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No. 1732/Rev. 1

Model Regulations for the Use of Radiation Sources and for the Management of the Associated Radioactive Waste

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MODEL REGULATIONS FOR THE USE OF RADIATION SOURCES AND FOR THE MANAGEMENT OF THE ASSOCIATED RADIOACTIVE WASTE

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IAEA-TECDOC-1732/Rev. 1

MODEL REGULATIONS FOR THE USE OF RADIATION SOURCES AND FOR THE MANAGEMENT OF THE ASSOCIATED RADIOACTIVE WASTE

INTERNATIONAL ATOMIC ENERGY AGENCY
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FOREWORD

IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety, requires that governments establish laws and statutes to make provisions for an effective governmental, legal and regulatory framework for safety. The framework for safety includes the establishment of a regulatory body having the authority and responsibility for preparing regulations and for the oversight of their implementation.

Regulations provide the framework for regulatory requirements and conditions to be incorporated into individual authorizations or applications for authorization. Regulations also establish criteria for assessing compliance with regulatory requirements.

This publication provides information on the drafting of regulations and includes model regulations covering all aspects of the safe use of radiation sources and the safe management of the associated radioactive waste. It presents an internationally developed model designed to serve as a reference for use by States drafting regulations for the first time and to assist States with the periodic review of their existing regulations and regulatory guides.

The model regulations presented here are intended to implement requirements established in the IAEA safety standards, in particular IAEA Safety Standards Series Nos GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, and GSR Part 5, Predisposal Management of Radioactive Waste. In accordance with IAEA safety standards, these model regulations emphasize the adoption of a graded approach in the oversight and control of radiation safety of facilities and activities involving ionizing radiation.

They may be adapted according to the legal and regulatory infrastructure of the State and other local conditions, considering the available technical resources and the scope of facilities and activities potentially or already subject to regulatory control; they are not intended to be incorporated directly as published here.

This publication is a revision of IAEA-TECDOC-1732, Model Regulations for the Use of Radiation Sources and for the Management of the Associated Radioactive Waste. It may be considered a supplement to IAEA Safety Standards Series No. GSG-13, Functions and Processes of the Regulatory Body for Safety, to provide information to States on the development of regulations for the safe use and control of radiation sources in medicine, industry, research, agriculture and education, and the management of the associated radioactive waste.

The IAEA is grateful to all those who contributed to this publication. The IAEA officers responsible for this publication were V. Kamenopoulou and J. Bosnjak of the Division of Radiation, Transport and Waste Safety.

EDITORIAL NOTE

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Guidance and recommendations provided here in relation to identified good practices represent expert opinion but are not made on the basis of a consensus of all Member States.

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1. INTRODUCTION

1.1. BACKGROUND

To discharge its responsibility for the protection of people and the environment from harmful effects of ionizing radiation, a State needs to establish and implement effective regulatory control for the safety of the facilities and activities involving ionizing radiation and the management of radioactive waste.

At the State level, the regulatory control for radiation safety and the management of radioactive waste depends on the national legal and governmental infrastructure in line with international standards and global best practice, including the establishment in law of a regulatory body having defined responsibilities and functions for the oversight and control for radiation safety and the security of radioactive sources.

The safety principles set out in IAEA Safety Standards Series No. SF-1, Fundamental Safety Principles [1], provide the bases for the IAEA Safety Standards. Principle 2 states that "**An effective legal and governmental framework for safety, including an independent regulatory body, must be established and sustained."** IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety [2], establishes general requirements for an adequate legislative and regulatory framework for radiation and nuclear safety.

Many IAEA and other international publications have contributed to the Model Regulations proposed in this publication; the main sources of reference are described below.

IAEA Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [3], establishes requirements for the protection of people and the environment from harmful effects of ionizing radiation and for the safety of radiation sources that may deliver such exposure. The way in which States apply the requirements in GSR Part 3 [3] varies depending upon each State's legal system, technical resources, the scope of regulatory oversight, the scale of facilities and activities and related factors.

The Code of Conduct on the Safety and Security of Radioactive Sources [4] provides governments and national authorities with a set of principles, objectives and guidance relating to the safety and security of sources. It has three main objectives:

(a) To achieve and maintain a high level of safety and security of radioactive sources;
(b) To prevent loss of control and malicious use of radioactive sources;
(c) To mitigate or minimize the radiological consequences of accidents and malicious acts involving radioactive sources.

The Code of Conduct is supplemented by two guides: the Guidance on Import and Export of Radioactive Sources [5] provides guidance to States on the authorization of the export and import of category 1 and category 2 radioactive sources and the Guidance on the Management of Disused Radioactive Sources [6] advises on the management options of disused radioactive sources.

Member States are encouraged to formally commit to the Code of Conduct (and its Supplementary Guidance) and in so doing, to reflect its principles, objectives and guidance in their national legislation.

The generation of radioactive waste follows inevitably from the use of radioactive material in diverse fields including medicine, industry, research, agriculture and education. The objective of safe management of radioactive waste is to deal with the waste in a manner that protects individuals, society and the environment, now and in the future, without imposing undue burdens on future generations. This is achieved by adopting waste management practices compliant with international safety standards on radiation safety and radioactive waste management.

Requirements relating to the management of radioactive waste are established in IAEA Safety Standards Series Nos GSR Part 5, Predisposal Management of Radioactive Waste [7], and SSR-5 Disposal of Radioactive Waste [8]. Also, the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste (the Joint Convention) [9] includes a comprehensive set of obligations that Contracting Parties need to include in their national legislation.

A number of other IAEA publications relating to the regulatory framework for radioactive waste management are directed at specific parties, such as countries with small programmes generating relatively small amounts of radioactive waste. These will be referenced where applicable.

IAEA Safety Standards Series No. GSG-13, Functions and Processes of the Regulatory Body for Safety [10] together with the IAEA Technical Report Series No. 1002, Notification, Authorization, Inspection and Enforcement for the Safety and Security of Radiation Sources [11] provide guidance and complementary information on national regulatory infrastructure for the control of facilities and activities involving radiation sources.

Persons involved in the drafting of regulations and guidance for the safety of facilities and activities involving ionizing radiation, need to strive to become familiar with the provisions and intent of the publications listed above and thereafter, to an extent appropriate to the system of the State, reflect or transpose the content of these publications (and others) into national regulations.

This publication is a revision of the IAEA-TECDOC-1732, Model Regulations for the Use of Radiation Sources and for the Management of the Associated Radioactive Waste [12].The revision of the TECDOC-1732 was deemed necessary as, since its publication, most of the IAEA related publications have been superseded by new ones, new experience on the matter has been gained and ideas for improvement have been addressed.

1.2. OBJECTIVE

The objective of this publication is to present an approach to drafting regulations that considers international best practice and to set out this material in a manner that facilitates States' development or revision of regulations covering all aspects of the use of radiation sources and the safe management of the associated radioactive waste. Using the Model Regulations provided, States may draft and/or compare their existing regulations and regulatory guides with a model widely adopted internationally.

This TECDOC supplements GSG-13 [10] in providing practical advice to States on the development of regulations for the safe use and control of radiation sources and the management of the associated radioactive waste.

1.3. SCOPE

This publication includes advisory material on State regulations in relation to the use of radiation sources and for the management of the associated radioactive waste. It is an informational publication and contributes to the implementation of SF-1[1], GSR Part 1 (Rev. 1) [2], GSR Part 3 [3], GSR Part 5 [7], SSR-5 [8], the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management [9], the Code of Conduct [4] and its Supplementary Guidance [5, 6], GSG-13 [10], as well as several Safety Guides on radioactive waste management, references to which are given in the "notes for Model Regulations".

This TECDOC follows logically, the IAEA Handbook of Nuclear Law [13], and the Handbook of Nuclear Law - Implementing Legislation [14]. These Handbooks deal with legislative provisions that establish the regulatory infrastructure for radiation safety and radioactive waste management and determine its scope, responsibilities and functions.

The Model Regulations proposed in this publication address the use of radiation sources in medicine, industry, research, agriculture and education, together with the safety of radioactive waste generated from the radioactive material in these areas. They do not cover the safety of radioactive waste generated in nuclear installations such as research reactors, nuclear power plants or any other facility from the nuclear fuel cycle. Regarding emergency preparedness and response, the relevant requirements in GSR Part 3 [3] related mostly to the emergency exposure situation are considered. IAEA Safety Standards Series No. GSR Part 7, Preparedness and Response for a Nuclear or Radiological Emergency [15], presents the safety requirements and the arrangements to be made for preparedness and response for a nuclear or radiological emergency.

The Model Regulations proposed in this publication are not to be considered a comprehensive set of requirements; as such, they cannot be merely 'copied and pasted' into a national regulatory framework. They set out a range of examples of requirements in the format, structure and phrasing of a typical set of regulations.

1.4. STRUCTURE

This publication consists of six sections and two appendices. The first section provides some background information, identifies the objective and scope of the publication and presents its structure. Section 2 describes the legal and regulatory framework for the safe use of radiation sources and for the management of the associated radioactive waste. Section 3 presents some basic characteristics of the law for radiation safety and information on other related legislation and overlapping jurisdictions. Section 4 focuses on the regulatory process, starting with the scope of the regulations, refers to the main responsibilities for protection and safety, introduces the main regulatory functions and describes the regulatory flexibility needed. Section 5 deals with regulations and guides and describes their scope, the process for their development, the application of the method of the graded approach, demonstrates the differences between the performance based and prescriptive regulations, and presents more information on regulatory guides. Section 6 introduces the Model Regulations for the use of radiation sources and for the management of the associated waste. Appendix I includes an example of regulations based on the IAEA safety standards to be considered by regulatory bodies when drafting their national regulations on the use of radiation sources and the management of the associated waste. Appendix II contains an example of prescriptive regulations for diagnostic and interventional radiology in case the regulatory bodies prefer to use this style of regulations.

2. LEGAL FRAMEWORK FOR THE SAFE USE OF RADIATION SOURCES AND FOR THE MANAGEMENT OF THE ASSOCIATED RADIOACTIVE WASTE

2.1. GENERAL CONSIDERATIONS

States are required to establish a governmental, legal and regulatory framework to regulate the safety of facilities and activities involving radiation sources, the management of the associated radioactive waste, and for the radiation protection of people (patients, workers and the public) and the environment [2].

The number and types of radiation sources and associated facilities and activities, and the amount and nature of radioactive waste present in the country, together with the types of activities planned for the future, influence the provisions of the legislation, as well as the extent of the regulatory infrastructure that is needed to ensure safety.

In establishing or amending elements of the national legal framework, the relevant requirements of GSR Part 1 (Rev. 1) [2] are to be implemented. Requirements arising from the articles of the Joint Convention [9] as well as from the Code of Conduct for Safety and Security of Radioactive Sources and its Supplementary Guidance [4, 5, 6] are also to be implemented in the national legal framework, where appropriate.

The legal framework is expected to ensure, among other things, that:

(a) Adequate supporting infrastructure including facilities and services such as training, personal dosimetry, environmental monitoring, calibration services and radioactive waste management are available;
(b) Sufficient human resources are available in the State to support the framework and that the necessary research and development work is being carried out;
(c) A regulatory body is established, with the necessary authority, resources and effective independence;
(d) All aspects of safety, radiation protection, safeguards, physical protection and security related to the control of radiation sources and to the management of radioactive waste are covered in a comprehensive and integrated manner.

Guidance on the legal framework and on the comprehensive legislation to regulate nuclear energy based technologies can be found in Refs [13, 14].

2.2. NATIONAL LEGAL HIERARCHY

The set of the legal documents for the control of radiation sources and radioactive waste management is part of a State's legal system. Despite of all the variants that can be found from one country to the next, the most common hierarchy starts with the State's Constitution.

A distinction is commonly made between primary legislation represented by the law (statutory law enacted by a parliament at the top level) and secondary legislation, also called regulations (subsidiary legislation promulgated by appropriate governmental bodies). The latter is made up of regulations that are often technical in nature. Finally, irrespective of whether the government or regulatory body has developed prescriptive regulations, the regulatory body gives consideration to supplementing its regulations with supporting guides that specify performance expectations in fulfilling the requirements established by the primary or secondary legislation.

Such an approach allows for a more efficient and timely adjustment to changes in circumstances, including technological developments or new directions in a national programme for the use of nuclear energy and ionizing radiation sources.

More details on the national legal hierarchy are given in Refs [13, 14].

2.3. NATIONAL POLICIES AND STRATEGIES

States are required to develop national policies and implementation strategies for safety, education and training, enforcement and for the safe management of radioactive waste [2].

The government establishes its national policy for safety by means of different instruments, statutes and laws, which expresses a long term commitment to safety. The national policy is to be promulgated as a statement of the government's intent. The strategy sets out the mechanisms for implementing the national policy. Typically, the regulatory body, as designated by the government, is charged with the implementation of policies by means of a regulatory programme and a strategy. For example, the government establishes laws and adopts policies pertaining to safety, whereas the regulatory body develops strategies and promulgates regulations in implementation of laws and policies [2].

Even where some States follow a national policy that is indirectly reflected in various legal documents but not written up in a standalone document, it is considered good practice to ensure that the policy is approved through a legal instrument as a statement of the government's intent.

A national strategy describes the various arrangements to be put into place to ensure proper implementation of the national policy and to make sure that the interaction between different steps is adequately considered. Whereas the national policy indicates the preferred options the State intends to follow, the implementation strategy explains what coordinated actions are needed to put that policy into practice. The separation between policy and strategy is not always obvious.

The development of a national policy and a national strategy is an important component of the national framework for safety. It is considered as a process divided into two differentiated but complementary stages: one for the national policy and the other for the national strategy. The reason for that is that the development of a national policy and the development of national strategy are conceptually and practically two different endeavours. The first one is a policymaking effort aimed to determine the government's vision and to set long term policy goals. The government, based on accepted principles and values and after considering the opinion and interests of all the government stakeholders with assigned responsibilities and consulting with other relevant interested parties as needed, decides on the course of action, and gives policy direction to guide the government stakeholders with assigned responsibilities in the realization of the government's vision towards achieving defined long term policy goals.

The development of the national strategy is primarily a planning effort carried out based on the assessment of current needs and the identification of the most pressing priorities to reach the long term goals set down in the national policy. Thus, the development of the national strategy entails extensive consultations and cooperation between governmental and non-governmental stakeholders with direct involvement in the utilization of facilities and activities and in the provision of services, as well as consultations with the public and non-governmental organizations to the extent necessary, to decide on priorities, set down realistic short term goals, formulate an implementation plan and put the plan into practice.

Publications relevant to the development of a national policy and strategy for safety include GSR Part 1 (Rev. 1) [2] and GSR Part 3 [3]. States also need to consider the provisions in the legal instruments to which they adhere to (e.g. the Joint Convention [9]).

Ref. [16] will provide useful advice and examples.

3. THE LAW

3.1. LEGAL BASIS

The legal basis for the radiation safety, the safety of radioactive waste management and associated regulatory control is provided by the law issued by the supreme law-making organ of the State (e.g. the national legislature or parliament). Guidance and model provisions for drafting or revising the law are given in Refs [13, 14].

