199	1×10^{2}	1×10^{6}
Tl-200	1×10^{1}	1×10^{6}
Tl-201	1×10^{2}	1×10^{6}
Tl-202	1×10^{2}	1×10^{6}
Tl-204	1×10^{4}	1×10^{4}
Pb-195m	1×10^{1}	1×10^{6}
Pb-198	1×10^{2}	1×10^{6}
Pb-199	1×10^{1}	1×10^{6}
Pb-200	1×10^{2}	1×10^{6}
Pb-201	1×10^{1}	1×10^{6}
Pb-202	1×10^{3}	1×10^{6}
Pb-202m	1×10^{1}	1×10^{6}
Pb-203	1×10^{2}	1×10^{6}
Pb-205	1×10^{4}	1×10^{7}
Pb-209	1×10^{5}	1×10^{6}
Pb-210[a]	1×10^{1}	1×10^{4}
Pb-211	1×10^{2}	1×10^{6}
Pb-212[a]	1×10^{1}	1×10^{5}
Pb-214	1×10^{2}	1×10^{6}
Bi-200	1×10^{1}	1×10^{6}
Bi-201	1×10^{1}	1×10^{6}
Bi-202	1×10^{1}	1×10^{6}
Bi-203	1×10^{1}	1×10^{6}
Bi-205	1×10^{1}	1×10^{6}
Bi-206	1×10^{1}	1×10^{5}
Bi-207	1×10^{1}	1×10^{6}
Bi-210	1×10^{3}	1×10^{6}
Bi-210m[a]	1×10^{1}	1×10^{5}
Bi-212[a]	1×10^{1}	1×10^{5}
Bi-213	1×10^{2}	1×10^{6}
Bi-214	1×10^{1}	1×10^{5}
Po-203	1×10^{1}	1×10^{6}
Po-205	1×10^{1}	1×10^{6}
Po-206	1×10^{1}	1×10^{6}
Po-207	1×10^{1}	1×10^{6}
Po-208	1×10^{1}	1×10^{4}
Po-209	1×10^{1}	1×10^{4}
Po-210	1×10^{1}	1×10^{4}
At-207	1×10^{1}	1×10^{6}
At-211	1×10^{3}	1×10^{7}
Fr-222	1×10^{3}	1×10^{5}
Fr-223	1×10^{2}	1×10^{6}
Rn-220[a]	1×10^{4}	1×10^{7}
Rn-222[a]	1×10^{1}	1×10^{8}
Ra-223[a]	1×10^{2}	1×10^{5}
Ra-224[a]	1×10^{1}	1×10^{5}
Ra-225	1×10^{2}	1×10^{5}
Ra-226[a]	1×10^{1}	1×10^{4}
Ra-227	1×10^{2}	1×10^{6}
Ra-228[a]	1×10^{1}	1×10^{5}
Ac-224	1×10^{2}	1×10^{6}
Ac-225[a]	1×10^{1}	1×10^{4}
Ac-226	1×10^{2}	1×10^{5}
Ac-227[a]	1×10^{-1}	1×10^{3}
Ac-228	1×10^{1}	1×10^{6}
Th-226[a]	1×10^{3}	1×10^{7}
Th-227	1×10^{1}	1×10^{4}
Th-228[a]	1×10^{0}	1×10^{4}
Th-229[a]	1×10^{0}	1×10^{3}
Th-230	1×10^{0}	1×10^{4}
Th-231	1×10^{3}	1×10^{7}
Th-232	1×10^{1}	1×10^{4}
Th-234[a]	1×10^{3}	1×10^{5}
Pa-227	1×10^{1}	1×10^{6}
Pa-228	1×10^{1}	1×10^{6}
Pa-230	1×10^{1}	1×10^{6}
Pa-231	1×10^{0}	1×10^{3}
Pa-232	1×10^{1}	1×10^{6}
Pa-233	1×10^{2}	1×10^{7}
Pa-234	1×10^{1}	1×10^{6}
U-230[a]	1×10^{1}	1×10^{5}
U-231	1×10^{2}	1×10^{7}
U-232[a]	1×10^{0}	1×10^{3}
U-233	1×10^{1}	1×10^{4}

Radionuclide	Activity concentration (Bq/g)	Activity (Bq)
U-234	1×10^{1}	1×10^{4}
U-235[a]	1×10^{1}	1×10^{4}
U-236	1×10^{1}	1×10^{4}
U-237	1×10^{2}	1×10^{6}
U-238[a]	1×10^{1}	1×10^{4}
U-239	1×10^{2}	1×10^{6}
U-240	1×10^{3}	1×10^{7}
U-240[a]	1×10^{1}	1×10^{6}
Np-232	1×10^{1}	1×10^{6}
Np-233	1×10^{2}	1×10^{7}
Np-234	1×10^{1}	1×10^{6}
Np-235	1×10^{3}	1×10^{7}
Np-236 ($1.15.10^{5}$y)	1×10^{2}	1×10^{5}
Np-236 (22.5h)	1×10^{3}	1×10^{7}
Np-237[a]	1×10^{0}	1×10^{3}
Np-238	1×10^{2}	1×10^{6}
Np-239	1×10^{2}	1×10^{7}
Np-240	1×10^{1}	1×10^{6}
Pu-234	1×10^{2}	1×10^{7}
Pu-235	1×10^{2}	1×10^{7}
Pu-236	1×10^{1}	1×10^{4}
Pu-237	1×10^{3}	1×10^{7}
Pu-238	1×10^{0}	1×10^{4}
Pu-239	1×10^{0}	1×10^{4}
Pu-240	1×10^{0}	1×10^{3}
Pu-241	1×10^{2}	1×10^{5}
Pu-242	1×10^{0}	1×10^{4}
Pu-243	1×10^{3}	1×10^{7}
Pu-244	1×10^{0}	1×10^{4}
Pu-245	1×10^{2}	1×10^{6}
Pu-246	1×10^{2}	1×10^{6}
Am-237	1×10^{2}	1×10^{6}
Am-238	1×10^{1}	1×10^{6}
Am-239	1×10^{2}	1×10^{6}
Am-240	1×10^{1}	1×10^{6}
Am-241	1×10^{0}	1×10^{4}
Am-242	1×10^{3}	1×10^{6}
Am-242m[a]	1×10^{0}	1×10^{4}
Am-243[a]	1×10^{0}	1×10^{3}

Radionuclide	Activity concentration (Bq/g)	Activity (Bq)
Am-244	1×10^{1}	1×10^{6}
Am-244m	1×10^{4}	1×10^{7}
Am-245	1×10^{3}	1×10^{6}
Am-246	1×10^{1}	1×10^{5}
Am-246m	1×10^{1}	1×10^{6}
Cm-238	1×10^{2}	1×10^{7}
Cm-240	1×10^{2}	1×10^{5}
Cm-241	1×10^{2}	1×10^{6}
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}
Cm-249	1×10^{3}	1×10^{6}
Cm-250	1×10^{-1}	1×10^{3}
Bk-245	1×10^{2}	1×10^{6}
Bk-246	1×10^{1}	1×10^{6}
Bk-247	1×10^{0}	1×10^{4}
Bk-249	1×10^{3}	1×10^{6}
Bk-250	1×10^{1}	1×10^{6}
Cf-244	1×10^{4}	1×10^{7}
Cf-246	1×10^{3}	1×10^{6}
Cf-248	1×10^{1}	1×10^{4}
Cf-249	1×10^{0}	1×10^{3}
Cf-250	1×10^{1}	1×10^{4}
Cf-251	1×10^{0}	1×10^{3}
Cf-252	1×10^{1}	1×10^{4}
Cf-253	1×10^{2}	1×10^{5}
Cf-254	1×10^{0}	1×10^{3}
Es-250	1×10^{2}	1×10^{6}
Es-251	1×10^{2}	1×10^{7}
Es-253	1×10^{2}	1×10^{5}
Es-254	1×10^{1}	1×10^{4}
Es-254m	1×10^{2}	1×10^{6}
Fm-252	1×10^{3}	1×10^{6}
Fm-253	1×10^{2}	1×10^{6}
Fm-254	1×10^{4}	1×10^{7}

Radionuclide	Activity concentration (Bq/g)	Activity (Bq)
Fm-255	1×10^{3}	1×10^{6}
Fm-257	1×10^{1}	1×10^{5}

Radionuclide	Activity concentration (Bq/g)	Activity (Bq)
Md-257	1×10^{2}	1×10^{7}
Md-258	1×10^{2}	1×10^{5}

[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:

Ge-68	Ga-68
Rb-83	Kr-83m
Sr-82	Rb-82
Sr-90	Y-90
Y-87	Sr-87m
Zr-93	Nb-93m
Zr-97	Nb-97
Ru-106	Rh-106
Ag-108m	Ag-108
Sn-121m	Sn-121 (0.776)
Sn-126	Sb-126m
Xe-122	I-122
Cs-137	Ba-137m
Ba-140	La-140
Ce-134	La-134
Ce-144	Pr-144
Gd-146	Eu-146
Hf-172	Lu-172
W-178	Ta-178
W-188	Re-188
Re-189	Os-189m (0.241)
Ir-189	Os-189m
Pt-188	Ir-188
Hg-194	Au-194
Hg-195m	Hg-195 (0.542)
Pb-210	Bi-210, Po-210
Pb-212	Bi-212, Tl-208 (0.36), Po-212 (0.64)
Bi-210m	Tl-206
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
Ac-225	Fr-221, At-217, Bi-213, Po-213 (0.978), Tl-209 (0.0216), Pb-209 (0.978)
Ac-227	Fr-223 (0.0138)
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
Np-237	Pa-233
Am-242m	Am-242
Am-243	Np-239