3.2. BASIC REQUIREMENTS

The regulatory system adopted in a particular State has to conform to the legal practice of that State, but the objective is the same, whatever the system. Basic requirements and obligations are decided upon by the legislator and the detail of how this is achieved could be provided in subordinate legislation (regulations). When revising regulations, there might be a difference between the basic requirements and obligations that don't need to change often and those that may need to change more often as circumstances change. If basic requirements and obligations change, the implications might be of sufficient importance to require attention of the legislature.

3.3. RELATED LEGISLATION AND OVERLAPPING JURISDICTIONS

Radiation sources and radioactive waste are associated with different applications that might create risks to people and the environment. They therefore merit control from various perspectives. Examples of such cross-cutting matters are to be found in the fields of environmental protection, health, industrial safety, medicine, security, mining, customs and excise, transportation and movement of goods, etc.

Also, in many States, legislation and regulatory authorities responsible for health and safety, environmental protection, mining etc. existed prior to the establishment of legislation and the regulatory body responsible for radiation safety and oversight of the management of radioactive waste.

Two actions can be taken to avoid gaps and overlaps in the radiation safety and the safety of the radioactive waste management infrastructure; to aid co-operation of governmental organizations; and to ensure that legislation covers all aspects of radiation safety and clearly allocates responsibilities between the government agencies. The first action is to examine the existing related legislation to understand how the involved governmental organizations might be affected and the extent to which these activities might already be covered by existing legislation. The second action is to involve the principal parties (stakeholders) in the development of legislation to ensure consistency and avoid gaps and overlaps. The latter is typically accomplished by forming an inter-agency drafting committee having appropriate technical and legal competence.

Also, the legislator needs to pay attention to the clear allocation of responsibilities between the various authorities. In particular, the powers and responsibilities of the regulatory body regulating radiation safety and radioactive waste management have to be clearly defined in the legislation establishing it.

The approach by States to the coordination and cooperation between government ministries and agencies will depend on national measures and culture.

Mechanisms to resolve juridical conflicts between national authorities are also necessary. For example, a memorandum of understanding between authorities needs to be formulated to clearly define the conditions under which either authority will take lead regulatory responsibility and how they will operate in a co-coordinated manner to limit regulatory gaps and overlaps. Finally, in addition to such legal mechanisms, good personal communication between members of the various regulatory authorities is probably the most efficient method to defuse potential conflicts before they arise.

It is a common practice that the establishment of an appropriate legal framework and regulatory infrastructure needs to proceed in steps. These steps include:

(a) Governmental commitment to radiation and waste safety; this is a prerequisite to reach the desired objective;
(b) Establishment of the national inventory of radiation sources, radioactive waste and waste streams present or anticipated in the country, to prioritize the operational activities;
(c) Establishment by the government of a national policy on radiation safety and radioactive waste management and its implementation through appropriate strategies;
(d) Involvement of agencies and technical experts with major interest in radiation safety and waste management (interested parties) in the process of assessing, drafting and/or revising the legislation;
(e) Establishment of a regulatory body through the implementation of the law;
(f) Development of regulations and guidance for the radiation safety and radioactive waste management;
(g) Development of import/export controls (at least for Category 1 and 2 radioactive sources);
(h) Availability or development of technical support services;
(i) Implementation of the regulatory system.

The text in Section 3.3 is based on Refs [10, 17].

4. THE REGULATORY PROCESS

4.1. SCOPE OF REGULATION

Most regulations, including those that address matters other than radiation safety, contain statements about their scope. The scope of a regulation establishes the boundaries for the regulation in defining, as precisely as practicable, what the regulatory requirements apply to, and who is responsible for applying, or complying with, the requirements.

The legal and regulatory framework needs to clearly specify those practices and activities within the practices (or facilities and activities) that are to be included in the scope of regulation.

The regulations are expected to specify if there are any exclusions from regulatory requirements. Exposures that are deemed to be not amenable to control, such as those from ^{40}K in the body and cosmic radiation at the surface of the earth, need to be specifically excluded from the overall scope of the legal and regulatory framework.

Additionally, the regulations need to determine when the regulatory body may exempt certain practices or sources within practices from some or all regulatory radiation safety requirements. Similarly, the legal and regulatory framework needs to make provisions for the regulatory body to approve which sources, including materials and objects, may be cleared from regulatory control. Exemption and clearance levels need to be specified in the regulations: schedule I of GSR Part 3 [3] provides the basis for this.

4.2. RESPONSIBILITY FOR PROTECTION AND SAFETY

National legislation provides the statutory basis for establishing requirements for protection and safety. One of the fundamental requirements in this regard is that the prime responsibility for protection and safety rests with the person or organization responsible for a facility or an activity that give rise to radiation risks (see Requirement 4 of GSR Part 3 [3] and Requirement 5 of GSR Part 1 (Rev. 1) [2]). The identification of the responsible person or organization is generally addressed in the regulations. Additionally, the legislation confers to the regulatory body the authority to require such persons or organizations to comply with stipulated regulatory requirements, as well as to demonstrate such compliance.

The responsible person or organization, in addition to submitting a notification to the regulatory body, may also have to apply for an authorization to conduct the practice, unless the notification of the facility or activity to regulatory body is considered sufficient (see paragraph 3.7 of GSR Part 3 [3]). The authorization may take the form of a registration or a licence. In terms of the graded approach to regulation, the decision as to which of these requirements apply in a given situation depends on the characteristics of the practice or the source within a practice, and on the likelihood and magnitude of exposures. In case of authorized practices, the regulations provide the means for placing on registrants and licensees whatever obligations are necessary to ensure the protection and safety of people and the environment.

Provisions for the identification of persons or organizations responsible for the radiation safety of facilities and activities and for the protection of people and the environment need to be included in the regulations, for example:

(a) The authorized parties (also referred to as registrants and licensees as according to Refs [2,3] the authorization takes the form of a registration or a licence);
(b) The applicants, if there are responsibilities that concern the phase of the application for an authorization.

Different national legal documents use different terms for the same concept, such as licence, authorization, permit, certificate. In the present publication the term ‘authorization’ is used to generally describe both registration and licensing, according to the IAEA Nuclear Safety and Security Glossary 2022 [17].

4.3. THE FUNCTIONS OF THE REGULATORY BODY FOR SAFETY

The regulatory body is an authority or a system of authorities designated by the government as having legal authority for conducting the regulatory process, including issuing authorizations,

and thereby regulating nuclear, radiation, radioactive waste and transport safety. The regulatory body is generally a national entity, established and empowered by law, whose organization, management, functions, processes, responsibilities and competences are subject to the requirements of IAEA safety standards [17]. Note that:

(a) The concept of the national competent authority for the regulation of transport of radioactive material in accordance with IAEA Safety Standards Series No SSR-6 (Rev. 1), Regulations for the Safe Transport of Radioactive Material [18], is included in this description, as is the regulatory body for protection and safety;
(b) This definition includes the one used in the Code of Conduct [4], which concerns only the regulatory control of the radioactive sources and the regulatory body is referred as: "An entity or organization or a system of entities or organizations designated by the government of a State as having legal authority for exercising regulatory control with respect to radioactive sources, including issuing authorizations, and thereby regulating one or more aspects of the safety or security of radioactive sources."

The core functions and responsibilities of a regulatory body, to be conferred through the legislation, are given in GSR Part 1 (Rev. 1) [2] and GSG-13 [10] and are grouped as follows: regulations and guides (development, review and promotion); notification and authorization; review and assessment; inspection; enforcement; emergency preparedness and response; communication and consultation with interested parties.

The regulatory body needs to specify the purposes of the various documents in the legal framework that are necessary to perform its functions. The documents are usually categorized, as legislation and regulations (mandatory by law), supporting guides (usually not mandatory) to be used either by the authorized parties or by the regulatory body (internal guidance) and other relevant documents. Internationally recognized standards and recommendations as well as technical standards developed by organizations working in various technological fields may be referenced by the regulatory body in its regulations and guides or in the authorization conditions or may be proposed by the authorized party in the authorization process [10].

GSG-13 [10] and IAEA Safety Standards Series No. GSG-12, Organization, Management and Staffing of the Regulatory Body for Safety [19] provide recommendations on the functions, processes, organization, management and staffing of a regulatory body for safety. In particular, paragraphs 3.10 – 3.27 of GSG-13 [10] address the responsibility of the regulatory body with regard to the development of regulations and guides.

4.4. REGULATORY FLEXIBILITY

The regulatory body has a clear obligation to apply its own regulations when exercising its functions and powers.

However, there may be cases that the regulatory body considers — or the applicant or authorized party demonstrates — that a particular prescriptive requirement does not seem appropriate and that there are alternative ways to achieve a satisfactory level of protection and safety. Such rare cases require a certain regulatory flexibility from the regulatory body, for example by:

(a) Imposing safety requirements in addition to those contained in the regulations, through conditions placed on the authorization, or by issuing an order after an authorization has been granted;

(b) Granting exemptions from certain regulatory requirements (under specific conditions), which relieve authorized parties from applying the requirements of the regulations to a practice or source if certain exemption criteria are met.

4.5. FRAMING OF REGULATORY REQUIREMENTS

There may be various ways in which the requirements of IAEA safety standards can be incorporated into regulations. The government or regulatory body, when developing regulations, may identify the most practicable options and compare the advantages and disadvantages of each before selecting the best option as a regulatory requirement. The way in which a requirement is formulated and incorporated into the regulations can have a significant influence on the regulatory and financial burden on registrants and licensees.

5. REGULATIONS AND GUIDES

5.1. OBJECTIVE

Requirement 32 of GSR Part 1 (Rev. 1) [2] states that "**The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based.**"

Requirement 33 of GSR Part 1 (Rev. 1) [2] states that "**Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and technical standards and of relevant experience gained**."

Requirement 34 of GSR Part 1 (Rev. 1) [2] states that "**The regulatory body shall notify interested parties and the public of the principles and associated criteria for safety established in its regulations and guides and shall make its regulations and guides available**."

The system of regulations and guides needs to be in accordance with the legal system of the State. The regulatory requirements for radiation safety will be based on the nature and extent of the facilities and activities to be regulated as well as the associated occupational, medical and public exposures. The regulations and guides specify the requirements and associated criteria for ensuring the protection of people and the environment.

Regulations and guides are a means for the regulatory body to: ensure that regulatory control is stable, unambiguous and consistent; emphasize the continuous enhancement of safety as a general objective; and build confidence among interested parties [2].

The regulatory body is required to be able to justify its decisions if they are challenged (see paragraph 4.25 of GSR Part 1 (Rev. 1) [2]). The provision of regulations and guides also enables the regulatory body to inform authorized parties and applicants of the objectives, principles and associated criteria for safety on which its requirements, judgements and decisions, in connection with its reviews and assessments, inspections and enforcement actions, are based.

Therefore, the objectives of regulations and guides are to ensure the stability and consistency of regulatory control and to prevent subjectivity in decision making by individual staff members of the regulatory body.

Regulations might be supported by separate practice-specific prescriptive and detailed regulatory documents (e.g. guides or codes of practice) describing how to meet the specific regulatory expectations.

5.2. APPLICATION OF A GRADED APPROACH TO REGULATORY CONTROL

All regulatory functions need to be consistent with the magnitude of the possible radiation risks arising from the facility or activity. This approach takes into account any exposures to radiation, and discharges or releases of radioactive substances in normal operation, anticipated operational occurrences and accident conditions, as well as the possibility of events with a very low probability of occurrence, without neglecting very low probability events with potentially high consequences (see paragraphs 2.1–2.10 of GSG-13 [10]).

Paragraph 3.9 of GSG-13 [10] states:

> "The regulatory body should establish a system to ensure that the development and implementation of regulations and guides is based on a graded approach, such that the application of regulatory requirements is commensurate with the radiation risks associated with the type of facility or activity."

When developing the regulations and guides, the following specific factors may be considered by the regulatory body in accordance with a graded approach:

(a) The need for new or updated regulations or guides in a specific area;
(b) The scope of the regulations and guides;
(c) The priorities for the development of regulations and guides;
(d) The necessary resources for the development of regulations and guides.

More information on the application of a graded approach in regulating the safety of radiation sources, including the development of regulations and guides, is available in IAEA-TECDOC-1974, Application of a Graded Approach in Regulating the Safety of Radioactive Sources [20].

5.3. REGULATIONS

The principal purpose for establishing regulations (or decrees, bylaws, etc – in accordance with the legal framework of the State) is to codify the legal requirements for ensuring the safe use of radiation sources and management of the associated radioactive waste. The regulations establish the administrative requirements for notification, authorization (by registration or licensing), inspection and enforcement, as well as the technical requirements that are considered essential from the standpoint of ensuring radiation safety of facilities and activities and the protection of workers, patients, public and the environment.

Regulations are generally issued by a government minister or the regulatory body for safety, as specified in the law. Whereas the law establishes the general framework, the regulations give specific requirements on how the law is to be applied in practice.

Nevertheless, regulations are still by necessity general in their application. They may apply to particular types of activities but are not usually specific to any one facility or activity. Other safety requirements, such as those applicable for only a short duration or relating to a particular characteristic of an individual facility or activity, can be specified in mandatory conditions attached to the authorization. However, the extent to which detailed provisions are made in

authorization conditions will depend upon the legal system and the approach to authorization of the State concerned [10].

As regulations are commonly more technical than the corresponding law, they need to be clear, easy to understand, unambiguous and precise for avoiding misinterpretation. The requirements established in GSR Part 3 [3], GSR Part 1 (Rev. 1) [2] and other IAEA safety requirements publications are intended to be incorporated in national regulations. However, they need to be adapted considering local circumstances, technical resources, the type and scale of facilities and activities, and other factors that determine the potential for their application. The structure and content of regulations will be founded on early decisions about the specifications for their scope, exposures to be excluded, practices and sources to be exempted and clearance levels to be defined.

5.4. DEVELOPMENT OF REGULATIONS

In developing regulations, the regulatory body is required to involve consultation with interested parties (see paragraph 4.27 of GSR Part 1 (Rev. 1) [2]) and take account of relevant national and international experience.

The relevant requirements established in the IAEA Safety Standards Series, with any necessary adaptations to take account of factors such as national situations, technical resources and the scale of the facilities concerned, provide the basis for the development of regulations. Due account also needs to be taken of any international conventions to which the State is a party, and of internationally recognized standards that may be relevant, such as those published by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC).

Care needs to be taken to ensure that the text of regulations: is consistent with, and closely linked to the law under which they fall; is clear, easy to understand, unambiguous and precise; covers all necessary aspects; avoids conflicts with other national regulations or laws; and does not give rise to unrealistic conditions of authorization.

Regulations and guides are required to be reviewed from time to time and amended where necessary (see Requirement 33 of GSR Part 1 (Rev. 1) [2]). Amendments are driven by available scientific information, advances in technology, feedback from users and operating experience within the regulatory body. Information obtained from national and international activities is to be considered.

When regulations are not established directly by the regulatory body, mechanisms established within the legal and governmental framework have to ensure that such regulations are developed and issued in a timely manner. Paragraph 3.5 of GSG-13 [10] states that “The regulatory body should advise the government on the need for regulations on matters affecting safety to be established or adopted.”

5.5. PERFORMANCE BASED VERSUS PRESCRIPTIVE REGULATIONS

The development of any particular regulation on the safe management of radiation sources and radioactive waste involves a balance between two differing requirements: the need for flexibility to permit easy adaptation of the regulations to evolving circumstances and technology, versus the need to include detailed requirements for ease in determining when the requirements are being met. A ‘performance based’ regulation, applicable in the first case, is

more general and simply specifies the overall safety requirements and basic operational parameters (that is, 'what' is to be accomplished as safety objectives). A 'prescriptive' regulation, applicable in the second situation, is more specific and states in greater detail 'how' to achieve such safety objectives.

In practice, most regulations contain both performance and prescriptive requirements, but can often be characterized as being either predominantly performance or prescriptive based.

An example of performance based regulations would be one of which that requires the user to plan and organize operations so that exposures are maintained as low as reasonably achievable and demonstrate this by using 'adequate' workplace monitoring and 'appropriate' instruments. It might also require the maintenance of 'adequate' records to demonstrate compliance. The equivalent prescriptive regulation would be more specific and might define exactly how to achieve adequate restriction of exposure and when and where to conduct workplace monitoring, what type of instrument to be used and how and what records to be maintained.

Therefore, performance based regulations are focused on objectives such as what is to be achieved in terms of safety. They can be made applicable to a range of activities and, if carefully drafted, do not need to be changed frequently to keep up to date with changing technology. However, they need to be interpreted in relation to each different situation. This requires a higher level of general knowledge and experience from both the regulatory body staff and the users than is needed for prescriptive regulations.

Prescriptive regulations are largely specific to particular types of facility or activity and provide the regulatory staff and the user with clearly defined requirements for a particular practice. They prescribe what to do to comply with the regulatory requirements and how to do it to achieve an adequate level of safety.

In principle, prescriptive regulations facilitate review and assessment, authorizations, and inspections. They enable the authorization and inspection process to focus on simple verification of compliance. However, a highly prescriptive approach can have an undesirable side effect as it can lead to a simple 'checking-of-compliance culture' rather than to a safety culture, unless positive steps are taken to prevent it. Prescriptive regulations require a more detailed knowledge and considerable experience of the specific activity in question by the drafters of the regulations. They are narrowly applicable to a specific situation and may need to be amended frequently to keep pace with technological changes. They are best suited to widespread practices where the equipment and procedures do not vary significantly among users. Due consideration is to be given that the prescriptive regulations need frequent amendments to follow the evolution of the technology.

The choice depends also on the approach followed at the national level. Generally, in practice, national regulations will often combine performance based requirements with prescriptive requirements. The relative importance of these two approaches depends upon national policies and strategies, because some States have a strongly prescriptive approach to all their regulations and others do not. The level of experience of a regulatory body, the knowledge and experience of the authorized parties and the maturity of the whole infrastructure for safety are to be considered[1].

[1] The Model Regulations proposed in this publication are mostly performance oriented. An example of prescriptive regulations is given in Article 72 in Appendix II.

5.6. REGULATORY GUIDANCE

Regulatory guides are normally issued by the regulatory body to provide detailed operational and technical guidelines to ensure that legislative and regulatory requirements are satisfied. They are meant to explain to an applicant or a licensee what the regulatory body considers to be an acceptable practice but may not necessarily represent obligations.

Regulatory guides are subject to revision and amendment with changes in the use of radioactive material and technical developments, or changes in the national policy or in international radiation protection and safety standards.

The level of detail in regulatory guides may vary in individual States and is influenced by several factors such as the number and extent of facilities and activities subject to the legislation. In some States, guidance is given on a case by case basis, but such a system is most applicable when only one or two similar facilities or activities are subject to control.

6. THE MODEL REGULATIONS

The Model Regulations proposed in Appendix I of this TECDOC are primarily based on the IAEA Safety Standards [2, 3, 7] and on the Code of Conduct on the Safety and Security of Radioactive Sources [4]. They provide an example of how regulations are commonly structured, of the topics to be covered and of the way in which they can be covered.

Given their nature, the Model Regulations cannot be simply copied into national regulations. Rather, they need to be considered as a catalogue of examples from which national authorities can select the parts that apply to their particular situation. National regulations need to be consistent not only with the text of the national law, but also with the international agreements to which the State is a party. National regulations are always closely linked to the law that they are implementing.

Usually, the regulations are written in the future or present tense, depending on the general legislative system of the State. These Model Regulations are formulated in the future tense; however, the user can adapt the text accordingly.

As the regulations are implemented by the applicants and the authorized parties, the proposed text is addressed to them.

Throughout the text, the regulatory body can identify actions that are to be implemented by them or by the government. They therefore need to pay particular attention to such issues that are prerequisites for the implementation of the regulations by interested parties.

For the purpose of this publication and in particular of Appendix I, which contains the Model Regulations, the following conventions have been applied:

(a) The words ‘shall’ and ‘must’ are deliberately used in order to convey language appropriate for the Model Regulations. It is stressed that these are included in example text and are not to be interpreted as consensus based requirements or recommendations (i.e. as is the case with the IAEA safety standards);
(b) Text from IAEA Safety Standards Series publications is not formatted as quoted text, as the Model Regulations are based almost entirely on the IAEA Safety Standards Series publications included in the list of references;

(c) The articles of the Model Regulations express the requirements, the text of which may be adapted to local circumstances;
(d) The notes indicate text that is not to be included in the regulations but that is provided for the attention of the interested parties and/or the regulatory body. Underlined text identifies actions to be implemented by the government or the regulatory body.

APPENDIX I.

MODEL REGULATIONS FOR THE USE OF RADIATION SOURCES AND FOR THE MANAGEMENT OF THE ASSOCIATED RADIOACTIVE WASTE

PART 1 - GENERAL PROVISIONS

Note:

The General Provisions set out the broad powers of the regulatory body for the performance of its functions and encompass potential situations that might not be contemplated by the more detailed regulatory requirements that follow.

Article 1: Preamble

Taking into consideration [*insert the Law and other legal documents, linked to the Regulations, as well as any relevant data according to the State's legal system*].

These Regulations have been prepared on the basis of International Atomic Energy Agency (IAEA) standards and international best practices.

Article 2: Purpose

1. These Regulations specify the basic requirements:
   (a) For protection of people against exposure to ionizing radiation, for the safety of radiation sources, for the safety of radioactive waste management and for protection of the environment, hereinafter termed 'protection and safety';
   (b) To implement the State's international commitments relevant to radiation protection and safety.

2. These Regulations shall not relieve any (authorized or not) legal or natural person of prime responsibility for safety, nor from the duty to take any such actions as may be appropriate and necessary to protect the health and safety of people and the environment.

3. The application of these Regulations shall be in accordance with a graded approach and shall also conform to any requirements specified by the regulatory body. Not all the provisions of these Regulations are relevant for every practice or source, or for all the actions specified in the scope (Article 3).

Article 3: Scope

1. These Regulations apply to all situations involving exposure to ionizing radiation that is amenable to control. Exposures deemed not amenable to control are out of scope of these Regulations.

2. These Regulations apply to all facilities and activities giving rise to radiation risks and to the three exposure situations (planned, existing and medical) and their categories of exposure (occupational, public and medical exposure), as applicable.

Notes:

For certain facilities and activities, such as nuclear installations, radioactive waste management facilities and activities, decommissioning, emergency planning and response, nuclear security, safeguards and the transport of radioactive material, other safety requirements, complementary to these Regulations, also apply.

Further clarification regarding the situations and categories of exposure are given in IAEA GSR Part 3 [3].

3. These Regulations apply to the following practices in planned exposure situations:

   (a) The production, supply and transport of radioactive material including sealed sources and unsealed sources, of devices that contain radioactive material and of consumer products;
   (b) The production and supply of devices that generate ionizing radiation;
   (c) The use of radiation or radioactive material for medical, industrial, veterinary, agricultural, legal or security purposes and the use of associated equipment, software or devices which may contribute to the likelihood and magnitude of exposure to radiation;
   (d) The use of radioactive material or radiation generators for education, training or research and the conduct of activities for such purposes that potentially or certainly involve exposure to radiation;
   (e) Mining and processing of raw materials that involve exposure to radioactive material including naturally occurring radioactive material (NORM);
   (f) Any other practice as specified by the regulatory body, that introduces additional risk 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 or the number of people exposed.

4. The requirements for planned exposure situations also apply to exposure as follows:

   (a) Facilities that contain radioactive material and facilities that operate radiation generators, including nuclear installations, medical radiation facilities, veterinary radiation facilities, facilities for the management of radioactive waste, installations for the processing of radioactive material, irradiation facilities, and mineral extraction and mineral processing facilities that involve or could involve exposure to radiation;
   (b) Individual sources of radiation, including sources within the types of facility listed in paragraph 4(a) in accordance with the requirements of the regulatory body.

Notes (planned exposure situations):

As guidance, the regulatory body may provide examples of planned exposure situations or exposure to sources within practices.

For example, a sterilization gamma irradiation unit or a medical X ray unit are sources for the practice of radiation preservation of food and radiodiagnosis, respectively.

A nuclear power plant is part of the practice of generating electricity and may be regarded as a single source (e.g. with respect to discharges) or as a collection of sources (e.g. for purposes of occupational radiation protection).

5. Requirements for planned exposure situations also apply to:

   (a) Exposure due to material in any practice specified in paragraph 3 (such as mining or mineral processing) where the activity concentration in the material of any radionuclide in the uranium decay chain or the thorium decay chain is greater than 1 Bq/g or the activity concentration of ^{40}K is greater than 10 Bq/g;
   (b) Public exposure due to discharges or due to the management of radioactive waste arising from a practice involving material as specified in paragraph 3;
   (c) Exposure due to ^{222}Rn and to ^{222}Rn progeny and due to ^{220}Rn and to ^{220}Rn progeny in workplaces in which occupational exposure due to other radionuclides in the uranium decay chain or the thorium decay chain is controlled as a planned exposure situation;
   (d) Exposure due to ^{222}Rn and to ^{222}Rn progeny where the annual average activity concentration of ^{222}Rn in air in workplaces remains above the reference level established in paragraph 1 of Article 53 after the fulfilment of the requirement in paragraph 3 of Article 53.

6. Regarding existing exposure situations, these Regulations apply to:

   (a) Exposure due to contamination of areas by residual radioactive material deriving from:
      (i) Past activities never subject to regulatory control or previously subject to regulatory control but not in accordance with these Regulations;
      (ii) A nuclear or radiological emergency, after an emergency has been declared to be ended;
   (b) Exposure due to commodities, including food, feed, drinking water and construction materials, that incorporate radionuclides deriving from residual radioactive material;
   (c) Exposure due to natural sources, including:
      (i) ^{222}Rn and its progeny and ^{220}Rn and its progeny, in workplaces other than those workplaces for which exposure due to other radionuclides in the uranium decay chain or the thorium decay chain 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, regardless of activity concentration, in commodities, including food, feed, drinking water, agricultural fertilizer and soil amendments and construction materials, and residual radioactive material in the environment;
      (iii) Materials, other than those stated in paragraph 6(c)(ii), in which the activity concentration of no radionuclide in either the uranium decay chain or the thorium decay chain exceeds 1 Bq/g and the activity concentration of ^{40}K does not exceed 10 Bq/g;
   (d) Exposure of aircrew and space crew to cosmic radiation;
   (e) Any other source of exposure as specified by the regulatory body.

7. These Regulations also apply to emergency exposure situations in respect of public exposure and protection of emergency workers for activities undertaken in preparedness for, and in response to a nuclear or radiological emergency.

8. The following exposures are not included in the scope of these Regulations:

(a) Exposures from natural radioactivity in the human body;
(b) Exposure of members of the public or workers (other than air or space crew) to cosmic radiation in flight or in space, or to cosmic radiation prevailing at ground level;
Any other radiation source that is essentially unamenable to control as may be determined by the regulatory body.

Notes (paragraph 8 of Article 3):

Identification of excluded exposures is not a substitute for a clearly stated scope. This is particularly important when the responsibilities of the regulatory body are divided among two or more agencies, each having its own regulations. Statements about excluded exposures are made only to clarify what is covered in the scope.

An example of this case is the above ground exposure to radionuclides present in the undisturbed earth's crust.

Article 4: Definitions[2]

Accident: Any unintended event, including operating errors, equipment failures and other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection and safety.

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. The SI unit for activity is reciprocal second (s^{-1}), termed the becquerel (Bq).

Authorization: The granting by a regulatory body or other governmental body of written permission for a person or organization (the operator) to conduct specified activities. Authorization could include, for example, licensing (issuing a licence), certification (issuing a certificate) or registration. The term authorization is sometimes used to describe the document granting such permission.

Note:

For activities that pose little or no health risk, the applicant may only be required to submit a notification only (see notification).

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[2] All definitions stated in the Model Regulations are taken from the IAEA Nuclear Safety and Security Glossary 2022 (Interim) Edition [17].

Authorized discharge: Discharge in accordance with an authorization.

Authorized party: The person or organization (the operator) responsible for an authorized facility or an authorized activity that gives rise to radiation risks who has been granted written permission (i.e. authorized) by a regulatory body or other governmental body to conduct specified activities.

Carers and comforters: Persons who willingly and voluntarily help (other than in their occupation) in the care, support and comfort of patients undergoing radiological procedures for medical diagnosis or medical treatment.

Clearance: Removal of regulatory control by the regulatory body from radioactive material or radioactive objects within notified or authorized facilities and activities. Removal of regulatory control in this context refers to regulatory control applied for radiation protection purposes.

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.

Consumer product: A device or manufactured item into which radionuclides have deliberately been incorporated or produced by activation, or which generates ionizing radiation, and which can be sold or made available to members of the public without special surveillance or regulatory control after sale.

Contamination: Radioactive substances on surfaces or within solids, liquids or gases (including the human body), where their presence is unintended or undesirable, or the process giving rise to their presence in such places.

Controlled area: 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 in normal working conditions and preventing or limiting the extent of potential exposures.

Decommissioning: Administrative and technical actions taken to allow the removal of some or all of the regulatory controls from a facility.

Decommissioning plan: A document containing detailed information on the proposed decommissioning of a facility.

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 radiation source or radioactive material and workers, members of the public or the environment, in operational states and, for some barriers, in accident conditions.

Diagnostic reference level: A level used in medical imaging to indicate whether, in routine conditions, the dose to the patient or the amount of radiopharmaceuticals administered in a specified radiological procedure for medical imaging is unusually high or unusually low for that procedure.

Discharge: Planned and controlled release of (usually gaseous or liquid) radioactive substances to the environment. Strictly, the act or process of releasing the radioactive substances, but also used to describe the radioactive substances released.

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

Disused source: A radioactive source that is no longer used, and is not intended to be used, for the practice for which an authorization has been granted.

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.