TABLE I-2: LEVELS FOR EXEMPTION OF BULK AMOUNTS OF MATERIAL WITHOUT FURTHER CONSIDERATION AND FOR CLEARANCE OF MATERIAL WITHOUT FURTHER CONSIDERATION: ACTIVITY CONCENTRATIONS OF RADIONUCLIDES OF ARTIFICIAL ORIGIN *(see footnote 45)*

Radionuclide	Activity concentration (Bq/g)	Radionuclide	Activity concentration (Bq/g)	Radionuclide	Activity concentration (Bq/g)
H-3	100	Co-58	1	Y-93	100
Be-7	10	Co-58m	10 000	Zr-93	10
C-14	1	Co-60	0.1	Zr-95[a]	1
F-18	10	Co-60m	1000	Zr-97[a]	10
Na-22	0.1	Co-61	100	Nb-93m	10
Na-24	1	Co-62m	10	Nb-94	0.1
Si-31	1000	Ni-59	100	Nb-95	1
P-32	1000	Ni-63	100	Nb-97[a]	10
P-33	1000	Ni-65	10	Nb-98	10
S-35	100	Cu-64	100	Mo-90	10
Cl-36	1	Zn-65	0.1	Mo-93	10
Cl-38	10	Zn-69	1000	Mo-99[a]	10
K-42	100	Zn-69m[a]	10	Mo-101[a]	10
K-43	10	Ga-72	10	Tc-96	1
Ca-45	100	Ge-71	10 000	Tc-96m	1000
Ca-47	10	As-73	1000	Tc-97	10
Sc-46	0.1	As-74	10	Tc-97m	100
Sc-47	100	As-76	10	Tc-99	1
Sc-48	1	As-77	1000	Tc-99m	100
V-48	1	Se-75	1	Ru-97	10
Cr-51	100	Br-82	1	Ru-103[a]	1
Mn-51	10	Rb-86	100	Ru-105[a]	10
Mn-52	1	Sr-85	1	Ru-106[a]	0.1
Mn-52m	10	Sr-85m	100	Rh-103m	10 000
Mn-53	100	Sr-87m	100	Rh-105	100
Mn-54	0.1	Sr-89	1000	Pd-103[a]	1000
Mn-56	10	Sr-90[a]	1	Pd-109[a]	100
Fe-52[a]	10	Sr-91[a]	10	Ag-105	1
Fe-55	1000	Sr-92	10	Ag-110m[a]	0.1
Fe-59	1	Y-90	1000	Ag-111	100
Co-55	10	Y-91	100	Cd-109[a]	1
Co-56	0.1	Y-91m	100	Cd-115[a]	10
Co-57	1	Y-92	100	Cd-115m[a]	100

Radionuclide	Activity concentration (Bq/g)
In-111	10
In-113m	100
In-114m[a]	10
In-115m	100
Sn-113[a]	1
Sn-125	10
Sb-122	10
Sb-124	1
Sb-125[a]	0.1
Te-123m	1
Te-125m	1000
Te-127	1000
Te-127m[a]	10
Te-129	100
Te-129m[a]	10
Te-131	100
Te-131m[a]	10
Te-132[a]	1
Te-133	10
Te-133m	10
Te-134	10
I-123	100
I-125	100
I-126	10
I-129	0.01
I-130	10
I-131	10
I-132	10
I-133	10
I-134	10
I-135	10
Cs-129	10
Cs-131	1000
Cs-132	10
Cs-134	0.1
Cs-134m	1000
Cs-135	100
Cs-136	1
Cs-137[a]	0.1
Cs-138	10
Ba-131	10
Ba-140	1
La-140	1
Ce-139	1
Ce-141	100
Ce-143	10
Ce-144	10
Pr-142	100
Pr-143	1000
Nd-147	100
Nd-149	100
Pm-147	1000
Pm-149	1000
Sm-151	1000
Sm-153	100
Eu-152	0.1
Eu-152m	100
Eu-154	0.1
Eu-155	1
Gd-153	10
Gd-159	100
Tb-160	1
Dy-165	1000
Dy-166	100
Ho-166	100
Er-169	1000
Er-171	100
Tm-170	100
Tm-171	1000
Yb-175	100
Lu-177	100
Hf-181	1
Ta-182	0.1
W-181	10
W-185	1000
W-187	10
Re-186	1000
Re-188	100
Os-185	1
Os-191	100
Os-191m	1000
Os-193	100
Ir-190	1
Ir-192	1
Ir-194	100
Pt-191	10
Pt-193m	1000
Pt-197	1000
Pt-197m	100
Au-198	10
Au-199	100
Hg-197	100
Hg-197m	100
Hg-203	10
Tl-200	10
Tl-201	100
Tl-202	10
Tl-204	1
Pb-203	10
Bi-206	1
Bi-207	0.1
Po-203	10
Po-205	10
Po-207	10
At-211	1000
Ra-225	10
Ra-227	100
Th-226	1000
Th-229	0.1
Pa-230	10
Pa-233	10
U-230[b]	10
U-231[a]	100
U-232[a]	0.1
U-233	1
U-236	10
U-237	100

Radionuclide	Activity concentration (Bq/g)	Radionuclide	Activity concentration (Bq/g)	Radionuclide	Activity concentration (Bq/g)
U-239	100	Pu-244[a]	0.1	Cf-249	0.1
U-240[a]	100	Am-241	0.1	Cf-250	1
Np-237[a]	1	Am-242	1000	Cf-251	0.1
Np-239	100	Am-242m[a]	0.1	Cf-252	1
Np-240	10	Am-243[a]	0.1	Cf-253	100
Pu-234	100	Cm-242	10	Cf-254	1
Pu-235	100	Cm-243	1	Es-253	100
Pu-236	1	Cm-244	1	Es-254[a]	0.1
Pu-237	100	Cm-245	0.1	Es-254m[a]	10
Pu-238	0.1	Cm-246	0.1	Fm-254	10 000
Pu-239	0.1	Cm-247[a]	0.1	Fm-255	100
Pu-240	0.1	Cm-248	0.1		
Pu-241	10	Bk-249	100		
Pu-242	0.1	Cf-246	1000		
Pu-243	1000	Cf-248	1		

[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:

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

TABLE I-3: LEVELS FOR CLEARANCE OF MATERIAL: ACTIVITY CONCENTRATIONS OF RADIONUCLIDES OF NATURAL ORIGIN

Radionuclide	Activity Concentration (Bq/g)
K-40	10
Each radionuclide in the uranium and thorium decay chains	1

Schedule II

TABLE II-I: CATEGORIES FOR SEALED SOURCES USED IN COMMON PRACTICES

Category	Ratio of Activity in the source to the activity that is considered dangerous[i] (A/D)	Example of sources[ii] and practices
1	A/D ≥ 1000	Radioisotope thermoelectric generators (RTGs) Irradiators Teletherapy sources Fixed, multi-beam teletherapy (gamma knife) sources
2	1000>A/D ≥ 10	Industrial gamma radiography sources High/medium dose-rate brachytherapy sources
3	10>A/D ≥ 1	Fixed industrial gauges that incorporate high activity sources Well logging gauges
4	1>A/D ≥ 0.01	Low dose-rate brachytherapy sources (except eye plaques and permanent implants) Industrial gauges that do not incorporate high activity sources Bone densitometers Static eliminators
5	0.01>A/D and A>Exempt[iii]	Low dose-rate brachytherapy eye plaques and permanent implant sources X ray fluorescence devices Electron capture devices Mossbauer spectrometry sources Positron Emission Tomography (PET) check sources

[i] A is the activity of the radionuclide in a source and D is the activity of that radionuclide that is regarded as dangerous, where a dangerous source is defined as one that could, if not under control, give rise to exposure sufficient to cause severe deterministic effects. Values of D for selected radionuclides are given in Table II-2 based on the quantity of radioactive material that could give rise to severe deterministic effects for given exposure scenarios and for given dose criteria. This column can then be used to determine the category of a source, based purely on A/D. This may be appropriate if, for example: the practice is not known or is not listed; if sources have a short half-life and/or are unsealed; or if sources are aggregated.

[ii] Factors other than A/D have been taken into consideration in assigning these sources to a particular category [27]

[iii] Exempt quantities are given in Schedule I.