Dose constraint: A prospective and source related value of individual dose that is used in planned exposure situations as a parameter for the optimization of protection and safety for the source, and that serves as a boundary in defining the range of options in optimization.

Dose limit: The value of the effective dose or the equivalent dose to individuals in planned exposure situations that is not to be exceeded.

Emergency: A non-routine situation or event that necessitates prompt action, primarily to mitigate a hazard or adverse consequences for human life, health, property and the environment. This includes nuclear and radiological emergencies and conventional emergencies such as fires, releases of hazardous chemicals, storms or earthquakes. This includes situations for which prompt action is warranted to mitigate the effects of a perceived hazard.

Emergency exposure situation: 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.

Note (Emergency exposure situation):

Exposure in an emergency can be reduced only by protective actions and other response actions.

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 worker: A person having specified duties as a worker in response to an emergency.

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.

Note (Environment):

Protection of the environment includes protection and conservation of:

(a) Non-human species, both animal and plant and their biodiversity;

(b) Environmental goods and services such as the production of food and feed;

(c) Resources used in agriculture, forestry, fisheries, and tourism;
(d) Amenities used in spiritual, cultural, and recreational activities;
(e) Media such as soil, water, and air;
(f) Natural processes such as carbon, nitrogen, and water cycles.

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 and the potential exposure due to the source or practice are 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: 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.

Existing exposure situation: A situation of exposure that already exists when a decision on the need for control needs to be taken.

External exposure: Exposure to radiation from a source outside the body.

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 subject to exposure to radiation from naturally occurring or artificial sources.

Note:

This term is intended to provide an alternative to the terminology of sources and practices to refer to general categories of situations.

Health professional: 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: A programme in which health tests or medical examinations are performed for the purpose of the early detection of disease.

Health surveillance: Medical supervision intended to ensure the initial and continuing fitness of workers for their intended tasks.

Individual monitoring: Monitoring using measurements by equipment worn by individuals, or measurements of quantities of radioactive substances in or on, or taken into, the bodies of individuals, or measurements of quantities of radioactive substances excreted from the body by individuals.

Inspection imaging device: An imaging device designed specifically for imaging persons or cargo conveyances for the purpose of detecting concealed objects on or within the human body or within cargo or a vehicle.

Interested party: A person, company, etc., with a concern or interest in the activities and performance of an organization, business, system, etc.

Note:

The regulatory body may specify relevant interested parties. The term includes the following: customers, owners, operators, employees, suppliers, partners and trade unions; the regulated industry or professionals; scientific bodies; governmental agencies, public representative bodies and lobbying groups, charitable institutions, the public etc.

Internal exposure: Exposure to radiation from a source within the body.

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 would be conducted.

Justification:

(a) The process of determining for a planned exposure situation whether a practice is, overall, beneficial; that is, whether the expected benefits to individuals and to society from introducing or continuing the practice outweigh the harm (including radiation detriment) resulting from the practice.

(b) The process of determining for an emergency exposure situation or an existing exposure situation whether a proposed protective action or remedial action is likely, overall, to be beneficial; that is, whether the expected 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.

Licence: A legal document issued by the regulatory body granting authorization to perform specified activities relating to a facility or activity.

Licensee: The holder of a current licence.

Management system: A set of interrelated or interacting elements (system) for establishing policies and objectives and enabling the objectives to be achieved in an efficient and effective manner.

Medical exposure: Exposure incurred by patients for the purposes of their own medical or dental diagnosis (diagnostic exposure) or medical treatment (therapeutic exposure); by carers and comforters; and by volunteers subject to exposure as part of a programme of biomedical research.

Notes:

For the purpose of these Regulations, the term 'patient' refers only to individuals undergoing radiological procedures. In some circumstances asymptomatic individuals are also included..

A patient receives the services of healthcare professionals and/or their agents, directed at:

(a) Health promotion;
(b) Prevention of illness and injury;
(c) Monitoring health;
(d) Maintaining health.

Medical physicist: A health professional, with specialist education and training in the concepts and techniques of applying physics in medicine and competent to practise independently in one or more of the subfields (specialties) of medical physics.

Notes (Medical physicist):

The competence of a medical physicist is normally assessed by the State through a formal mechanism of registration, accreditation or certification of qualification in various specialties (e.g. diagnostic radiology, radiation therapy, nuclear medicine).

States yet to develop such mechanisms have to assess the education, training and competence of any individual the licensee proposes to employ as a medical physicist and decide on the basis of international accreditation standards and/or the standards of the State, whether the proposed individual could safely and competently undertake the functions of a medical physicist within the required specialty.

Medical radiation facility: A medical facility in which radiological procedures are performed.

Medical radiation technologist: A health professional, with specialist education and training in medical radiation technology, competent to perform radiological procedures, on delegation from the radiological medical practitioner, in one or more of the specialties of medical radiation technology.

Notes (Medical radiation technologist):

The competence of a medical radiation technologist is normally assessed by the State through a formal mechanism of registration, accreditation or certification of qualification in various specialties (e.g. diagnostic radiology, radiation therapy, nuclear medicine).

States yet to develop such mechanisms need to assess the education, training and competence of any individual the licensee proposes to employ as a medical radiation technologist and decide on the basis of international accreditation standards and/or the standards of the State, whether the proposed individual could safely and competently undertake the functions of a medical radiation technologist within the required specialty.

Medical radiological equipment: 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 X ray machines or medical linear accelerators; to devices containing sealed sources, such as ^{60}Co teletherapy units; to devices used in medical imaging to capture images, such as gamma cameras, image intensifiers or flat panel detectors; and to hybrid systems such as positron emission tomography–computed tomography PET–CT) scanners.

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.

Optimization of protection and safety: The process of determining what level of protection and safety would result in the magnitude of individual doses, the number of individuals (workers and members of the public) subject to exposure and the likelihood of exposure being as low as reasonably achievable, economic and social factors being taken into account (ALARA). For medical exposures of patients, the optimization of protection and safety is the management of the radiation dose to the patient commensurate with the medical purpose.

Planned exposure situation: A situation of exposure that arises from the planned operation of a source or from a planned activity that results in an exposure due to a source.

Practice: Any human activity that introduces additional sources of exposure or additional exposure pathways or that 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.

Protection and safety: The protection of people against exposure to ionizing radiation or exposure due to 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 if they do occur.

Qualified expert: An individual who, by virtue of certification by appropriate boards or societies, professional licence or academic qualifications and experience, is duly recognized as having expertise in a relevant field of specialization, for example medical physics, radiation protection, occupational health, fire safety, quality management or any relevant engineering or safety speciality.

Notes (Qualified expert):

Qualified experts are those that:

(a) *Have expertise in a relevant field of specialization, such as 'medical physics' and 'radiation protection' (GSR Part 3 – Definitions [3]);*
(b) *Are identified and consulted on the proper observance of requirements for protection and safety (see paragraph 2.46 of GSR Part 3 [3]) for all the categories of exposure (occupational, public and medical) and to ensure the safety of sources.*

The following two main categories of qualified experts can be identified:

(a) *Experts in medical physics (e.g. medical physicists), consulted and performing tasks to ensure protection against unjustified or non-optimized medical exposure (protection of patients);*
(b) *Experts in radiation protection consulted and performing tasks to ensure protection against occupational and public exposure (protection of workers and the public), and the safety and security of sources.*

Quality assurance: The function of a management system that provides confidence that specified requirements will be fulfilled.

Quality control: Part of quality management intended to verify that structures, systems and components correspond to predetermined requirements.

Radiation generator: 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.

Radiation protection officer (RPO): 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 regulatory requirements.

Notes (Radiation protection officer (RPO)):

RPOs oversee the application of regulatory requirements, implementing the advice of qualified experts in radiation protection, and others as applicable.

In line with the scope of duties of the qualified expert in radiation protection as defined above (e.g. occupational and public exposure and safety of sources), the RPO oversees the application of, and compliance with, relevant regulatory requirements (see paragraph 3.66 of IAEA Safety Standards Series No. GSG-7, Occupational Radiation Protection [21]) for occupational and public radiation protection and has no direct responsibilities or role with respect to patient radiation protection (see paragraph 2.96 of IAEA Safety Standards Series No.SSG-46, Radiation Protection and Safety in Medical Uses of Ionizing Radiation [22]).

Radiation protection programme: Systematic arrangements that are aimed at providing adequate consideration of radiation protection measures.

Radioactive material: Material designated in national law or by a regulatory body as being subject to regulatory control because of its radioactivity.

Radioactive source:

(a) A source containing radioactive material that is used as a source of radiation.
(b) Radioactive material that is permanently sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. This also includes any radioactive material released if the radioactive source is leaking or broken but does not include material encapsulated for disposal, or nuclear material within the nuclear fuel cycles of research and power reactors.

Notes (radioactive source):

Radioactive sources may be categorized as Category 1, Category 2, Category 3, Category 4 or Category 5 as described in Schedule II to GSR Part 3 [3] and in IAEA Safety Standards Series No. RS-G-1.9, Categorization of Radioactive Sources [23].

Radioactive waste: For legal and regulatory purposes, material for which no further use is foreseen that contains, or is contaminated with, radionuclides at activity concentrations greater than clearance levels as established by the regulatory body.

Radiological medical practitioner: A health professional with specialist education and training in the medical uses of radiation, who is competent to perform independently or to oversee radiological procedures in a given specialty.

Notes (Radiological medical practitioner):

The competence of a radiological medical practitioner is normally assessed by the State through a formal mechanism of registration, accreditation or certification of qualification in various specialties (e.g. diagnostic radiology, radiation therapy, nuclear medicine).

States yet to develop such mechanisms need to assess the education, training and competence of any individual the licensee proposes to employ as a radiological medical practitioner and decide, on the basis of international accreditation standards and/or the standards of the State, whether the proposed individual could safely and competently undertake the functions of a radiological medical practitioner within the required specialty.

Radiological procedure: A medical imaging procedure or therapeutic procedure that involves ionizing radiation — such as a procedure in diagnostic radiology, nuclear medicine or radiation therapy, or a planning procedure, image guided interventional procedure or other interventional procedure involving radiation — delivered by a radiation generator, a device containing a sealed source or an unsealed source, or by means of a radiopharmaceutical administered to a patient.

Radiopharmacist: A health professional, with specialist education and training in radiopharmacy, who is competent to prepare and dispense radiopharmaceuticals used for the purposes of medical diagnosis and therapy.

Radon: Any combination of isotopes of the element radon.

Radon progeny: The short-lived radioactive decay products of ^{220}Rn and of ^{222}Rn.

Reference level: For an emergency exposure situation or an existing exposure situation, the level of dose, risk or activity concentration above which it is not appropriate to plan to allow exposures to occur and below which optimization of protection and safety would continue to be implemented.

Note (Reference level):

The chosen value for a reference level will depend upon the prevailing circumstances for the exposure under consideration.

Referring medical practitioner: A health professional who, in accordance with national requirements, may refer individuals to a radiological medical practitioner for medical exposure.

Registrant: The holder of a current registration.

Registration: A form of authorization for facilities and activities 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.

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.

Regulatory control: Any form of control or regulation applied to facilities or activities by a regulatory body for reasons relating to nuclear safety and radiation protection or to nuclear security.

Remedial action: The removal of a source or the reduction of its magnitude (in terms of activity or amount) for the purposes of preventing or reducing exposures that might otherwise occur in an emergency or in an existing exposure situation.

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

Note (Representative person):

ICRP Publication 101 [24] states that dose to the representative person 'is the equivalent of, and replaces, the mean dose in the critical group'. It also provides guidance on assessing doses to the representative person. The concept of critical group remains valid.

Safety case: A collection of arguments and evidence in support of the safety of a facility or activity. This will normally include the findings of a safety assessment and a statement of confidence in these findings.

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.

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

Source: Anything that may cause radiation exposure — such as by emitting ionizing radiation or by releasing radioactive substances or radioactive material — and can be treated as a single entity for purposes of protection and safety.

Note:

When used in these Regulations, the term includes all the following: natural source, radiation generator, dangerous source, radioactive source, sealed source, spent source, unsealed source (see definition of "source" in GSR Part 3 [3]).

Storage: The holding of radioactive sources, radioactive material, spent fuel or radioactive waste in a facility that provides for their/its containment with the intention of retrieval.

Structures, systems and components: A general term encompassing all elements (items) of a facility or activity that contribute to protection and safety, except human factors.

Supervised area: A defined area not designated as a controlled area but for which occupational exposure conditions are kept under review, even though specific protection measures or safety provisions are not normally needed.

Supplier (of a source): Any person or organization to whom a registrant or licensee assigns duties, totally or partially, in relation to the design, manufacture, production or construction of a source.

Note (Supplier):

The term supplier (of a source) includes designers, manufacturers, producers, constructors, assemblers, installers, distributors, sellers, importers or exporters of a source.

Notes (Import and Export)

For the purpose of these Regulations, "import" and "export" are defined as:

Import: The physical transfer, into an importing State or to a recipient in an importing State, originating from an exporting State, of one or more radioactive source(s) covered by these Regulations.

Export: The physical transfer, originating from an exporting State, into an importing State or to a recipient in an importing State, of one or more radioactive source(s) covered by these Regulations.

Article 5: Principal Parties

1. The person or organization defined in the authorization as responsible for any facility or activity that gives rise to radiation risks shall have the prime responsibility for protection and safety, which cannot be delegated.

2. The principal parties responsible for the application of these Regulations shall include:
   (a) Registrants and licensees responsible for regulated facilities and activities;
   (b) The name of the person or organization responsible for facilities and activities for which notification only is required;
   (c) Employers, in relation to occupational exposure;
   (d) Medical radiological practitioners, in relation to medical exposure;
   (e) Those persons or organizations designated to deal with emergency exposure situations or existing exposure situations.

Note (Principal parties):

In some States it is the 'legal person' that carries prime responsibility. This may be an individual or an organization, in accordance with the legislative system of the State. Nevertheless, this entity has to be clearly defined in the authorization of a facility or activity involving ionizing radiation and assigned in law, prime responsibility for ensuring compliance with the regulatory requirements.

Note (Article 5.2(e)):

The phrase 'persons or organizations' is used here to be inclusive of persons subject to requirements for notification only. While requirements applicable to notification only may be minor relative to those that require authorization through licensing, they are still requirements.

3. Other parties shall have specified responsibilities for the application of these Regulations. These parties may include, as applicable:
   (a) Suppliers of radiation sources, providers of equipment and software and providers of consumer products;
   (b) Radiation protection officers (RPOs);
   (c) Referring medical practitioners;
   (d) Qualified experts, or any other party to whom a principal party has assigned specific responsibilities;
   (e) Workers involved in activities utilising radiation sources, other than those workers listed in subparagraphs 3(a)–(d);
   (f) Ethics committees.

4. The principal parties shall establish and implement a protection and safety programme appropriate for the exposure situation. The protection and safety programme shall:
   (a) Adopt objectives for protection and safety in accordance with the requirements of these Regulations;

(b) Apply measures for protection and safety commensurate with the radiation risks associated with the exposure situation and sufficient to ensure compliance with the requirements of these Regulations.

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

(a) Measures and resources have been determined and duly provided to achieve the objectives for protection and safety;
(b) The programme is periodically reviewed to assess its effectiveness and continued fitness for purpose;
(c) Any failures or shortcomings in protection and safety are identified and corrected, with steps being taken to prevent their recurrence;
(d) Arrangements are made to consult with interested parties on matters of protection and safety;
(e) Appropriate records are maintained.

6. The principal parties shall grant facility access to authorized representatives of the regulatory body to carry out inspections of the facilities and activities and to review protection and safety records. The principal parties shall cooperate in their conduct.

7. The principal parties shall ensure that qualified experts are identified and consulted as necessary on the proper observance of these Regulations.

8. The principal parties and other parties having specified responsibilities in relation to protection and safety, shall ensure that personnel engaged in activities relevant to protection and safety have and maintain appropriate education, training, and qualifications sufficient to understand their responsibilities and perform their duties competently, with appropriate judgement and in accordance with procedures.

Article 6: Interpretation

Except as specifically authorized, no official interpretation of these Regulations binding on the regulatory body shall be made by any officer, employee or other representative of the regulatory body, unless in the case of a written interpretation by [*identify who in the regulatory body is authorized to make the official interpretation that will be binding – typically the Director of the Regulatory Body or the Chairman of the Board*].

Article 7: Applicability of other Regulations and Requirements and Resolution of Conflicts

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Note (Article 7):

The requirements of these Regulations have not to replace or modify any other international, national or local (regional) legislation or regulations. The requirements of these Regulations form part of the national legislation. Where a potential conflict is identified between requirements contained herein and other laws or regulations, the regulatory body, upon being notified of such conflict, initiate steps towards resolution.

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1. Nothing in these Regulations shall be construed as relieving principal parties and employers from a duty to ensure compliance with applicable national and local laws and regulations governing safety.

2. Nothing in these Regulations shall be construed as restricting any actions that may be necessary for the continued assurance or restoration of protection and safety.

PART 2: REGULATORY CONTROL

Article 8: General Obligations

No person or organization shall adopt, introduce, conduct, discontinue or cease a practice or, as applicable, mine, extract, process, design, manufacture, construct, assemble, install, acquire, import, export, supply, provide, distribute, loan, hire, receive, site, locate, commission, possess, use, operate, maintain, repair, transfer, decommission, disassemble, transport, store or dispose of a source (as defined in Article 4) within a practice other than in accordance with the requirements of these Regulations.

Article 9: Exemption

1. Practices and sources within practices may be exempted from some or all the safety requirements of these Regulations provided they comply with criteria for exemption, or any exemption levels defined by the regulatory body (Annex I of these Regulations), as described in paragraphs 3 and 4.

2. Exemptions shall not be granted for practices deemed not justified, as specified in Article 24.

3. A practice or a source within a practice may be exempted by the regulatory body from some or all requirements of these Regulations where risks arising from the practice or source within the practice are sufficiently low as not to warrant regulatory control, with no appreciable likelihood of situations arising that could lead to a failure to meet the general criterion for exemption.

4. A practice or source within a practice may be exempted without further consideration from some or all requirements of these Regulations provided that under reasonably foreseeable circumstances, the effective dose expected to be incurred by any individual owing to the exempt practice or exempt source within the practice, is of the order of 10 μSv or less in a year. Where there is a low probability of exposure, the effective dose expected to be incurred by any individual shall not exceed 1 mSv in a year.

5. The following practices and sources within a practice are generically exempted from the requirements of these Regulations, including requirements for notification, registration or licensing:

   (a) Material in a moderate amount for which either the total activity of an individual radionuclide on the premises, or the activity concentration used in the practice, does not exceed the applicable exemption level given in Annex I;
   (b) Radioactive material in bulk amount for which the activity concentration of a given radionuclide of artificial origin used in the practice does not exceed the relevant value given in Annex I of these Regulations;
   (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 display of visual images, provided that:

(i) Under normal operating conditions they do 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 equipment;
(ii) The maximum energy of radiation generated is no greater than 5 keV.

Note (Paragraphs 5(a) and (b)):

Annex I of these Regulations can be taken directly from Schedule I of GSR Part 3 [3]. However, it is recommended that the regulatory body fully considers all the requirements established in GSR Part 3 [3] before modification or transposition of the tables in Schedule I into national regulations. Recommendations on exemption are provided in IAEA Safety Standards Series No. GSG-17, Application of the Concept of Exemption [25].

6. In the case of practices involving radionuclides of natural origin, exemption of bulk amounts of material shall be considered on a case-by-case basis using a dose criterion to be established by the regulatory *body [insert a dose criterion]* commensurate with typical doses due to natural background levels of radiation.

Note (Paragraph 6):

A dose criterion of the order of 1mSv per year is proposed in GSR Part 3 [3].

7. Where a practice or source within a practice does not comply with generic exemptions, or the exemptions cannot be applied, the applicant may make an application for specific exemption on a case-by-case basis, providing the appropriate justification of the exemption.

Note (Paragraph 7):

Some examples of exemption cases are:

(a) Equipment containing radioactive material exceeding the quantities or concentrations specified above, may be exempted provided that:
(i) the equipment containing the radioactive material is of a type approved by the regulatory body;
(ii) the radioactive material is in the form of a sealed source that effectively prevents any contact with the radioactive material and prevents its leakage;
(iii) in normal operating conditions the equipment 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;
(b) Surface contaminated commodities and certain consumer products.

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

9. The values provided in Annex I of these Regulations are not intended to be applied to the control of discharges or to the control of residual radioactive material in the environment.

Article 10: Requirements for Notification

1. A person or organization intending to carry out any of the activities specified in Article 8 shall submit a notification to the regulatory body of such intention.

2. Notification alone is sufficient for facilities or activities that are specified by the regulatory body [*insert the list here or in a separate regulatory document*].

3. For consumer products, notification is sufficient for manufacture, maintenance, import, export, provision, distribution and (except in specified cases) disposal.

Notes (Notification):

The regulatory body may make a template available to applicants setting out information for notification such as administrative information, details of the legal person, data relating to the radiation sources and the purpose for which the sources be used.

The regulatory body may provide a list of practices or sources within practices for which notification only is sufficient (e.g. the use of some of Category 5 radioactive sources for security purposes).

The regulatory body needs to identify the applicable safety requirements for practices for which notification alone is sufficient (e.g. a requirement to dispose of the source after its useful life or limitations on the purpose for which the sources may be used).

If the regulatory body intends to charge a fee for the notification, relevant provisions need to be added.

Recommendations on notification are provided in GSG-13 [10] and further information is provided in Ref. [11].

Article 11: Requirements for Authorization

1. Except as provided in Article 9 and Article 10 of these Regulations, any person or organization intending to operate a facility or conduct an activity involving a radiation source shall apply to the regulatory body for an authorization which shall take the form of either a registration or a licence.

2. An authorization for a facility shall include authorization of the activities taking place at the facility (e.g. operation, maintenance and engineering activities).

3. Authorization by registration is required for practices that pose a low to moderate radiation risk. Annex II sets out the risk criteria determined by the regulatory body and provides an illustrative list of practices subject to registration.

Notes (Paragraph 3)

Typical practices that are suitable for 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 training requirements for safety are minimal;*
- *(d) There is a history of few problems relating to safety in operations.*

Registration is best suited to those practices for which operations do not vary significantly (see footnote 19 in GSR Part 3 [3]).

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4. Authorization by licensing is required for facilities and activities that pose or potentially pose a high radiation risk. Annex II "Categories for sealed sources used in common practices" includes risk criteria determined by the regulatory body and provides an illustrative list of practices subject to authorization by licensing.

5. An applicant is not allowed to engage in a practice or carry out activities specified in Article 8 until an authorization is issued in the form of a registration or licence, as applicable.

6. An applicant seeking authorization shall:

   (a) Assess the nature, likelihood and magnitude of expected exposures to people due to the facility or activity and take all necessary measures for protection and safety;
   (b) Perform a safety assessment, in accordance with Article 34 and submit the assessment to the regulatory body as part of the application;
   (c) Perform an assessment of radiological environmental impact associated with the facility or activity, following guidance issued by the regulatory body;
   (d) Demonstrate compliance with all applicable requirements for safety following relevant guidance issued by the regulatory body, including application of a graded approach to risk, based on the probability and potential magnitude of harm to people and the environment.

7. An applicant seeking authorization shall submit to the regulatory body relevant information necessary to support the application, including:

   (a) Legal and administrative information about the applicant;
   (b) Responsibilities and organizational arrangements for protection and safety;
   (c) Characteristics of the facility;
   (d) Information on radiation sources;
   (e) Staff qualifications and training;
   (f) Description of the management system;
   (g) Safety assessments in accordance with paragraph 6(b);
   (h) Arrangements for protection of workers, under the radiation protection programme;
   (i) Arrangements for protection of the public and environment;
   (j) Arrangements for radiation protection of patients undergoing medical exposure;
   (k) Radioactive waste management plan describing arrangements for the management of radioactive waste generated throughout the lifetime of the facility or activity, including decommissioning and management of disused sealed radioactive sources;
   (l) Preliminary decommissioning plan;
   (m) Clearance and conditional clearance;
   (n) Financial arrangements for activities related to decommissioning and management of disused sources, as applicable;
   (o) Emergency preparedness and response plan describing arrangements for preparedness and response to emergencies, as applicable;
   (p) Information on other programmes established in support of its safety activities, such as maintenance and testing of equipment and sources;

(q) A description of arrangements for safe management of the source(s), including financial provisions where appropriate once they become disused.

8. Different authorizations shall be obtained for the different stages in the lifetime of a facility or the duration of an activity.

Note:

Different stages in the lifetime of a facility or the duration of an activity might include site evaluation, design, construction, commissioning, operation, shutdown and decommissioning (or closure).

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9. In the granting of an authorization for a facility or an activity, the regulatory body may impose, limits, conditions and controls on the authorized party's subsequent activities.

10. The registrants and licensees may appeal against a regulatory decision relating to an authorization for a facility or an activity or a condition attached to an authorization.

11. An authorization may have to be reconsidered and/or renewed in the different stages in the lifetime of the facility or the duration of the activity concerned. In this case the authorized party shall apply for a new regulatory decision which may require the amendment, renewal, suspension, or revocation of the authorization.

Notes (Requirements for authorization):

The regulatory body is expected to issue guidance for applicants on how to apply for authorization. This guidance may include, as appropriate:

(a) The format and content of documents to be submitted in support of the application;
(b) A list clearly stating the applicable legislation, regulations and requirements;
(c) Information on requirements for each major stage of authorization (e.g. siting, design, construction, commissioning, operation and decommissioning or closure of a facility or termination of an activity).

The level of detail of information submitted with an application for authorization needs to be related to the risk associated with the practice or source within the practice (recommendations are provided in GSG-13 [10] and more information is given in TECDOC-1974 [20] on a graded approach to regulatory control).

As applicable, the regulatory body may provide guidance on necessary security measures, including the content of the security plan submitted as part of the application.

Authorizations may be granted:

(a) For a specific time period (e.g. 2 years, 10 years, 40 years) or for a specific stage in the lifetime of the facility (e.g. construction, operation) or for the duration of an activity;
(b) Indefinitely under certain conditions and until the authorization is terminated by the regulatory body. Such an indefinite period of authorization is not to have any influence on the frequency of inspections.

The regulatory body may attach conditions to an authorization and state circumstances and criteria that may lead it to suspend or revoke all or part of an authorization in the event of a violation of its conditions or in any circumstances in which the regulatory body determines that continued activity would pose an unacceptable risk to public health, safety and environment. (see also paragraphs 3.112–3.114 of GSG-13 [10]).

Confidential information in the application for authorization needs to be clearly identified by the applicant.

In the case of a practice involving medical exposure, the application needs to include information on the radiation protection and safety qualifications of medical practitioners permitted to prescribe medical exposure by means of the authorized source (referring practitioners).

In the case of an application for authorization to export sources of category 1 and 2, the applicant needs to include a copy of the importing State's necessary authorizations for receipt and possession of the source or sources to be exported, including at least the following:

(a) Name of the recipient;
(b) Recipient location and legal address or principal place of business;
(c) Relevant radionuclides and radioactivity;
(d) Intended uses of the source(s), if appropriate;
(e) Recipient authorization expiration date (if any).

In the case of import of sources of category 1 and 2 the application for authorization needs to include:

(a) Name of the exporter;
(b) Exporter location and legal address or principal place of business;
(c) Name of the recipient;
(d) Recipient location and legal address or principal place of business;
(e) Radionuclides and their activity;
(f) Intended uses of the source(s), if appropriate;
(g) Details of arrangements for safe management of the source(s), including financial provisions where appropriate and copies of any contractual agreements once the sources have become disused.

Recommendations on authorization are provided in GSG-13 [10] and further information is given in Ref. [11].

Further guidance on the import and export of category 1 and 2 radioactive sources can be found in Ref. [5].

Notes (Authorization - registration or licensing):

The regulatory body's authorization system considers the nature and level of risk or complexity associated with a practice or source within a practice. This is the basis of a graded approach to regulatory control in accordance with the requirements of GSR Part 1 (Rev. 1) [2] and GSR Part 3 [3]. Further information can be found in Ref. [20].

Annex II can be taken directly from GSR Part 3 [3]. However, it is recommended that the regulatory body study GSR Part 3 [3] and these tables, before considering their modification or transposition into national regulations.

Reference [20] provides useful information on the application of graded approach to the regulatory oversight.

SSG-46 [21] and Ref. [17] provide examples of practices or sources within practices that may be candidates for registration or licensing.

Reference [11] on notification, authorization, inspection and enforcement for the safety and security of radiation sources, provide more practical information on regulatory functions and includes specific check lists to be used by the regulatory body.

The regulatory body is expected to issue instructions on how to appeal against a regulatory decision.

Article 12: Clearance from Regulatory Control

1. Radiation sources, including substances, radioactive material, radioactive waste and objects within notified or authorized practices may be cleared from regulatory control provided they comply with the general criteria for clearance specified by the regulatory body.

2. The general criteria for clearance are:

   (a) Radiation risks arising from the cleared material are sufficiently low as to not warrant regulatory control and there is no likelihood of a future circumstance leading to failure to meet the general criterion for clearance; or
   (b) Continued regulatory control of the material would yield no net benefit, in that no reasonable control measures would achieve a worthwhile return in terms of reduction of individual doses or reduction of health risks.

Notes (Clearance):

Clearance levels are established by the regulatory body for specific situations using criteria described paragraphs 2–4, with account taken of the physical or chemical form of the radioactive material and its use or the means of its disposal.

Clearance levels may be specified in terms of activity concentration per unit mass or activity concentration per unit surface area.

Clearance criteria are proposed in Schedule I of GSR Part 3 [3].

Further information on clearance can be found in IAEA Safety Standards Series No. GSG-18, Application of the Concept of Clearance [26].

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3. Material may be cleared without further consideration under the terms of paragraph 2(a) provided that, in reasonably foreseeable circumstances, the effective dose expected to be incurred by any individual owing to the cleared material is of the order of 10 μSv or less in a year.