TABLE II-2. ACTIVITY[a] CORRESPONDING TO A DANGEROUS SOURCE (D VALUE[b]) FOR SELECTED RADIONUCLIDES

Radionuclide	D TBq
Am-241	6×10^{-2}
Am-241/Be	6×10^{-2}
Au-198	2×10^{-1}
Cd-109	2×10^{1}
Cf-252	2×10^{-2}
Cm-244	5×10^{-2}
Co-57	7×10^{-1}
Co-60	3×10^{-2}
Cs-137	1×10^{-1}
Fe-55	8×10^{2}
Gd-153	1×10^{0}
Ge-68	7×10^{-2}
H-3	2×10^{3}
I-125	2×10^{-1}
I-131	2×10^{-1}
Ir-192	8×10^{-2}
Kr-85	3×10^{1}
Mo-99	3×10^{-1}
Ni-63	6×10^{1}
P-32	1×10^{1}
Pd-103	9×10^{1}
Pm-147	4×10^{1}
Po-210	6×10^{-2}
Pu-238	6×10^{-2}
Pu-239/Be	6×10^{-2}
Ra-226	4×10^{-2}
Ru-106 (Rh-106)	3×10^{-1}
Se-75	2×10^{-1}
Sr-90 (Y-90)	1×10^{0}
$Tc\text{-}99^{m}$	7×10^{-1}
Tl-204	2×10^{1}
Tm-170	2×10^{1}
Yb-169	3×10^{-1}

[a] Since Table II-2 does not show which dose criteria were used, these *D* values should not be used in reverse to derive possible doses due to sources of known activity.

[b] Full details of the derivation of the *D* values and *D* values for additional radionuclides are provided in Ref. [28].

Schedule III

DOSE LIMITS FOR PLANNED EXPOSURE SITUATIONS

OCCUPATIONAL EXPOSURE

III-1. For occupational exposure of workers over the age of 18 years, the dose limits are:

(a) An effective dose of 20 mSv per year averaged over five consecutive years[53] (100 mSv in 5 years), and 50 mSv in any single year;
(b) An equivalent dose to the lens of the eye of 150 mSv in a year;
(c) An equivalent dose to the extremities (hands and feet) or the skin[54] of 500 mSv in a year.

Additional restrictions apply to the occupational exposure of a female worker who has notified pregnancy or is breast feeding (see para. 3.114).

III-2. For occupational exposure of apprentices of 16 to 18 years of age who are being trained for employment involving exposure to radiation and of students of age 16 to 18 who are required to use sources in the course of their studies, the dose limits are:

(a) An effective dose of 6 mSv in a year;
(b) An equivalent dose to the lens of the eye of 50 mSv in a year;
(c) An equivalent dose to the extremities or the skin[54] of 150 mSv in a year.

PUBLIC EXPOSURE

III-3. For public exposure, the dose limits for members of the public are:

(a) An effective dose of 1 mSv in a year;
(b) In special circumstances, a higher value of effective dose in a single year, provided that the average effective dose over five consecutive years does not exceed 1 mSv per year;
(c) An equivalent dose to the lens of the eye of 15 mSv in a year;

[53] The start of the averaging period shall be coincident with the first day of the relevant annual period after the date of entry into force of these Standards, with no retroactive averaging.

[54] The equivalent dose limits for the skin apply to the average dose over 1 cm^2 of the most highly irradiated area of the skin. Skin dose also contributes to the effective dose, this contribution being the average dose to the entire skin multiplied by the tissue weighting factor for the skin.

(d) An equivalent dose to the skin of 50 mSv in a year.

VERIFICATION OF COMPLIANCE WITH DOSE LIMITS

III-4. The effective dose limits specified in Schedule III apply to the sum of the relevant doses from external exposure in the specified period and the relevant committed doses from intakes in the same period; the period for calculating the committed dose shall normally be 50 years for intakes by adults and to age 70 years for intakes by children[55].

III-5. For occupational exposure, the personal dose equivalent $H_p(10)$ may be used as an approximation of the effective dose from external exposure to penetrating radiation.

III-6. Values of the effective dose and absorbed dose in an organ or tissue per unit air kerma free-in-air and per unit particle fluence are those given in Table III-X [29].

III-7. Dose coefficients and procedures for the estimation of the committed effective dose and absorbed dose in an organ or tissue for a given intake or a measured bioassay quantity in a case of ingestion and inhalation of radionuclides are those given in Table III-X [30, 31].

III-8. The values of conversion coefficients for exposure to radon progeny and thoron progeny in homes and workplaces are given in Table III-1 [values (and reference) to be inserted when available].

[55] Procedures for the assessment of the effective dose to workers and members of the public are given in the IAEA Safety Guides and ICRP publications.

TABLE III-I. CONVERSION COEFFICIENTS FOR RADON AND THORON PROGENY

VALUES TO BE BE PROVIDED WHEN AVAILABLE

Quantity	Unit
Radon progeny[a]	
Effective dose per unit potential alpha energy intake at work	mSv/mJ
Effective dose per unit potential alpha energy exposure:	
At home[b]	mSv per ($mJ \cdot h \cdot m^{-3}$)
At work	mSv per ($mJ \cdot h \cdot m^{-3}$)
Annual average exposure per unit radon concentration[c]:	
At home[b]	($mJ \cdot h \cdot m^{-3}$) per (Bq/m^3)
At work	($mJ \cdot h \cdot m^{-3}$) per (Bq/m^3)
Annual dose per unit radon concentration[c]	
At home[b]	mSv per (Bq/m^3)
At work	mSv per (Bq/m^3)
Thoron progeny[d]	
Effective dose per unit potential alpha energy intake at work	mSv/mJ
Effective dose per unit alpha energy exposure at work	mSv per ($mJ \cdot h \cdot m^{-3}$)

[a] Radon progeny: short lived decay products of Rn-222: Po-218, Pb-214, Bi-214, and Po-214.
[b] The dosimetry for homes should also apply to other buildings with high occupancy by the public.
[c] Assuming 7000 h/a indoors or 2000 h/a at work and an equilibrium factor of 0.4.
[d] Thoron progeny: short lived decay products of Rn-220: Po-216, Pb-212, Bi-212, Po-212, Tl-208.

Schedule IV
CRITERIA FOR USE IN EMERGENCY PREPAREDNESS AND RESPONSE

TABLE IV-1: GENERIC CRITERIA FOR ACUTE DOSES AT WHICH PROTECTIVE AND OTHER ACTIONS ARE EXPECTED TO BE UNDERTAKEN UNDER ANY CIRCUMSTANCES TO AVOID OR MINIMIZE SEVERE DETERMINISTIC HEALTH EFFECTS

External acute exposure (< 10 hours) $AD_{Red\ marrow}$[(a)]: 1 Gy AD_{Foetus}: 0.1 Gy AD_{Tissue}[(b)]: 25 Gy at 0.5 cm AD_{Skin}[(c)]: 10 Gy to 100 cm^2 **Internal exposure from acute intake (Δ = 30 days[(d)])** $AD(\Delta)_{Red\ marrow}$: 0.2 Gy for radionuclides with Z ≥ 90; 2 Gy for radionuclides with Z ≤ 89 $AD(\Delta)_{Thyroid}$: 2 Gy $AD(\Delta)_{Lung}$[(e)]: 30 Gy $AD(\Delta)_{Colon}$: 20 Gy $AD(\Delta')_{Foetus}$[(f)] 0.1 Gy	If the dose is projected, take: - Precautionary urgent protective actions immediately (even under difficult conditions) to keep doses below the generic criteria, public information and warning, urgent decontamination If the dose has been received, perform: -Immediate medical examination, consultation and indicated treatment -Contamination control -Immediate decorporation[(g)] (if applicable) -Registration for long term medical follow-up -Comprehensive psychological counselling

(a) $AD_{Red\ marrow}$ represents the average RBE weighted absorbed dose to internal tissue or organs (e.g., red marrow, lung, small intestine, gonads, thyroid, etc.) and lens of eye from irradiation in a uniform field of strongly penetrating radiation.

(b) Dose delivered to 100 cm^2 at the depth of 0.5 cm under the body surface in tissue due to close contact with a radioactive source (e.g. source carried in hand or pocket).

(c) The dose is to the 100 cm^2 derma (skin structures at a depth of 40 mg/cm^2 (or 0.4 mm) under the surface).

(d) $AD(\Delta)$ is the RBE-weighted absorbed dose delivered over the period of Δ by the intake (I_{05}) that will result in a severe deterministic effects in 5% of exposed persons.

(e) For purposes of this document "Lung" means the Alveolar-interstitial region of the respiratory tract.

(f) For this particular case Δ' means a period of *in utero* development

(g) The generic criteria for decorporation is based on projected dose without decorporation. Decorporation is defined as the biological processes facilitated by a chemical or biological agent by which incorporated radionuclides are removed from a human body.

TABLE IV-2**:** GUIDANCE VALUES FOR RESTRICTING EXPOSURE OF EMERGENCY WORKERS

Tasks	**Guidance value**[a]
Life saving actions	$H_P(10)^b < 500$ mSv This value may be exceeded under the circumstances where the benefit to others clearly outweighs the emergency worker's own risk and the emergency worker volunteers to take the action, and understands and accepts this risk.
Actions, to prevent severe deterministic health effects and Actions to prevent the development of catastrophic conditions	$H_P(10) < 500$ mSv
Actions to avert a large collective dose	$H_P(10) < 100$ mSv

[a] These values apply only to exposure from external penetrating radiation. The dose from non-penetrating external radiation and from intake or skin contamination need to be prevented by all possible means. Should this not be feasible, the effective dose and equivalent dose to an organ received shall be limited to minimize the health risk to the individual in line with the risk associated with the guidance values given here.

[b] $H_p(10)$ is the personal dose equivalent $H_p(d)$ where d = 10 mm.