4. For low probability scenarios whereby the effective dose expected to be incurred by any individual does not exceed 1 mSv in a year, material may be cleared without further consideration.

5. 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 in solid form does not exceed the relevant level given in Annex I of these Regulations;
   (b) The activity concentrations of radionuclides of natural origin does not exceed the relevant level given in Annex I of these Regulations; or
   (c) For radionuclides of natural origin in residues that might be recycled into construction materials, or for the disposal of radionuclides of natural origin which may contaminate drinking water supplies the activity concentration in the residues does not exceed specific values derived to meet a dose criterion of 1 mSv in a year, this being commensurate with typical doses due to natural background levels of radiation.

6. Clearance may be granted by the regulatory body for specific situations, on the basis of the criteria of Annex I, with account taken of the physical or chemical form of the radioactive material, and its use or the means of its disposal. Such clearance levels may be specified in terms of activity concentration per unit mass or activity concentration per unit surface area.

7. For clearance of bulk quantities of material containing a mixture of radionuclides of natural origin and radionuclides of artificial origin, the relevant levels given in Annex I of these Regulations shall not be exceeded for individual radionuclides and for their mixture.

8. The registrant or licensee shall adopt provisions for clearance and its control to ensure that:

    (a) A formal mechanism is in place, including control measures, to demonstrate compliance with regulatory requirements in respect of clearance;

    (b) Deliberate dilution of material to meet clearance criteria is prohibited, unless dilution takes place in normal operations performed in compliance with regulatory requirements;
    (c) Radiation marking is removed from any material no longer subject to these Regulations.

9. Information on material removed from regulatory control shall be recorded, retained within the management system of the registrant or licensee for [*insert the required time period*].

10. Notification of the clearance of material in accordance with these Regulations shall be made to the regulatory body.

Article 13: Review and Assessment

On receipt of an application, and during the process of its review and assessment, the applicant, upon request of the regulatory body, shall submit further information or modify the application as appropriate, respecting the time limit to be set by the regulatory body.

Notes (Review and assessment):

The regulatory body, on receipt of an application, conducts a verification to ensure that the information provided is complete and adequate for technical review. If an application is incomplete or unclear, the regulatory body requests the applicant to submit further information or to modify the application as appropriate. In all such cases the regulatory body sets a time limit for the submission of further information, after which the regulatory body may require a new application or refuse the application for authorization and as appropriate, commence enforcement actions.

After administrative verification that the application for authorization is complete, and in accordance with a graded approach based on verified risk categorisation, the regulatory body informs the applicant of the date by which a regulatory decision shall be made to:

(a) Grant the authorization;
(b) Grant the authorization with conditions, limitations, or controls; or
(c) Reject the application for authorization.

When conducting the review and assessment of information submitted by the applicant, the regulatory body:

(a) Collects all necessary inputs in addition to the application, such as legal requirements and internal guidance;
(b) Establishes a review and assessment plan specifying the purpose and technical scope of the review and assessment, such as key elements and acceptance criteria, as well as a schedule and assigned responsibilities for conducting the review and assessment;
(c) Performs the review and assessment to determine whether regulatory requirements have been met for each aspect or topic;
(d) Collects and integrates assessment results, documenting the results as an input to the authorization decision.

When needed, such as in the case of complex practices, the regulatory body performs verification on-site visits to determine whether the applicant is in compliance with the regulatory requirements.

Recommendations on review and assessment are provided in GSG-13 [10] and further information is given in Ref. [11].

Article 14: Regulatory Inspections

1. The registrant, licensee or employer shall permit access to authorized representatives of the regulatory body to carry out inspections of facilities and activities and of protection and safety records.

2. The registrant, licensee or employer shall cooperate in the conduct of inspections.

Notes (Regulatory inspection):

Paragraph 4.50 of GSR Part 1 (Rev. 1) [2] states: "The regulatory body shall develop and implement a programme of inspection of facilities and activities to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections) and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach."

The priority and frequency of inspections have to reflect the risk associated with the radiation source and the complexity of the facility or activity, as well as possible consequences of an accident and the type and frequency of any regulatory non-compliances found by inspections.

The following specific factors may be considered in establishing an inspection programme of facilities and activities in accordance with a graded approach:

(a) Regulatory body resources;
(b) Priority and frequency of inspections;
(c) Methods of inspection;
(d) Types of regulatory inspection;
(e) General national legislation.

Recommendations on regulatory inspections are provided in GSG-13 [10] and further information is given in Ref. [11].

Article 15: Enforcement

1. Persons or organizations responsible for facilities or activities are subject to administrative and/or legal enforcement actions in accordance with the legal system of the State.

2. Wilful violations or attempted violations of the regulations or requirements may be referred to [*insert National Justice Authority*] for prosecution under national criminal statutes and codes.

3. Persons or organizations responsible for facilities or activities who fail to notify the regulatory body are subject to administrative and/or legal enforcement actions in accordance with the legal system of the State.

Notes (Regulatory enforcement):

The enforcement actions taken by the regulatory body are expected to be commensurate with the significance for safety of the non-compliance, in accordance with a graded approach. Enforcement actions may include documented verbal instructions, written notifications, the imposition of additional regulatory requirements and conditions, written warnings, civil penalties, prosecution, revocation of the authorization, and enforcing the cessation of activities or the closure of facilities.

The regulatory body need to develop and implement an enforcement policy compatible with the existing national legal framework. The enforcement policy is usually publicly available so that the public, interested parties and other stakeholders, in addition to registrants and licensees, are aware of the policy and the scope of enforcement actions for non-compliances.

Recommendations on enforcement actions are provided in GSG-13 [10] and further information is given in Ref. [11].

Article 16: Consultation and Communication

Communication and consultation with interested parties are an integral part of the regulatory process. The active involvement of interested parties allows individuals and societal groups to participate in the regulatory decision making process and to influence or even challenge the regulatory body and the information it uses to perform its regulatory functions.

Notes (Article 16):

The communication and consultation with the interested parties is one of the core functions of the regulatory body.

Requirement 36 of GSR Part 1 (Rev. 1) [2] states that "The regulatory body shall promote the establishment of appropriate means of informing and consulting interested parties and the public about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body."

Recommendations on consultation and communication are provided in IAEA Safety Standards Series Nos GSG-6, Communication and Consultation with Interested Parties by the Regulatory Body [27], GSG-12 [19] and GSG-13 [10].

Article 17: Interfaces Between Safety and Security

1. Safety measures and security measures have in common the aim of protecting human life and health and the environment. The registrant or licensee shall implement measures in accordance with the requirements of the related regulatory framework to ensure the security of authorized facilities to prevent unauthorized access by individuals and the unauthorized removal of radioactive material.

2. Safety measures and security measures shall be designed and implemented in an integrated manner, so that security measures do not compromise safety and safety measures do not compromise security.

Article 18: Nuclear Safeguards

The registrant or licensee shall consider nuclear safeguards requirements in the design, the operation and decommissioning of facilities to which nuclear safeguards apply. These requirements shall be implemented in such a way that the safety of the facility is not compromised. Relevant records will be maintained by the registrant or licensee.

Article 19: Technical Service Providers

1. Any person or organization proposing to provide services relating to radiation protection and safety shall apply to the regulatory body for [*an approval or an authorization as appropriate*].

2. Applicants shall submit relevant documentation with regard to the legal status of the organization (or the person), administrative data, organizational structure and working environment, control of products, monitoring and review of the management system and independent assessment.

3. The application shall demonstrate:

    (a) Suitable qualification of the experts (personal), and experience in relevant areas (e.g. accreditation, certification, list of references);
    (b) Adequate knowledge of specific methodologies, applicable criteria and requirements, codes, tools or approaches for the work it proposes to undertake;
    (c) Effective access directly or through subcontractors, to necessary tools, codes and data (for which permissions and competences for use can be demonstrated) standards and expertise to accomplish the scope of work.

Notes (Technical service providers):

The regulatory body needs to issue technical guidance on the requirements to be met by applicants intending to provide a service for protection and safety. The regulatory body may require specific data depending on the nature of the service such as the traceability of source certificates, information on methodology measurements, etc.

Further information on Technical and Scientific Support Organizations (TSO) is available in IAEA-TECDOC 1835, Technical and Scientific Support Organizations Providing Support to Regulatory Functions, [28];

GSG-12 [19] provides recommendations on integration of the regulatory body management system with the management system of TSOs that provide services to the regulatory body.

Article 20: Requirements for Existing Exposure Situations

Notes (Existing exposure situations):

Some of the existing exposure situations are out of scope of these Regulations.

The identification of existing exposure situations can be performed by the regulatory body or any other relevant authority with assigned responsibilities.

1. Identified existing exposure situations shall be evaluated to determine the magnitude of risk of public and occupational exposures taking into account the existing exposure situations described in the scope of these Regulations (Article 3).

2. Those persons or organizations designated by the regulatory body or any other governmental authority to deal with existing exposure situations have the prime responsibility for safety.

3. For existing exposure situations, registrants and licensees with responsibilities for protection and safety shall ensure that remedial actions and protective actions are justified, and that protection and safety are optimized.

4. Licensees in planning for the preparedness and response for a radiological emergency shall ensure that arrangements are planned and implemented as appropriate for the transition from an emergency exposure situation to an existing exposure situation.

Notes (Existing exposure situations):

General principles of radiation protection to reduce exposure when remedial actions and protective actions have been determined to be justified are:

(a) Assignment of responsibilities for the establishment and implementation of radiation protection programmes - including the regulatory body and other relevant authorities (such as the health authority) and as appropriate to licensees and other parties involved in the implementation of remedial and protective actions;
(b) The involvement of interested parties in decisions regarding the development and implementation of the radiation protection programme, as appropriate.

The regulatory body or other relevant authority as assigned, needs to establish a protection strategy for an existing exposure situation to define:

(a) The objectives to be achieved by the radiation protection programme;
(b) Appropriate reference levels.

The regulatory body or other relevant authority responsible for implementing the radiation protection programme, needs to:

(a) Arrange for evaluation of the available remedial actions and protective actions for achieving the objectives and for evaluation of the efficiency of the actions planned and implemented;
(b) Ensure that information is available to individuals subject to exposure on potential health risks and on the means available for reducing their exposures and the associated risks.

The government and the regulatory body or other relevant authority as assigned need to ensure that the protection strategy for the management of existing exposure situations is commensurate with the radiation risks associated with the existing exposure situation and that remedial actions or protective actions are expected to yield sufficient benefits to outweigh the detriments associated with taking them, including detriments in the form of radiation risks.

The regulatory body or other relevant authority as assigned and other parties responsible for remedial actions or protective actions need to ensure that the form, scale and duration of such actions are optimized to provide protection for all individuals subject to exposure. However, priority will be given to those groups for whom residual dose exceeds the reference level. All reasonable steps shall be taken to prevent doses remaining above the reference levels (e.g. the 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 experience in managing similar situations in the past).

The regulatory body or other relevant authority as assigned need to periodically review reference levels to ensure they remain appropriate in the light of the prevailing circumstances. The government will ensure that existing exposure situations are identified and evaluated from the point of view of public and occupational exposure concern, responsibilities for protection and safety are assigned and appropriate reference levels are established.

Relevant recommendations are provided in IAEA Safety Standards Series Nos SSG-32, Protection of the Public against Exposure Indoors due to Radon and Other Natural Sources of Radiation [29] and GSG-8, Radiation Protection of the Public and the Environment [30]. Further information is given in IAEA-TECDOC-1951, Protection against Exposure Due to Radon Indoors and Gamma Radiation from Construction Materials — Methods of Prevention and Mitigation [31] and IAEA Safety Standards Series No. SRS-114, Exposure due to Radionuclides in Food Other than During a Nuclear or Radiological Emergency [32].

PART 3: REQUIREMENTS FOR RADIATION PROTECTION AND SAFETY

Article 21: General Principles of Radiation Protection

1. Each party with responsibilities for radiation protection and safety shall ensure:
    (a) For all exposure situations, that protection and safety is optimized;
    (b) For planned exposure situations, that no practice is undertaken unless it is justified;
    (c) For planned exposure situations other than for medical exposure, specified dose limits are not exceeded;
    (d) For emergency exposure situations and existing exposure situations, that protective actions or remedial actions are justified and undertaken in such a way as to achieve the objectives set out in a protection strategy.

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

Article 22: Responsibilities of Registrants and Licensees in Planned Exposure Situations

1. The registrant or licensee shall bear responsibility for establishing and implementing technical and organizational measures necessary for protection and safety for their authorized facilities and activities.
    (a) The registrant or licensee may designate suitably qualified persons to carry out tasks relating to these responsibilities but shall retain prime responsibility for protection and safety;
    (b) The registrant or licensee shall document the names and responsibilities of persons designated to ensure compliance with the requirements of these Regulations.

2. The registrant or licensee shall notify the regulatory body of any intention to introduce modifications to an authorized facility or activity that could have significant implications for protection and safety and any such modification shall not be carried out until it is specifically authorized by the regulatory body. A description of the process and mechanism for doing this needs to be included.

3. The registrant or licensee shall:

   (a) Establish clear lines of responsibility and accountability for protection and safety for the facilities and activities for which they are authorized and shall establish organizational arrangements for protection and safety;
   (b) Ensure that any delegation of responsibilities by a principal party is documented;
   (c) Conduct a safety assessment for the facilities and activities for which they are authorized and for which a safety assessment is required and keep it up to date;
   (d) Conduct and maintain a prospective assessment for the facilities and activities for which they are authorized and for which the regulatory body requires such an assessment to be made for radiological environmental impacts (Article 11);
   (e) Assess the likelihood and magnitude of potential exposures, their likely consequences and the number of individuals who may be affected by them;
   (f) Have operating procedures and arrangements for protection and safety that are subject to periodic review and updating under a management system;
   (g) Establish procedures for reporting on and learning from, accidents and other incidents;
   (h) Establish arrangements for the periodic review of the overall effectiveness of measures for protection and safety;
   (i) Ensure that maintenance, testing and servicing are carried out as necessary in accordance with supplier specifications and authorization conditions or annually but not to exceed every 12 months, so that sources remain capable of fulfilling their design requirements for protection and safety throughout their lifetime;
   (j) Ensure safe management and control of all radioactive waste generated and dispose of such waste in accordance with the national strategy and regulatory requirements.

Article 23: Justification

1. Practices resulting in exposure to ionizing radiation shall be justified before being adopted, taking into account occupational and public exposure.

2. For planned exposure situations only justified practices shall be authorized.

3. The following practices are not justified:

   (a) Practices that result in an increase in activity by the deliberate addition of radioactive substances or by activation, in food, feed, beverages, cosmetics or any other commodity or product intended for ingestion, inhalation or percutaneous intake by, or application to, a person, unless they are justified practices involving medical exposure;
   (b) Practices involving the frivolous use of radiation or radioactive substances in commodities or in consumer products such as toys and personal jewellery or adornments, which result in an increase in activity by the deliberate addition of radioactive substances or by activation;

(c) Human imaging using radiation that is performed as a form of art or for publicity purposes;
(d) Human imaging using radiation for theft detection purposes.