Annex to Schedule IV

GENERIC CRITERIA FOR PROTECTIVE ACTIONS AND OTHER RESPONSE ACTIONS IN EMERGENCY EXPOSURE SITUATIONS TO REDUCE THE RISK OF STOCHASTIC HEALTH EFFECTS

A.1. Table A-1 in the Annex provides a set of generic criteria for use within the protection strategy and are based on reference levels within a range of 20-100 mSv and further details for specific actions in different timeframes.

A.2. For the thyroid, iodine thyroid blocking is an urgent protective action prescribed: (i) if radioactive iodine is involved, (ii) before or shortly after a release of radioactive iodine and (iii) only within a short period after the intake of radioactive iodine.

A.3. In the absence of national guidance, the generic criteria could be used as a basis for the development of national criteria. In exceptional situations, a higher value of generic criteria may be necessary, such as when replacement food/water is not available.

TABLE A-1: GENERIC CRITERIA FOR PROTECTIVE ACTIONS AND OTHER RESPONSE ACTIONS IN EMERGENCY EXPOSURE SITUATIONS TO REDUCE THE RISK OF STOCHASTIC HEALTH EFFECTS

Generic criteria		**Example protective actions and other response actions**
Projected dose that exceeds the following generic criteria: Take urgent protective actions and other response actions		
$H_{Thyroid}$:	50 mSv in the first 7 days	Iodine thyroid blocking
E: H_{Fetus}:	100 mSv in the first 7 days 100 mSv in the first 7 days	Sheltering, evacuation, decontamination, restriction of food, milk and water consumption, contamination control, public reassurance
Projected dose that exceeds the following generic criteria: Take protective actions and other response actions early in the response		
E: H_{Fetus}:	100 mSv per annum 100 mSv per period of *in utero* development	Temporary relocation, decontamination, replacement of food, milk and water, public reassurance
Dose that has been received and which exceeds the following generic criteria: Take longer term medical actions to detect and to effectively treat radiation induced health effects		
E:	100 mSv in a month	Screening based on equivalent doses to specific radiosensitive organs (as a basis for medical follow-up), basic counselling
H_{Fetus}:	100 mSv per period of *in utero* development	Counselling to allow informed decisions to be made in individual circumstances

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GLOSSARY

[TO BE REVIEWED AND UPDATED DURING THE EDITORIAL REVIEW]

["modified" has been placed in brackets after those terms for which the definition has been modified from the IAEA Safety Glossary, and "new term" has been placed after those terms that do not appear in the IAEA Safety Glossary]

The following meanings apply for the purposes of these Standards.

absorbed dose

See *dose quantities*.

accident

Any unintended *event*, including operating errors, equipment *failures* or other mishaps, the consequences or potential consequences of which are not negligible from the point of view of *protection* or *safety*.

activation

The *process* of inducing *radioactivity*.

activity

The quantity A for an amount of radionuclide in a given energy state at a given time, defined as:

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

where dN is the expectation value of the number of spontaneous nuclear transformations from the given energy state in the time interval dt.

ambient dose equivalent

See *dose equivalent quantities.*

annual dose

See *dose concepts.*

approval

The granting of consent by a regulatory body.

area

controlled area. (modified) A defined area in which specific *protection* measures and *safety* provisions are or could be required for controlling *exposures* or preventing the spread of *contamination* during normal working conditions, and preventing or limiting the extent of *potential exposures*.

supervised area. (modified) A defined area not designated as a *controlled area* but for which *occupational exposure* conditions are kept under review, even though specific *protection* measures and *safety* provisions are not normally needed.

assessment

The *process*, and the result, of analyzing systematically and evaluating the hazards associated with *sources* and *practices*, and associated *protection and safety* measures.

dose assessment. *Assessment* of the *dose(s)* to an individual or group of people.

safety assessment. *Assessment* of all aspects of a *practice* that are relevant to *protection and safety*; for an *authorized facility*, this includes *siting*, *design* and *operation* of the *facility*.

hazard assessment. (new term) Assessment of hazards associated with *facilities*, *activities* or *sources* within or beyond the borders of a State in order to identify:

(a) Those *events* and the associated areas for which *protective actions* may be *required* within the State;

(b) The actions that would be effective in mitigating the consequences of such *events*.

authorization

The granting by a *regulatory body* or other governmental body of written permission for a person or organization to conduct specified *activities*.

bioassay

Any *procedure* used to determine the nature, *activity*, location or retention of radionuclides in the body by direct (in vivo) measurement or by in vitro analysis of material excreted or otherwise removed from the body.

carers and comforters (new term)

Persons who willingly and voluntarily help (other than in their occupation) in the care, support and comfort of patients undergoing medical diagnosis or treatment.

clearance

The removal from *regulatory control* by the *regulatory body* of *radioactive material* or *radioactive* objects within notified or authorized *practices*.

clearance level

See *level.*

collective dose

See *dose*

committed dose

See *dose concepts* and *dose (2).*

committed effective dose

See *dose quantities.*

committed equivalent dose

See *dose quantities.*

confinement

Prevention or control of releases of radioactive material to the environment in operation or in accidents.

consumer product (modified)

Device produced for sale to the general public, such as a smoke detector, luminous dial or ion generating tube that contains a small amount of *radioactive material*.

constraint (modified)

A prospective and *source* related value of individual dose (dose constraint) or risk (risk constraint) used as a tool in the optimization of protection and safety of the source, which serves as a boundary in defining the range of options in optimization.

> Θ For occupational exposure, a constraint on individual dose to workers established and used by registrants and licensees to set the range of options in optimizing the protection and safety of the source.

Θ For public exposure, the dose constraint is a source related value established or approved by the government or regulatory body, taking into account the doses from planned operations of all controlled sources. The dose constraint for each particular source is intended, inter alia, to ensure that the sum of doses from planned operations of all controlled sources remain within the dose limit.

Θ For medical exposure, the dose constraint is a source related value used in optimizing the protection of carers and comforters and of persons exposed for biomedical research purposes.

containment

Methods or physical *structures* designed to prevent or *control* the release and the *dispersion* of *radioactive material*.

contamination

Radioactive material on surfaces, or within solids, liquids or gases (including the human body), where its presence is unintended or undesirable, or the process giving rise to its presence in such places.

controlled area

See *area.*

decontamination

The complete or partial removal of *contamination* by a deliberate physical, chemical or biological process.

defence in depth

A hierarchical deployment of different levels of diverse equipment and *procedures* to prevent the escalation of *anticipated operational occurrences* and to maintain the effectiveness of physical *barriers* placed between a *source* or *radioactive material* and *workers*, *members of the public* or the environment, in *operational states* and, for some *barriers*, in *accident conditions*.

deterministic effect

See *health effects (of radiation).*

diagnostic reference level (new term)

See *level.*

directional dose equivalent

See *dose equivalent quantities*.

discharge

Planned and controlled release of (usually gaseous or liquid) *radioactive material* to the environment.

disposal

1. Emplacement of *waste* in an appropriate *facility* without the intention of retrieval.

2. The act or *process* of getting rid of *waste*, without the intention of retrieval.

disposition

Consignment of, or arrangements for the *consignment* of, *radioactive waste* for some specified (interim or final) destination, for example for the purpose of *processing*, *disposal* or *storage*.

dose

1. A measure of the energy deposited by *radiation* in a target.

2. *Absorbed dose*, *committed equivalent dose*, *committed effective dose*, *effective dose*, *equivalent dose* or *organ dose*, as indicated by the context.

committed dose. *committed equivalent dose* or *committed effective dose*.

dose coefficient

Θ Used by the International Commission on Radiological Protection and others as a synonym for *dose per unit intake*, but sometimes also used to describe other coefficients linking quantities or concentrations of *activity* to *doses* or *dose rates*, such as the external *dose rate* at a specified distance above a surface with a deposit of a specified *activity* per unit area of a specified radionuclide. To avoid confusion, the term *dose coefficient* should be used with care.

dose concepts

annual dose. The *dose* due to *external exposure* in a year plus the *committed dose* from *intakes* of radionuclides in that year.

collective dose: The total *effective dose* incurred by a population.

Θ This is the sum of all of the *individual doses* to members of the population. If the *doses* continue for longer than a year, then the *annual individual doses* must also be integrated over time. Unless otherwise specified, the time over which the

dose is integrated is infinite; if a finite upper limit is applied to the time integration, the *collective dose* is described as 'truncated' at that time.
Θ Unit: man-sievert (man Sv). This is, strictly, just a *sievert*, but the unit man-sievert is used to distinguish the *collective dose* from the *individual dose* which a dosimeter would measure (just as, for example, 'person-hours' are used to measure the total effort devoted to a task, as opposed to the elapsed time that would be shown by a clock).
Θ When exposures occur over large populations, large geographical areas, or long time periods, the total collective effective dose is not a useful tool for making decisions because it may aggregate information inappropriately and could be misleading for selecting protective actions.

committed dose. The *lifetime dose* expected to result from an *intake*.

projected dose. (modified) The *dose* that would be expected to be received in the absence of planned protective actions.

residual dose. (modified) The *dose* expected to be incurred after *protective actions* have been fully implemented (or a decision has been taken not to implement any *protective actions*).

Θ This applies in an *existing exposure situation* or an *emergency exposure situation*.

dose constraint

See *constraint*.

dose equivalent quantities

ambient dose equivalent, $H^*(d)$. The *dose equivalent* that would be produced by the corresponding aligned and expanded field in the *ICRU sphere* at a depth *d* on the radius opposing the direction of the aligned field.

directional dose equivalent, $H'(d,\Omega)$. The *dose equivalent* that would be produced by the corresponding expanded field in the *ICRU sphere* at a depth *d* on a radius in a specified direction Ω.

personal dose equivalent, $H_p(d)$. The *dose equivalent* in soft tissue below a specified point on the body at an appropriate depth *d*.

Θ 'Soft tissue' is commonly interpreted as the *ICRU sphere*.

dose limit

See *limit*.

dose quantities

absorbed dose, *D.* (modified) The fundamental dosimetric quantity *D*, defined as:

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

where $\mathrm{d}\bar{\varepsilon}$ is the mean energy imparted to matter of mass d*m* by *ionizing radiation*.

Θ The energy can be averaged over any defined volume, the average *dose* being equal to the total energy imparted in the volume divided by the mass in the volume.

Θ *Absorbed dose* is defined at a point; for the average *dose* in a tissue or organ, see *organ dose*.

Θ The unit for absorbed dose is joule per kilogram (J kg^{-1}) and its special name is gray (Gy).

committed effective dose, *E(τ).* The quantity $E(\tau)$, defined as:

$$E(\tau) = \sum_{\mathrm{T}} w_{\mathrm{T}} \cdot H_{\mathrm{T}}(\tau)$$

where $H_{\mathrm{T}}(\tau)$ is the *committed equivalent dose* to tissue T over the integration time τ and w_{T} is the *tissue weighting factor* for tissue T. When τ is not specified, it will be taken to be 50 years for adults and the time to age 70 years for *intakes* by children.

committed equivalent dose, $H_T(\tau)$. The quantity $H_{\mathrm{T}}(\tau)$, defined as:

$$H_{\mathrm{T}}(\tau) = \int_{t_0}^{t_0+\tau} \dot{H}_{\mathrm{T}}(t)\mathrm{d}t$$

where t_0 is the time of *intake*, $\dot{H}_{\mathrm{T}}(t)$ is the *equivalent dose rate* at time t in organ or tissue T and τ is the time elapsed after an intake of *radioactive material*. When τ is not specified, it will be taken to be 50 years for adults and the time to age 70 years for *intakes* by children.

effective dose, *E.* The quantity *E*, defined as a summation of all the tissue *equivalent doses*, each multiplied by the appropriate *tissue weighting factor*:

$$E = \sum_{\mathrm{T}} w_{\mathrm{T}} \cdot H_{\mathrm{T}}$$

where H_T is the *equivalent dose* in tissue T and w_T is the *tissue weighting factor* for tissue T. From the definition of *equivalent dose*, it follows that:

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

where w_R is the *radiation weighting factor* for *radiation* R and $D_{T,R}$ is the average *absorbed dose* in the organ or tissue T.

Θ The unit for the effective dose is the same as for absorbed dose, J kg^{-1}, and its special name is *sievert* (Sv). An explanation of the quantity is given in Annex B of ICRP 103 [1].

Θ Effective dose should not be used to quantify higher doses or to make decisions on the need for any treatment related to deterministic effects.

equivalent dose, H_T. The quantity $H_{T,R}$, defined as:

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

where $D_{T,R}$ is the *absorbed dose* delivered by *radiation* type R averaged over a tissue or organ T and w_R is the *radiation weighting factor* for *radiation* type R. When the *radiation* field is composed of different *radiation* types with different values of w_R the *equivalent dose* is:

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

Θ The unit for the equivalent dose is the same as for absorbed dose, J kg^{-1}, and its special name is *sievert* (Sv). An explanation of the quantity is given in Annex B of ICRP 103 [1].

Θ Equivalent dose should not be used to quantify higher doses or to make decisions on the need for any treatment related to deterministic effects.

relative biological effectiveness weighted (RBE-weighted) absorbed dose, AD_T

The quantity $AD_{T,R}$, defined as:

$$AD_{T,R} = D_{T,R} \times RBE_{T,R}$$

where $D_{T,R}$ is the *absorbed dose* delivered by *radiation of* type R averaged over a tissue or organ T and $RBE_{T,R}$ is the *relative biological effectiveness* for *radiation of* type R in the production of severe deterministic effects in a tissue or organ T. When the *radiation* field is composed of different *radiation* types with different values of $RBE_{T,R}$, the *RBE-weighted absorbed dose* is given by:

$$AD_T = \sum_R D_{T,R} \times RBE_{T,R}$$ (from Ref. [32])

Θ The unit of *RBE-weighted absorbed dose* is the *gray (Gy),* equal to 1 J/kg.

Θ *RBE-weighted absorbed dose* is a measure of the *dose* to a tissue or organ designed to reflect the risk of development of severe deterministic effects.

Θ Values of *RBE-weighted absorbed dose* to a specified tissue from any type(s) of *radiation* can be compared directly.

effective dose

See *dose quantities*.

emergency

A non-routine situation 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* and conventional *emergencies* such as fires, release of hazardous chemicals, storms or earthquakes. It includes situations for which prompt action is warranted to mitigate the effects of a perceived hazard.

nuclear or radiological emergency. An *emergency* in which there is, or is perceived to be, a hazard due to:

1. The energy resulting from a nuclear chain reaction or from the decay of the products of a chain reaction; or
2. *Radiation exposure*.

emergency action level, EAL

See *level*.

emergency exposure situation (new)

See *exposure situations*.

emergency plan

A description of the objectives, policy and concept of *operations* for the response to an *emergency* and of the *structure*, authorities and responsibilities for a systematic, coordinated and effective response. The *emergency plan* serves as the basis for the development of other plans, *procedures* and checklists.

emergency preparedness

The capability to take actions that will effectively mitigate the consequences of an *emergency* for human health and *safety*, quality of life, property and the environment.

emergency procedures

A set of instructions describing in detail the actions to be taken by response personnel in an *emergency*.

emergency response

The performance of actions to mitigate the consequences of an *emergency* for human health and *safety*, quality of life, property and the environment. It may also provide a basis for the resumption of normal social and economic activity.

emergency response arrangements

The integrated set of infrastructural elements necessary to provide the capability for performing a specified function or task *required* in response to a *nuclear or radiological emergency*. These elements may include authorities and responsibilities, organization, coordination, personnel, plans, *procedures*, *facilities*, equipment or training.

emergency worker (modified)

Any person having a defined role as a worker in response to an *emergency*.

Θ Emergency workers may include those employed by registrants and licensees as well as personnel from responding organizations, such as police officers, fire-fighters, medical personnel and drivers and crews of evacuation vehicles.

employer (modified)

A person or organization with recognized responsibility, commitment and duties towards a *worker* in his or her employment by virtue of a mutually agreed relationship. (A self-employed person is regarded as being both an *employer* and a *worker*).

environment

The conditions under which people, animals and plants live or develop and which sustain all life and development; especially such conditions as affected by human activities.

Θ ***protection of the environment*** includes the protection of: non-human species, both animal and plant; environmental goods and services such as the production of food and feed; resources used in agriculture, forestry, fisheries and tourism; amenities used in spiritual, cultural and recreational activities; media such as soil, water and air; and natural processes such as carbon, nitrogen and water cycles.

environmental monitoring

See *monitoring*.

equilibrium equivalent concentration

The *activity concentration* of *radon* or *thoron* in *radioactive equilibrium* with its short lived progeny that would have the same *potential alpha energy* concentration as the actual (non-equilibrium) mixture.

Θ The *equilibrium equivalent concentration* of *radon* is given by

$EEC\ radon = 0.104 \times C(^{218}\mathrm{Po}) + 0.514 \times C(^{214}\mathrm{Pb}) + 0.382 \times C(^{214}\mathrm{Bi})$

where $C(x)$ is the concentration of nuclide x in air. 1 Bq/m3 *EEC radon* corresponds to 5.56 × 10–6 $\mathrm{mJ/m^3}$.

Θ The *equilibrium equivalent concentration* of *thoron* is given by

$EEC\ thoron = 0.913 \times C(^{212}\mathrm{Pb}) + 0.087 \times C(^{212}\mathrm{Bi})$

where $C(x)$ is the concentration of nuclide x in air. 1 Bq/m3 *EEC thoron* corresponds to 7.57 × 10–5 $\mathrm{mJ/m^3}$.

equilibrium factor

The ratio of the *equilibrium equivalent concentration* of *radon* to the actual *radon* concentration.

equivalent dose

See *dose quantities*.

event

In the context of the reporting and *analysis* of *events*, an *event* is any occurrence unintended by the *operator*, including operator error, equipment *failure* or other mishap, and deliberate action on the part of others, the consequences or potential consequences of which are not negligible from the point of view of *protection* or *safety*.

exemption

The determination by a *regulatory body* that a *source* or *practice* need not be subject to some or all aspects of *regulatory control* on the basis that the *exposure* (including *potential exposure*) due to the *source* or *practice* is too small to warrant the application of those aspects or that this is the optimum option for *protection* irrespective of the actual level of the *doses* or *risks*.

exemption level.