Notes (Paragraph 3):

If other practices are deemed to be not justified, include them here.

Recommendations on consumer products are provided in IAEA Safety Standards Series No. SSG-36, Radiation Safety for Consumer Products [33].

4. Human imaging, using radiation, performed for occupational, legal or health insurance purposes and undertaken without reference to clinical indication, shall normally be not justified.

5. If, in exceptional circumstances, the justification of human imaging is to be considered for specific practices, such as those in paragraph 4, then Articles 25 and 40 shall apply.

6. Human imaging using radiation for anti-smuggling purposes or to detect concealed objects that can be used for criminal acts or that pose a national security threat shall be justified only by the government. If, in exceptional circumstances, the government or the regulatory body decides that the justification of such human imaging is to be considered, the requirements of Article 40 shall apply.

Notes (Justification):

The regulatory body may review the justification of practices where there is new evidence about their efficacy, risk versus benefit and/or potential consequences. A list of justified practices needs to be available to applicants applying for a new authorization.

The regulatory body provide a list of documentation required for the justification of any new practice.

When considering justification of a practice or a source within a practice it is important to remember to avoid placing undue weight on the radiological component of justification at the expense of other social and economic factors. It may sometimes be useful to appoint a committee of appropriate qualified persons to provide advice on the benefit side of a justification issue.

Notes (Paragraph. 4):

Human imaging using radiation may include such purposes as: assessment of fitness for employment (prior to employment or periodically during employment); assessment of physiological suitability for a career or a sport; determination of age for legal purposes; obtaining evidence for legal purposes; detection of drugs concealed within the body; immigration or emigration requirements; pre-insurance checks; and obtaining evidence for the purposes of a compensation claim.

Recommendations are provided in IAEA Safety Standards Series No. GSG-5 Justification of Practices, Including Non-Medical Human Imaging, [34].

Article 24: Optimization of Protection and Safety

1. The applicant for an authorization shall present to the regulatory body documentation addressing the optimization of protection and safety in the associated facilities and activities. The registrant or licensee shall ensure that protection and safety is optimized.

2. For occupational exposure and public exposure, the registrant or licensee shall ensure the optimization of protection and safety to contribute to achieving the following objectives:

    (a) To determine and implement measures for protection and safety, optimized for the prevailing circumstances, with account taken of the nature, likelihood and magnitude of exposures, appropriate for each use and location;
    (b) To establish criteria (and plans and procedures to implement them) for restricting the likelihood and magnitudes of exposures by means of measures for incident/accident prevention and for mitigating the consequences of such events if they do occur.

3. For remedial or protective actions the registrant or licensee shall:

    (a) Ensure that the form, scale and duration of such actions are optimized to provide protection for all individuals subject to exposure;
    (b) Give priority to those individuals for whom dose exceeds the reference level;
    (c) Prevent doses from remaining above reference levels set in accordance with Article 26.

4. Requirements for the optimization of medical exposure are specified in Article 60.

Article 25: Dose Constraints

1. Dose constraints proposed by the registrant or licensee and approved by the Regulatory Bodies or established by the regulatory Body [*insert the proposed values or specify that they will be proposed in another regulatory document*] shall be used for optimization of protection and safety, such that all exposures are controlled to levels that are as low as reasonably achievable.

2. For occupational exposure, the registrant or licensee shall, where appropriate, optimize protection and safety by setting and applying dose constraints within the radiation protection programme for each source under control.

3. For public exposure in planned exposure situations, the dose constraints equal to [*to be established by the government or the regulatory body in these regulations or separately*].

4. For medical exposure, dose constraints shall apply for the optimization of protection of carers and comforters and volunteers participating in a justified programme of medical or biomedical research (Article 65).

5. Dose constraints equal to [*to be established by the regulatory body in these regulations or separately*] for human imaging shall apply to the use where justified, of radiation without clinical indications for employment, legal or health insurance purposes. All such procedures shall be performed by medical personnel (Article 40).

Notes (Article 25):
The regulatory body ensure dose constraints for occupational and public exposure are consistent with dose limits set in Article 27 for the sum of doses to the same individual from all authorized practices.

When establishing or approving dose constraints in respect of a source within a practice, the government or the regulatory body, as appropriate, take account of:

(a) The characteristics of the source and practice relevant to public exposure;
(b) Good practice in the operation of similar sources;
(c) Dose contributions from other authorized practices or possible future authorized practices, estimated at the design and planning stage, so that total public dose is not expected to exceed the dose limit at any time after operation of the source;
(d) The views of interested parties.

Note (Dose constraints for radioactive releases to the environment):

For facilities and activities that may release radioactive material to the environment, dose constraints need to be established so that prospective annual doses to the public, summed over all exposure pathways, including contributions from other facilities and activities, are unlikely to exceed dose limits specified in Article 27 or any lower values established by the regulatory body.

Article 26: Reference Levels

1. Reference levels [*to be established by the regulatory body*] shall be used for optimization of protection and safety in existing exposure situations and emergency exposure situations.

2. Strategies established in the radiation protection programme shall be applied to keep doses below the reference level. In an emergency exposure situation or where an existing exposure situation has been identified, the reference level shall be used to determine whether further protective actions are necessary and, if so, to prioritize their application.

3. For emergency exposure situations and existing exposure situations, the person or response organization designated to deal with an emergency exposure situation or existing exposure situation shall ensure as appropriate, that relevant reference levels are used in the optimization of protection and safety.

4. Reference levels proposed by the licensee in the remediation plan and approved by the regulatory body shall typically be expressed as an annual effective dose to the representative person in the range of 1–20 mSv or other corresponding quantity, the actual value depending on the feasibility of controlling the situation and on experience in managing similar situations in the past.

5. Reference levels shall be periodically reviewed and updated by the licensee and presented to the regulatory body for approval to ensure that they remain appropriate in the light of the prevailing circumstances.

Notes (Reference levels):

The choices of reference levels have to take into account both radiation protection requirements and societal criteria.

For existing exposure situations involving exposure to radon, reference levels need to be set in terms of radon activity concentration in air as specified in Article 81 for members of the public and Article 53 for workers.

Article 27: Dose Limits

1. The registrant or licensee shall ensure that exposures of individuals due to authorized facilities and activities are restricted so that neither the effective dose nor the equivalent dose to tissues or organs exceeds the applicable dose limit specified in these Regulations.

2. 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 (100 mSv in 5 years) and of 50 mSv in any single year;

   (b) An equivalent dose to the lens of the eye of 20 mSv per year averaged over five consecutive years (100 mSv in 5 years) and of 50 mSv in any single year;
   (c) An equivalent dose to the extremities (hands and feet) or to the skin of 500 mSv in a year.

3. For occupational exposure of apprentices of 16 to 18 years of age being trained for employment involving radiation and for exposure of students of age 16 to 18 years who 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 20 mSv in a year;
   (c) An equivalent dose to the extremities (hands and feet) or to skin of 150 mSv in a year.

4. For public exposure, the dose limits 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 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;
   (d) An equivalent dose to the skin of 50 mSv in a year.

Notes (Dose limits):

The regulatory body determines what additional restrictions, if any, are to be complied with by registrant or licensee to ensure that specified dose limits are not exceeded due to possible combinations of doses from exposure from other authorized facilities and activities.

Equivalent dose limits for the skin apply to average dose over 1 cm^2 of the most highly irradiated area of skin.

Effective dose limits specified in this Article 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 is normally 50 years for intakes by adults and up to age 70 years for intakes by children.

For occupational exposure, personal dose equivalent $H_p(10)$ may be used as an approximation of effective dose from external exposure to penetrating radiation.

Internal exposure caused by inhalation or ingestion of radioactive material shall be estimated in accordance with the dose per unit intake values listed in GSR Part 3 [3].

Dose limits do not apply to medical exposures.

Article 28: Management System Elements

1. Registrants and licensees shall ensure that protection and safety is effectively integrated into the overall management system (in line with a graded approach) of the organizations for which they are responsible. Registrants and licensees shall demonstrate commitment to protection and safety at the highest levels within the organizations for which they are responsible.

2. Registrants and licensees shall explicitly include policies, rules and procedures for the assurance of radiation protection and safety.

3. The registrants and licensees shall ensure that their management system is designed and applied to enhance protection and safety by:

    (a) Applying requirements for protection and safety coherently with other requirements, including requirements for operational performance and guidelines for security;
    (b) Describing the planned and systematic actions necessary to ensure protection and safety requirements are fulfilled;
    (c) Ensuring that protection and safety is not compromised by other requirements;
    (d) Providing for regular assessment of the effectiveness of protection and safety policies, rules and procedures and for applying lessons learned from experience;
    (e) Promoting safety culture.

Article 29: Safety Culture

1. The principal parties (Article 5) shall promote and maintain a safety culture by:

    (a) Demonstrating commitment to protection and safety at all levels of the organization ensuring a common understanding through training and safe performance of the key aspects of safety culture and prioritising good safety practice during operation of regulated facilities and activities;
    (b) Providing resources to individuals and teams that ensure safe completion of tasks, with account taken of the interactions between individuals, technology and the organization;
    (c) Formally, through the management system, involving workers, their representatives and other relevant persons in the development and implementation of protection and safety policies, rules and procedures;
    (d) Ensuring through the management system and job descriptions, the protection and safety accountability of individuals at all levels of the organization;
    (e) Establishing through the management system, mechanisms for open communication about protection and safety within the organization and externally with relevant parties, as appropriate;
    (f) Establishing formal mechanisms to support a questioning and learning attitude and discourage complacency with regard to protection and safety;
    (g) Establishing mechanisms through the management system for continuous improvement of the safety culture.

Article 30: Human Factors

The registrant and licensee shall take into account human factors and support good performance and practices to prevent human and organizational failures, by ensuring that:

(a) Equipment design and operating procedures facilitate safe operation, minimize operator errors and reduce the potential for misinterpretation of indicators of normal and abnormal conditions;
(b) Appropriate equipment, safety systems and procedural requirements are provided, and other necessary provision is made to:
    (i) Reduce, as far as practicable, the possibility that human errors or inadvertent actions give rise to accidents or to other incidents leading to the exposure of any person;
    (ii) Provide means for detecting human errors and for correcting or compensating for them;
    (iii) Facilitate protective actions and corrective actions in the event of failures of safety systems or failures of measures for protection and safety.

Article 31: Responsibilities for Education, Training and Provision of Information

1. The registrant or licensee shall ensure that personnel engaged in activities relevant to protection and safety have, and can show evidence of continuing education, training and qualifications sufficient to understand their responsibilities and perform their duties competently and safely, with appropriate judgement and in accordance with procedures.
2. The employer, in cooperation with the registrant or licensee shall:
    (a) Provide all workers with adequate information on health risks due to their occupational exposure in normal operation, anticipated operational occurrences and accident conditions, adequate instruction and training and periodic retraining in protection and safety, and adequate information on the significance of their actions for protection and safety;
    (b) Provide all workers who could be involved in, or affected by the response to an emergency, with appropriate information and adequate instruction, training and periodic retraining on protection and safety;
    (c) Maintain records of the education, training and qualifications of all personnel, including periodic re-training or new learning.

Note (Article 31):

The government shall ensure that, among others, requirements are established for education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety.

Article 32: Radiation Protection Officers

1. The registrant or licensee, in cooperation with employers where appropriate, shall establish, maintain and keep under review a programme for workplace monitoring under the supervision of a radiation protection officer (RPO) or qualified expert.
2. The registrant or licensee shall designate one or more RPOs for each facility and activity as specified by the regulatory body and provide them with the means necessary to perform their tasks.

3. An RPO shall be technically competent in radiation protection matters relevant to a given practice.

4. The RPO shall oversee application of the requirements of these Regulations relevant to each facility and/or activity to which they have been assigned.

5. The RPO shall report directly to the person responsible for the facility or activity to which the RPO has been assigned.

6. The organization's management system, policy and procedures shall explicitly state the responsibilities and duties of the RPO in relation to protection and safety, including at least the following:

    (a) Supervising the work to ensure compliance with local rules, national regulations and authorization limits and conditions;
    (b) Carrying out, or supervising workplace monitoring;
    (c) Supervising arrangements for individual monitoring and health surveillance;
    (d) Making and keeping radiation sources, including the disused sealed radioactive sources and radioactive waste records updated;
    (e) Ensuring the safe and secure management, including storage, of disused sealed radioactive sources and radioactive waste;
    (f) Ensuring safety and warning systems are maintained and checked;
    (g) Ensuring that equipment is appropriately validated and tested before first use and maintained thereafter;
    (h) Reviewing emergency plans and supervising emergency drills;
    (i) Ensuring the provision of information and training for exposed workers;
    (j) Liaising with qualified experts, facility management and with the regulatory body, as needed;
    (k) Drafting and presenting to the registrant or licensee reports or other documents required by the regulatory body;
    (l) Implementing the radiation protection programme and the radioactive waste management plan.

If other responsibilities are assigned on case by case attention shall be given to avoid conflict with the criteria established by the regulatory body for any specific RPO's designation.

Notes (Radiation protection officer (RPO)):

The regulatory body decides in which practices the designation of an RPO is required.

The required levels of RPO education, training and professional experience are practice-specific and have to be reflected in regulatory criteria for the facility or practice. As a minimum, a secondary level education that includes a scientific or technical component would be expected, but for complex applications or facilities, a tertiary level education may be essential.

RPO training has to be focused on the radiation safety aspects of the practice to which the RPO is assigned. Trainees typically work under supervision until they have sufficient experience and self-confidence to reliably discharge the duties of the RPO.

Recognizing that in some situations the registrant, licensee or employer might not have the necessary expertise, the prospective RPO has to, at the employer's expense, attend a course offered by an external training provider.

Article 33: Qualified Experts

1. Qualified experts shall be identified and consulted on the proper observance of the requirements of these Regulations for protection and safety for all the categories of exposure (occupational, public and medical), and for ensuring the safety of sources.

2. The following two main categories of qualified expert can be identified:

   (a) In medical physics (e.g. medical physicists), to ensure protection during medical exposures (protection of patients);

   (b) In radiation protection, to ensure protection of the workers and the public, and the safety of sources.

4. The registrant or licensee shall identify and engage qualified experts formally recognised by [*the regulatory body*] (and as defined in Article 5) to advise on the fulfilment of the regulatory requirements in specific technical matters, when so required by the regulatory body.

5. Where the practice involves medical exposure and the conditions of the licence so require, the registrant or licensee shall employ a qualified expert. Some of the duties of this qualified expert are the oversight of the technical parameters of radiological equipment, the performance of physical measurements, calculations, calibrations of radiation sources and evaluation in accordance with both the equipment specification and the practice, ensuring that technical parameters including radiation doses to patients and others remain within specified tolerances.