See *level*.

existing exposure situation

See *exposure situations*.

exposure

The act or condition of being subject to irradiation.

external exposure. *Exposure* to *radiation* from a *source* outside the body.

internal exposure. *Exposure* to *radiation* from a *source* within the body.

exposure, categories of

medical exposure. (modified) *Exposure* incurred by patients for the purpose of medical or dental diagnosis or treatment; by *carers and comforters*; and by volunteers in a programme of biomedical research involving their *exposure*.

Θ A patient is a person who is recipient of services of health care professionals and/or their agents that are addressed at (1) health promotion; (2) prevention of illness and injury; (3) monitoring of health; (4) maintenance of health; and (5) treatment of diseases, disorders, and injuries in order to obtain cure or, failing that, optimum comfort and function. Therefore, asymptomatic individuals are included in the definition of this term. For the purpose of these Standards, the term patient refers only to those undergoing radiological procedures.

occupational exposure. (modified) *Exposure* of *workers* incurred in the course of their work.

public exposure. (modified) *Exposure* incurred by *members of the public* from *sources* in *planned exposure situations*, *emergency exposure situations* and *existing exposure situations*, excluding any *occupational* or *medical exposure*. **exposure situations**

emergency exposure situation. (new term) An emergency exposure situation is a situation of exposure that arises as a result of an accident, a malicious act, or

any other unexpected event, and requires prompt action in order to avoid or reduce adverse consequences.

Θ Exposures can be reduced only by protective and other actions.

existing exposure situation. (new term) An existing exposure situation is a situation of exposure which already exists when a decision on the need for control needs to be taken.

Θ Existing exposure situations include exposure to natural background radiation; and exposure to residual radioactive material from past practices that were never subject to regulatory control, or were regulated but not in accordance with current standards, or from a nuclear or radiological emergency after an emergency exposure situation has been declared ended.

planned exposure situations. (new term) A planned exposure situation is a situation of exposure that arises from the planned operation of a source or from a planned activity that results in an exposure from a source.

Θ Since provisions for protection and safety can be made before embarking on the activity concerned, the associated exposures and their probability of occurrence can be restricted from the outset. The primary means of controlling exposure in planned exposure situations is by good design of installations, equipment and operating procedures. In planned exposure situations, a certain level of exposure is reasonably expected to occur.

exposure pathway

A route by which *radiation* or radionuclides can reach humans and cause *exposure*.

facilities and activities

A general term encompassing *nuclear facilities*, uses of all *sources* of *ionizing radiation*, all *radioactive waste management activities*, *transport* of *radioactive material* and any other *practice* or circumstances in which people may be exposed to *radiation* from naturally occurring or artificial *sources*.

medical radiation facility. (new term) A medical *facility* in which *radiological procedures* are carried out.

feed (new term)

Any single or multiple materials, whether processed, semi-processed or raw, which is intended to be fed directly to *food* producing animals.

fluence

[Definition to be added by technical editor]

food (new term)

Any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of "food" but does not include cosmetics or tobacco or substances used only as drugs.

graded approach

For a system of *control*, such as a regulatory system or a *safety system*, a *process* or method in which the stringency of the *control* measures and conditions to be applied is commensurate, to the extent practicable, with the likelihood and possible consequences of, and the level of *risk* associated with, a loss of *control*.

hazard assessment (new term)

see assessment

health authority (new term)

The governmental entity (at the national, regional or local level) responsible for policies and interventions, including the development of standards and provision of guidance, aimed at maintaining or improving human health, and has the legal power of enforcing compliance to such policies and interventions.

health effects (of radiation)

deterministic effect. A *health effect* of *radiation* for which generally a threshold level of *dose* exists above which the severity of the effect is greater for a higher *dose*.

Θ Such an effect is described as a *severe deterministic effect* if it is fatal or life threatening or results in a permanent injury that reduces quality of life.

Θ Deterministic effects are also referred to as 'harmful tissue reactions'.

stochastic effect. A *radiation* induced *health effect*, the probability of occurrence of which is greater for a higher *radiation dose* and the severity of which (if it occurs) is independent of *dose*.

health professional (modified)

An individual who has been formally recognized through appropriate national *procedures* to practise a profession related to health (e.g. medicine, dentistry, chiropractic, podiatry, nursing, medical physics, medical radiation technology, radiopharmacy, occupational health).

health screening programme (new term)

A programme in which a test or examination for the early detection of disease is performed on people.

health surveillance

See *workers' health surveillance*.

incident

Any unintended *event*, including operating errors, equipment *failures*, *initiating events*, *accident precursors*, *near misses* or other mishaps, or unauthorized act, *malicious* or non-malicious, the consequences or potential consequences of which are not negligible from the point of view of *protection* or *safety*.

individual monitoring

See *monitoring* (1).

inspection imaging devices (new term)

An imaging device designed specifically for screening persons or cargo conveyances for the purpose of detecting concealed objects within or on the human body or within cargo or a vehicle.

> Θ Some types of inspection imaging devices use ionizing radiation to produce images by backscatter, transmission or both. Other types of inspection imaging devices instead may utilize: electrical and magnetic sources, ultrasound and sonar, nuclear magnetic resonance, microwaves, terahertz rays, infrared radiation or visible light.

intake

1. The act or *process* of taking radionuclides into the body by inhalation or ingestion or through the skin.

2. The *activity* of a radionuclide taken into the body in a given time period or as a result of a given *event*.

interested party

A person, company, etc., with a concern or interest in the activities of an organization, business, system, etc.

> Θ The term *interested party* is used in a broad sense to mean a person or group having an interest in the performance of an organization. Those who can influence *events* may effectively become interested parties — whether their 'interest' is regarded as 'genuine' or not — in the sense that their views need to be considered. Interested parties have typically included the following: customers, owners, *operators*, employees, *suppliers*, partners, trade unions; the regulated industry or professionals; scientific bodies; governmental agencies or regulators (local, regional and national) whose responsibilities may cover nuclear energy; the media; the public (individuals, community groups and interest groups); and other States, especially neighbouring States that have entered into agreements providing for an exchange of information concerning possible transboundary impacts, or States involved in the export or import of certain technologies or materials.

investigation level

See *level*.

ionizing radiation

See *radiation*.

justification (modified)

1. The *process* of determining whether in a *planned exposure situation* a *practice* is, overall, beneficial, as required by the *System of Radiological Protection*, i.e. whether the benefits to individuals and to society from introducing or continuing the *practice* outweigh the harm (including *radiation detriment*) resulting from the *practice*.

2. The *process* of determining whether in an *emergency exposure situation* or an *existing exposure situation* a proposed *protective action* or *remedial action* is likely, overall, to be beneficial, as required by the *System of Radiological Protection*, i.e. whether the benefits to individuals and to society (including the reduction in radiation detriment) from introducing or continuing the *protective action* or *remedial action* outweigh the cost of such action and any harm or damage caused by the action.

kerma

[Definition to be added by technical editor]

level

clearance level. A value, established by a *regulatory body* and expressed in terms of *activity concentration*, at or below which *regulatory control* may be removed from a *source* of *radiation* within a notified or authorized practice.

diagnostic reference level (DRL). (modified) A *level* used in medical imaging to indicate whether, in routine conditions, the *dose* to the patient or the quantity of *radioactive material* administered in a specified *radiological procedure* is unusually high or low for that procedure.

emergency action level (EAL). A specific, predetermined, observable criterion used to detect, recognize and determine the *emergency class*.

exemption level. A value, established by a *regulatory body* and expressed in terms of *activity concentration*, total *activity*, *dose rate* or *radiation* energy, at or below which a *source* of *radiation* need not be subject to some or all aspects of *regulatory control*.

investigation level. The value of a quantity such as *effective dose*, *intake*, or *contamination* per unit area or volume at or above which an investigation should be conducted.

operational intervention level (OIL). (modified) A set *level* of a measurable quantity that corresponds to a generic criterion.

recording level. A level of *dose*, *exposure* or *intake* specified by the *regulatory body* at or above which values of *dose*, *exposure* or *intake* received by *workers* are to be entered in their individual *exposure* records.

reference level. (modified) In an *emergency exposure situation* or an *existing exposure situation*, the level of *dose* or *risk* or *activity* concentration above which it is inappropriate to plan to allow *exposures* to occur and below which optimization of protection should continue to be implemented.

Θ The chosen value for a reference level will depend upon the prevailing circumstances of the exposure under consideration.

licence

A legal document issued by the *regulatory body* granting *authorization* to perform specified *activities* related to a *facility or activity*.

licensee. The holder of a current *licence*.

licensee

See *licence*.

limit

The value of a quantity used in certain specified *activities* or circumstances that must not be exceeded.

dose limit. The value of the *effective dose* or the *equivalent dose* to individuals in planned exposure situations that is not to be exceeded.

operational limits and conditions. A set of rules setting forth parameter *limits*, the functional capability and the performance levels of equipment and personnel approved by the *regulatory body* for safe *operation* of an *authorized facility*.

management system

A set of interrelated or interacting elements (the system) for establishing policies and objectives and enabling the objectives to be achieved in an efficient and effective manner.

medical exposure

See *exposure, categories of*.

medical physicist (new term)

A *health professional,* with education and specialist training in the concepts and techniques of applying physics in medicine, competent to practise independently in one or more of the subfields (specialties) of medical physics.

Θ Competence of persons is normally assessed by the State by having a formal mechanism for registration, accreditation or certification of medical physicists in the various specialties (e.g. diagnostic radiology, radiation therapy, nuclear medicine). States that have yet to develop such a mechanism would need to assess the education, training and competence of any individual proposed by the licensee to act as a medical physicist and decide, based either on international accreditation standards or standards of a State where such an accreditation system exists, whether such an individual could undertake the functions of a medical physicist, within the required specialty.

medical radiation facility (new term)

See *facilities and activities*.

medical radiation technologist (new term)

A *health professional*, with specialist education and training in medical radiation technology, competent to carry out *radiological procedures,* on delegation from the *radiological medical practitioner,* in one or more of the specialties of medical radiation technology.

Θ Competence of persons is normally assessed by the State by having a formal mechanism for registration, accreditation or certification of medical radiation technologists in the various specialties (e.g. diagnostic radiology, radiation therapy, nuclear medicine). States that have yet to develop such a mechanism would need to assess the education, training and competence of any individual proposed by the licensee to act as a medical radiation technologist and decide, based either on international standards or standards of a State where such a system exists, whether such an individual could undertake the functions of a medical radiation technologist, within the required specialty.

medical radiological equipment (new term)

Radiological equipment, used in medical radiation facilities to perform radiological procedures, that either delivers an exposure to a person or directly controls or influences the extent of such exposure. The term applies to radiation generators, such as an X ray machine or a medical linear accelerator; to devices containing sealed sources, such as cobalt-60 teletherapy units; and to devices used in medical imaging to capture images, such as a gamma camera, image intensifier, or a positron emission tomography scanner.

member of the public

In a general sense, any individual in the population except, for *protection and safety* purposes, when subject to *occupational* or *medical exposure*. For the purpose of verifying compliance with the *annual dose limit* for *public exposure*, this is the representative person.

monitoring

[to be added during editorial review]

natural source

See *source*.

notification

A document submitted to the *regulatory body* by a person or organization to notify an intention to carry out a *practice* or other use of a *source*.

nuclear fuel cycle

All *operations* associated with the production of nuclear energy, including:

(a) Mining and processing of uranium or thorium ores;

(b) Enrichment of uranium;

(c) Manufacture of nuclear fuel;

(d) Operation of nuclear reactors (including research reactors);

(e) Reprocessing of spent fuel;

(f) All waste management activities (including decommissioning) relating to operations associated with the production of nuclear energy;

(g) Any related research and development activities.

nuclear or radiological emergency

See *emergency*.

(nuclear) security

The prevention and detection of, and response to, theft, *sabotage*, unauthorized access, illegal transfer or other *malicious* acts involving *nuclear material*, other *radioactive material* or their associated *facilities*.

occupancy factor (new term)

A typical fraction of the time for which a place is occupied by an individual or group.

occupational exposure

See *exposure, categories of*.

operational intervention level, OIL

See *level*.

optimization of protection (and safety) (modified)

The *process* of determining what level of *protection and safety* would result in the magnitude of individual doses and the number of people (workers and the public) exposed, and the probability and magnitude of *potential exposures* being "as low as

reasonably achievable, economic and societal factors being taken into account" (*ALARA*), as required by the *System of Radiological Protection*.

For medical exposures of patients, optimization of protection and safety is the management of the radiation dose to the patient commensurate with the medical purpose.

planned exposure situation

See *exposure situations*.

planning target volume (new term to IAEA Glossary, term in current BSS)

A geometrical concept used in radiation oncology for planning treatment with consideration of the net effect of movements of the patient and of the tissues to be irradiated, variations in size and shape of the tissue, and variations in beam geometry such as beam size and beam direction.

potential exposure

Exposure that is not expected to be delivered with certainty but that may result from an *accident* at a *source* or owing to an *event* or sequence of *events* of a probabilistic nature, including equipment *failures* and operating errors.

Θ *Potential exposure* includes prospectively considered exposures from a source due to an event or sequence of events of a probabilistic nature, including those resulting from an accident, equipment failures, operating errors, natural phenomena (such as hurricanes, earthquakes and floods) and inadvertent human intrusion (such as the intrusion into a near-surface waste disposal facility after institutional control ceases).

practice

Any human activity that introduces additional *sources* of *exposure* or additional *exposure pathways,* or modifies the network of *exposure pathways* from existing *sources*, so as to increase the *exposure* or the likelihood of *exposure* of people or the number of people exposed.

precautionary urgent protective action

A protective action in the event of a *nuclear or radiological emergency* which must be taken before or shortly after a release of *radioactive material,* or before an *exposure,* on the basis of the prevailing conditions to reduce the *risk* of *severe deterministic effects.*

projected dose

See *dose concepts*.

protection

(Against radiation):

radiation protection (also **radiological protection**). The *protection* of people from the effects of *exposure* to *ionizing radiation*, and the means for achieving this.

protection and safety

The *protection* of people against *exposure* to *ionizing radiation* or *radioactive material* and the *safety* of *sources*, including the means for achieving this, and the means for preventing *accidents* and for mitigating the consequences of *accidents* should they occur.

protective action (modified)

An action for the purposes of avoiding or reducing *doses* that might otherwise be received in an *emergency exposure situation* or an *existing exposure situation*.

longer term protective action. A *protective action* that is not an *urgent protective action*.

urgent protective action. A *protective action* in the event of an *emergency* which must be taken promptly (normally within hours) in order to be effective, and the effectiveness of which will be markedly reduced if it is delayed.

public exposure

See *exposure, categories of*.

qualified expert

An individual who, by virtue of certification by appropriate boards or societies, professional licences or academic qualifications and experience, is duly recognized as having expertise in a relevant field of specialization, e.g. medical physics, *radiation protection*, occupational health, fire safety, *quality assurance* or any relevant engineering or *safety* specialty.

quality assurance (QA)

The function of a *management system* that provides confidence that specified requirements will be fulfilled.

radiation

ionizing radiation. For the purposes of *radiation protection*, *radiation* capable of producing ion pairs in biological material(s).

Θ When used in IAEA publications, the term *radiation* normally refers only to *ionizing radiation*. The IAEA has no statutory responsibilities in relation to non-ionizing *radiation*.

radiation generator

See *source*.

radiation protection

See *protection.*

radiation protection officer

A person technically competent in *radiation protection* matters relevant for a given type of *practice* who is designated by the *registrant, licensee* or employer to oversee the application of relevant *requirements* such as those established in international *safety standards*.

radiation risks

- Detrimental *health effects* of *exposure* to *radiation* (including the likelihood of such effects occurring).
- Any other *safety* related *risks* (including those to ecosystems in the environment) that might arise as a direct consequence of:
  - *Exposure* to *radiation*;
  - The presence of *radioactive material* (including *radioactive waste*) or its release to the environment;
  - A loss of *control* over a nuclear reactor core, nuclear chain reaction, *radioactive source* or any other *source* of *radiation*.

radiation weighting factor, w_R

A number, as specified in the *System for Radiological Protection*, by which the *absorbed dose* in a tissue or organ is multiplied to reflect the *relative biological effectiveness* of the *radiation* in inducing *stochastic effects* at low *doses*, the result being the *equivalent dose*.

Θ Table to be added during editorial review.

radioactive material

Material designated in national law or by a *regulatory body* as being subject to *regulatory control* because of its *radioactivity*.

radioactive source

See *source*.

radioactive waste

See *waste, radioactive*.

radioactive waste management

See *waste management, radioactive*.

radioactive waste management facility

See *waste management facility, radioactive*.

radiological medical practitioner (new term)

A *health professional,* with education and specialist training in the medical uses of radiation, who is competent to independently perform or oversee procedures involving *medical exposure* in a given specialty.

> Θ Competence of persons is normally assessed by the State by having a formal mechanism for registration, accreditation or certification of such a health professional in the given specialty (e.g. radiology, radiation therapy, nuclear medicine, dentistry, cardiology, etc.). States that have yet to develop such a mechanism need to assess the education, training and competence of any individual proposed by the licensee to act as a radiological medical practitioner and decide, based either on international standards or standards of a State where such a system exists, whether such an individual can undertake the functions of a radiological medical practitioner, within the required specialty.

radiological procedure (new term)

A medical imaging procedure or a therapeutic procedure involving *ionizing radiation*, such as a procedure in diagnostic radiology, nuclear medicine, or radiation oncology, or any interventional, planning or image-guided procedure involving radiation, delivered by a *radiation generator*, by a device containing a *sealed source*, by an *unsealed source* or by a radiopharmaceutical administered to a patient.

radiopharmacist (new term)

A *health professional*, with education and specialist training in radiopharmacy, who is competent to prepare and dispense radiopharmaceuticals used for the purposes of medical diagnosis and therapy.

> Θ Competence of persons is normally assessed by the State by having a formal mechanism for registration, accreditation or certification of radiopharmacists. States that have yet to develop such a mechanism need to assess the education, training and competence of any individual proposed by the licensee to act as a radiopharmacist and decide, based either on international standards or standards of a State where such a system exists, whether such an individual can undertake the functions of a radiopharmacist.

radon

Radon-222

radon progeny

The short lived *radioactive* decay products of radon-222.

> Θ This includes the decay chain up to but not including lead-210, namely polonium-218 (sometimes called radium A), lead-214 (radium B), bismuth-214 (radium C) and polonium-214 (radium C′), plus traces of astatine-218, thallium-210 (radium C″) and lead-209. Lead-210 (radium D), which has a *half-life* of 22.3 years, and its *radioactive* progeny — bismuth-210 (radium E) and polonium-210 (radium F), plus traces of mercury-206 and thallium-206 — are, strictly, progeny of radon-222, but they are not normally included in the meaning of the term *radon progeny*, because they will not normally be present in significant amounts in airborne form. The stable decay product lead-206 is sometimes known as radium G.

recording level

See *level*.

reference level

See *level*.

referring medical practitioner (new term)

A *health professional* who, in accordance with national requirements, may refer individuals to a *radiological medical practitioner* for *medical exposure*.

registrant

See *registration.*

registration

A form of *authorization* for *practices* of low or moderate *risks* whereby the person or organization responsible for the *practice* has, as appropriate, prepared and submitted a *safety assessment* of the *facilities* and equipment to the *regulatory body*. The *practice* or use is authorized with conditions or limitations as appropriate.

registrant. The holder of a current *registration.*

regulatory body

An authority or a system of authorities designated by the government of a State as having legal authority for conducting the regulatory *process*, including issuing *authorizations*, and thereby regulating *nuclear*, *radiation*, *radioactive waste* and *transport safety*.

remedial action (modified)

The removal of a *source* or the reduction of its magnitude for the purposes of preventing or reducing *exposures* that might otherwise occur in an *existing exposure situation.*

relative biological effectiveness (RBE)

A measure of the relative effectiveness of different *radiation* types at inducing a specified *health effect,* expressed as the inverse ratio of the *absorbed doses* of two different *radiation* types that would produce the same degree of a defined biological *end point.*

> Θ Values of ***relative biological effectiveness*** for developing *deterministic effects* are selected to be representative of the *severe deterministic effects significant for emergency preparedness and response.* The tissue specific and radiation specific values of $RBE_{T,R}$ for developing selected *severe deterministic effects* are as shown in the table.

Health effect	Critical organ	Exposure[a]	$RBE_{T,R}$
Haematopoietic syndrome	Red marrow	External and internal γ	1
		External and internal *n*	3
		Internal β	1
		Internal α	2
Pneumonitis	Lung[b]	External and internal γ	1
		External and internal *n*	3
		Internal β	1
		Internal α	7
Gastrointestinal syndrome	Colon	External and internal γ	1
		External and internal *n*	3
		Internal β	1
		Internal α	0[c]
Necrosis	Tissue[d]	External β, γ	1
		External *n*	3
Moist desquamation	Skin[e]	External β, γ	1
		External *n*	3
Hypothyroidism	Thyroid	Intake of iodine isotopes[f]	0.2
		Other thyroid seekers	1

[a] External β, γ exposure includes the exposure due to bremsstrahlung produced within the source materials.

[b] Tissue of the alveolar-interstitial region of the respiratory tract.

[c] For alpha emitters uniformly distributed in the contents of the colon, it is assumed that irradiation of the walls of the intestine is negligible.

[d] Tissue at a depth of 5 mm below the skin surface over an area of more than 100 cm^2.

[e] Tissue at a depth of 0.5 mm below the skin surface over an area of more than 100 cm^2.

[f] Uniform irradiation of the tissue of the thyroid gland is considered to be five times more likely to produce deterministic effects than internal exposure due to low energy beta emitting isotopes of iodine, such as ^{131}I, ^{129}I, ^{125}I, ^{124}I and ^{123}I. Thyroid seeking radionuclides have a heterogeneous distribution in thyroid tissue. ^{131}I emits low energy beta particles, which leads to a reduced effectiveness of irradiation of critical thyroid tissues owing to the dissipation of the energy of the particles within other tissues.

remediation

Any measures that may be carried out to reduce the *radiation exposure* from existing *contamination* of land areas through actions applied to the *contamination* itself (the *source*) or to the *exposure pathways* to humans.

Θ Complete removal of the *contamination* is not implied.

Θ The more informal term *cleanup* is also used. If used, it should be used with the same meaning as *remediation*, not to attempt to convey a different meaning.

Θ The terms *rehabilitation* and *restoration* may be taken to imply that the conditions that prevailed before the *contamination* can be achieved again, which is not normally the case (e.g. owing to the effects of the *remedial action* itself). Their use is discouraged.

Θ See *decontamination*.

representative person (new term)

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

Θ ICRP Publication 101 indicates that *the dose to representative person "… is the equivalent of, and replaces, the mean dose in the 'critical group'* ", and provides guidance on assessing doses to the *representative person*. The concept of critical group remains valid.

residual dose

See *dose concepts*.

response organization

An organization designated or otherwise recognized by a State as being responsible for managing or implementing any aspect of an *emergency response*.

risk

A multiattribute quantity expressing hazard, danger or chance of harmful or injurious consequences associated with exposures or *potential exposures*. It relates to quantities such as the probability that specific deleterious consequences may arise and the magnitude and character of such consequences.

risk constraint (new term)

See *constraint*.

safety

See *protection and safety*.

safety assessment

See *assessment*.

safety culture

The assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, *protection and safety* issues receive the attention warranted by their significance.

safety standards

Standards of *safety* issued pursuant to Article III(A)(6)[54] of the Statute of the IAEA.

sealed source

See *source: radioactive source*.

security

See *(nuclear) security*.

severe deterministic effect.

See *health effects (of radiation): severe deterministic effect.*

source

Anything that may cause *radiation exposure* – such as by emitting *ionizing radiation* or by releasing *radioactive material* – and can be treated as a single entity for *protection and safety* purposes.

> Θ For example, materials emitting *radon* are *sources* in the environment, a sterilization gamma irradiation unit is a *source* for the *practice* of *radiation* preservation of food, an X ray unit may be a *source* for the *practice* of radiodiagnosis; a nuclear power plant is part of the *practice* of generating electricity by nuclear fission, and may be regarded as a *source* (e.g. with respect to *discharges* to the environment) or as a collection of *sources* (e.g. for occupational *radiation protection* purposes). A complex or multiple installation situated at one location or site may, as appropriate, be considered a single *source* for the purposes of application of international *safety standards*.

[54] "[The Agency is authorized…] To establish or adopt, in consultation and, where appropriate, in collaboration with the competent organs of the United Nations and with the specialized agencies concerned, standards of safety for protection of health and minimization of danger to life and property (including such standards for labour conditions)…"

natural source (modified) A naturally occurring *source* of *radiation*, such as the sun and stars (*sources* of cosmic *radiation*) and rocks and soil (terrestrial *sources* of *radiation*), or any other material whose *radioactivity* is for all intents and purposes due only to radionuclides of natural origin, such as products or residues from the processing of minerals; but excluding radioactive material for use in a nuclear installation and radioactive waste generated in such an installation.

radiation generator (new term) A device capable of generating *ionizing radiation*, such as X rays, neutrons, electrons or other charged particles, that may be used for scientific, industrial or medical purposes.

radioactive source (modified) A *source* containing *radioactive material* that is utilized for its *radioactivity*.

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

unsealed source (modified) A *radioactive source* in which the *radioactive material* is neither (a) permanently sealed in a capsule nor (b) closely bonded in a solid form.

standards dosimetry laboratory (new term)

A laboratory, designated by the relevant national authority, that possesses certification or accreditation necessary for the purpose of developing, maintaining or improving primary or secondary standards for radiation dosimetry.

stochastic effect

See *health effects (of radiation)*.

supervised area

see *area*.

suppliers

Any person or organization to whom a registrant or licensee delegates duties, totally or partially, in relation to the design, manufacture, production or construction

of a source.

Θ The term ‘suppliers’ includes designers, manufacturers, producers, constructors, assemblers, installers, distributors, sellers, exporters or importers of a source.

thoron

Radon-220

thoron progeny

The (short lived) *radioactive* decay products of *thoron*.

Θ Namely, polonium-216 (sometimes called thorium A), lead-212 (thorium B), bismuth-212 (thorium C), polonium-212 (thorium C′, 64%) and thallium-208 (thorium C″, 36%). The stable decay product lead-208 is sometimes known as thorium D.

tissue weighting factor, w_T

Multiplier of the *equivalent dose* to an organ or tissue, as given by the *System for Radiological Protection*, used for *radiation protection* purposes to account for the different sensitivities of different organs and tissues to the induction of *stochastic effects* of *radiation*.

Θ Table to be added during editorial review.

trigger

A level or condition that is selected to act as an initiator for setting off an action (especially a response).

unsealed source

See *source: radioactive source*.

urgent protective action

See *protective action.*

waste, radioactive

For legal and regulatory purposes, material for which no further use is foreseen that contains, or is contaminated with, radionuclides at concentrations or *activities* greater than *clearance levels* as established by the *regulatory body*.

waste management, radioactive

All administrative and operational *activities* involved in the handling, *pretreatment*, *treatment*, *conditioning*, *transport*, *storage* and *disposal* of *radioactive waste*.

waste management facility, radioactive

Facility specifically designed to handle, treat, condition, temporarily store or permanently dispose of *radioactive waste*.

worker

Any person who works, whether full time, part time or temporarily, for an *employer* and who has recognized rights and duties in relation to occupational *radiation protection.*

Θ A self-employed person is regarded as having the duties of both an *employer* and a *worker*.

workers' health surveillance

Medical supervision intended to ensure the initial and continuing fitness of *workers* for their intended tasks.