Notes (Qualified expert in radiation protection):

The system of formal recognition of a qualified expert relates to the competences needed to advise in relevant areas, together with the education, training and professional experience necessary to achieve such competence. These parameters are specified by the regulatory body with respect to each regulated practice. Recognition may be based on:

(a) Practices (e.g. diagnostic radiology, nuclear medicine, radiotherapy, industrial applications - high risks sources (e.g. industrial irradiators, industrial radiography), industrial applications – lower risk sources (e.g. industrial gauges involving low activity sources), mining, radioactive waste disposal facilities, nuclear fuel cycle, etc.);
(b) Area of expertise (e.g. radiation safety, predisposal radioactive waste management, dose and risk assessment, shielding calculation, safety assessment, etc.);
(c) Type of source (unsealed sources, sealed sources, accelerators (up to a certain energy level), low-energy X ray generators, etc.). (Based on the State's experience and needs).

Advice provided by a qualified expert will cover areas where each licensee has radiation safety and protection responsibilities with respect to workers, the public and/or patients and the safety of sources. The main areas are, inter alia:

(a) Application of the principle of a graded approach;
(b) Notification and authorization;
(c) Establishing procedures and implementing activities to ensure protection and safety in planned exposure situations, including:
  (i) Safety assessment;
  (ii) Prospective assessment of radiological environmental impacts;
  (iii) Assessment of the likelihood and magnitude of potential exposures;
  (iv) Operational arrangements for protection and safety that are subject to periodic review and updating;

(v) Reporting on and learning from accidents and other incidents, adequate maintenance;
(vi) Testing and servicing as necessary so that sources remain capable of fulfilling their design requirements safely throughout their lifetime;
(vii) Safe management and control over radioactive waste generated and disposal of such waste in accordance with regulatory requirements;

(d) Optimization of protection and safety;
(e) Compliance with dose limits for occupational and public exposure;
(f) Individual, workplace and environmental monitoring;
(g) Monitoring to verify compliance with requirements for protection and safety;
(h) Application of good engineering practice and practicable measures to prevent accidents and to mitigate their consequences;
(i) Investigations of abnormal conditions arising in the operation of facilities or the conduct of activities and dissemination of information significant for protection and safety;
(j) Arrangements to ensure safety of radiation generators and radioactive sources;
(k) Arrangements to ensure protection and safety in the use of ionizing radiation for human imaging for purposes other than medical.

The scope of advice provided by the qualified expert may be specific to practices and/or sources or more general, depending on the system of recognition of their professional skills and experience.

Specific provisions regarding the expertise of a qualified expert can be provided in regulations or guidance or as conditions of a licence (see paragraph 2.46 of GSR Part 3 [3]).

Article 34: Safety Assessment

1. The persons or organizations responsible for a facility or activity that gives rise to radiation risks shall conduct an appropriate safety assessment of that facility or activity, as required under Article 11. This safety assessment shall be either generic or specific to the practice or source for which they are responsible, according to guidance issued by the regulatory body.

2. Safety assessments shall be conducted at a periodicity established by the regulatory body and at different stages, including siting, design, manufacture, construction, assembly, commissioning, operation, maintenance, and decommissioning (or closure) of facilities or parts thereof, as appropriate so as:

   (a) To identify ways in which exposures might be incurred, account being taken of the effects of external events as well as of events directly involving the sources and associated equipment;
   (b) To determine the expected magnitudes and likelihood of exposures in normal operation and, to the extent practicable, make an assessment of potential exposures;
   (c) To assess the adequacy of existing provisions for protection and safety.

3. A 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, including software and procedures relating 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 relating to protection and safety might be erroneous and the consequences of such errors;
   (e) The implications for protection and safety of any modifications;

(f) The implications for protection and safety of security measures, or of any modifications to security measures;
(g) Any uncertainties or assumptions and their implications for protection and safety.

4. The registrant or licensee shall take into account in the safety assessment:

(a) Factors that could give rise to a substantial release of radioactive material, the measures available to prevent or to control such a release and the maximum activity of radioactive material that, in the event of a major failure of the containment, could be released to the environment;
(b) Factors that could give rise to a smaller but continuing release of radioactive material and the measures available to detect and to prevent or to control such a release;
(c) Factors that could give rise to unintended operation of any radiation generator or a loss of shielding and the measures available to detect and prevent or control such occurrences;

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

5. The registrant or licensee shall ensure the safety assessment is documented and where appropriate, independently reviewed under the relevant management system.

6. The registrant or licensee shall perform additional safety assessment reviews as necessary to ensure technical specifications or conditions of use continue to be met when:

(a) Significant modifications to the facility or to its operating procedures or maintenance procedures are envisaged;
(b) Significant changes occur on the site that could affect the safety of the facility or of activities on the site;
(c) Information on operating experience, or information about accidents and other incidents that could result in 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 have been made or are envisaged.

7. If, as a result of a safety assessment or for any other reason, any changes to the radiation protection programme or modifications to the facility or activities are deemed necessary or desirable, these changes shall be approved by the regulatory body prior to implementation.

Note (Safety assessment)

Requirements for safety assessment are established in IAEA Safety Standards Series No. GSR Part 4 (Rev.1), Safety Assessment for Facilities and Activities [35].

Article 35: Monitoring, Testing and Verification of Compliance

1. Registrants, licensees and employers shall ensure the conduct of monitoring to verify compliance with the requirements for protection and safety and the conditions and controls established in the authorization.

2. The registrant, licensee and employers shall ensure that:

    (a) Monitoring and measurements of parameters are performed as necessary for verification of compliance with the requirements of regulations and authorization conditions and in accordance with equipment specifications;
    (b) Suitable measurement and testing equipment is provided and procedures for verification are implemented;
    (c) 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, including records of tests and calibrations carried out in accordance with these Regulations and authorization conditions;
    (e) Results of monitoring and verification of compliance are shared with the regulatory body as required by these Regulations or in the authorization conditions.

Note:

Recommendations are provided in IAEA Safety Standards Series No. RS-G-1.8, Environmental and Source Monitoring for Purposes of Radiation Protection [36].

Article 36: Inventory and Records

1. The registrant or licensee shall establish, maintain and be able to retrieve records relating to:

    (a) The inventory of sealed sources and radiation generators, including disused sealed radioactive sources;
    (b) Records of doses from occupational exposures;
    (c) Records relating to facilities and activities;
    (d) The inventory of radioactive waste;
    (e) Records of events, including non-routine release of radioactive material to the environment;
    (f) Records necessary for decommissioning or closure of facilities;
    (g) The transfer of radioactive sources;
    (h) Records of discharged materials;
    (i) Records of cleared radioactive material;
    (j) Records of workplace monitoring;
    (k) Records of training of the occupationally exposed workers;
    (l) The testing of instruments and safety systems and calibrations carried in accordance with the requirements of these Regulations;
    (m) Records related to medical exposure (see Article 70);
    (n) Changes to procedures;
    (o) Changes to the radiation protection programme;
    (p) Lists of personnel having access to certain sources or devices.

2. Individual sealed source records shall include the following information:

   (a) Location of the source;
   (b) Radionuclide(s);
   (c) Activity on a specified date;
   (d) Serial number or unique identifier;
   (e) Chemical and physical form;
   (f) Source use history, including recording of all movements into and out of the storage location;
   (g) Receipt, transfer or disposal of the source;
   (h) Leak test certificates;
   (i) Other information, as appropriate, to enable the source to be identifiable and traceable.

3. The records will be kept for [*define a time frame*].

4. The registrant or licensee shall provide the regulatory body as required, with appropriate information from their inventory records.

5. The registrant or licensee shall check the inventory periodically to confirm that radiation sources and radioactive waste are in their assigned locations and remain under control.

Article 37: Prevention and Mitigation of Accidents

1. The registrant or licensee shall apply good engineering practice and shall take all practicable measures to prevent accidents and to mitigate the consequences of those accidents that do occur.

Good engineering practice

2. The registrant or licensee, in cooperation with other responsible parties, shall:

   (a) Ensure the relevant protection and safety requirements of these Regulations and all other applicable legislation and requirements are applied to the siting, location, design, construction, assembly, commissioning, operation, maintenance and decommissioning (or closure) of facilities or parts, taking due account of international and national standards;
   (b) Through the management system, establish the managerial and organizational infrastructure to ensure protection and safety throughout the lifetime of the facility;
   (c) Demonstrate that safety margins in the design and construction of the facility and in activities involving the facility, ensure reliable performance in normal operation, and take account of the necessary quality, redundancy and capability for inspection, with emphasis on preventing accidents, mitigating their consequences that do occur and restricting any possible future exposures;
   (d) In the continuous improvement of policy, rules and procedures, take account of relevant developments concerning technical criteria, including relevant research on protection and safety and feedback of information on lessons learned from experience.

Defence in depth

3. The registrant or licensee shall ensure that a multilevel (defence in depth) system of sequential, independent provisions for protection and safety commensurate with the likelihood and magnitude of potential exposures is applied to sources for which the registrant or licensee are authorized. The registrant or licensee shall ensure that if one level of protection were to fail, the subsequent independent level of protection would be available. Such defence in depth shall be applied for the purposes of:

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

Accident prevention

4. The registrant or licensee shall, through the management system, implement policy, rules and procedures to ensure that structures, systems and components, including software, related to protection and safety of facilities and activities are designed, constructed, commissioned, operated and maintained so as to prevent accidents as far as reasonably practicable.

5. The registrant or licensee shall maintain resources, competencies and other capacity as may be necessary to:

    (a) To prevent reasonably foreseeable accidents in the facility or during the conduct of the activity;
    (b) Mitigate the consequences of accidents and incidents;
    (c) Provide workers with information, instruction, training and equipment necessary to restrict potential exposures;
    (d) Ensure continued control and management of the facility in the event of reasonably foreseeable accidents and incidents;
    (e) Ensure that structures, systems and components important to safety, including software and other equipment, is inspected and tested regularly for any degradation that could lead to abnormal conditions or inadequate performance;
    (f) Ensure that maintenance, inspection and testing appropriate to protection and safety provisions can be carried out without undue occupational exposure;
    (g) Provide, wherever appropriate, automatic systems for safely shutting off or reducing radioactive releases from facilities in the event that operating conditions are outside stipulated ranges;
    (h) Ensure that abnormal operating conditions that could significantly affect protection and safety are detected by systems that respond sufficiently quickly to allow for corrective actions to be taken in a timely manner;
    (i) Ensure that all relevant safety documentation is available in the appropriate languages understandable to users.

Emergency preparedness and response

6. If the safety assessment indicates that there is a reasonable likelihood of an emergency, the registrant or licensee shall prepare an emergency plan for the protection of people and the environment. As part of this emergency plan, the registrant or licensee shall include arrangements for the prompt identification of an emergency, and for determining the appropriate level of the emergency response.

In relation to the arrangements for the emergency response at the scene by the registrant or licensee, the emergency plan shall include, in particular:

(a) Provision for individual monitoring and area monitoring, and arrangements for medical treatment;
(b) Arrangements for assessing and mitigating any consequences of an emergency.

7. 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 conditions that could lead to a loss of control over a source or to the escalation of such conditions, registrants and licensees shall, as appropriate:

(a) Develop, maintain and implement procedures to provide the means for preventing loss of control over the source and for regaining control over the source as necessary;
(b) Make available equipment, instrumentation and diagnostic aids that may be needed;
(c) Train and periodically retrain personnel in the procedures to be followed and exercise the procedures.

Article 38: Investigations and Feedback of Operating Experience

1. The registrant or licensee shall conduct formal investigations of abnormal conditions arising in the operation of facilities or the conduct of activities.

2. Registrant or licensee shall ensure that information and lessons learned on both normal operation and abnormal conditions that are significant for protection and safety are disseminated or made available, as appropriate, to the regulatory body and relevant parties, as specified by the regulatory body.

3. Where applicable, the registrant or licensee shall make arrangements with suppliers of sources to establish and maintain mechanisms for the transfer of information on use, maintenance, disposal and malfunctioning that may be relevant for future improvements in the design and manufacture of sources supplied.

4. 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 as prescribed by the regulatory body, including exposures giving rise to doses exceeding a dose limit.

5. The registrant or licensee shall immediately report to the regulatory body any event in which a dose limit is exceeded.

6. The registrant or licensee shall conduct an investigation as specified by the regulatory body in the event that:

(a) A quantity or operating parameter relating to protection and safety exceeds an investigation level;
(b) A quantity or operating parameter relating to protection and safety is outside the stipulated range of operating conditions;
(c) Any equipment failure, accident, error, mishap or other unusual event or condition occurs having the potential for causing a quantity to exceed any relevant limit or operating restriction.

7. As soon as possible after an event [*depending on the regulatory approach, a specific duration may be entered here*] the registrant or licensee shall conduct an investigation and prepare a written record of its causes, or suspected causes, including verification or determination of doses received or committed and recommendations for preventing recurrence of the event and occurrence of similar events.

Article 39: Radiation Generators and Radioactive Sources

1. Manufacturers and suppliers of radiation generators, radioactive sources and components (collectively, radiological devices) associated with the production or release of ionizing radiation, shall ensure the following, as applicable:
   (a) The processes of design, manufacture and construction of such devices shall:
      (i) Provide for protection and safety in accordance with the requirements of these Regulations;
      (ii) Meet engineering, performance and functional specifications established in these Regulations or other such national legislation, requirements or standards, including international standards as listed in Annex III of these Regulations;
      (iii) Meet quality standards defined in national legislation for protection and for the safety of systems and components, including software;
      (iv) Provide clear displays, gauges and instructions on operating consoles in a language understandable to the users;
   (b) Radiation generators and radioactive sources shall be tested prior to delivery and on commissioning at the regulated facility, to demonstrate compliance with relevant specifications;
   (c) Information shall be available, in an appropriate language understandable to users, on proper installation and safe use of such radiological devices including performance specifications, instructions for operating and maintenance and instructions for protection and safety in compliance with relevant national and international standards regarding documentation;
   (d) Protection provided by shielding and by other protective devices is optimized and in accordance with the requirements of these Regulations and other applicable national and international requirements.

Note (Radiation generators and radioactive sources):

Such equipment needs to conform to applicable technical standards such as IEC and ISO or equivalent standards specified by the regulatory body. Standards applied in the country of origin of equipment are not admissible unless formally accepted by the relevant national competent authorities.

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2. Where applicable, the registrant or licensee shall make suitable arrangements with suppliers of radiation generators and radioactive sources, the regulatory body and relevant parties for the purposes of:
   (a) Obtaining information on conditions of use and operating experience that may be important for protection and safety;
   (b) Providing feedback and information that may have implications for protection and safety for other users, or that may have implications for the possibility for improvements in protection and safety for radiation generators and radioactive sources.

3. When choosing a location to use or to store a radiation generator or radioactive source, the registrant or licensee shall take due account of factors relating to:

   (a) Safe and secure management and control of the radiation generator or radioactive source;
   (b) Occupational exposure and public exposure due to the radiation generator or radioactive source, in use and in storage;
   (c) Engineering design with respect to subparagraphs (a) and (b) above.

4. In selecting a site for a facility that will use radioactive material and have the potential for release of radioactive material, the registrant or licensee shall consider protection and safety with emphasis on the integrity and functioning of the facility and feasibility of performing off-site protective actions if they become necessary.

5. The registrant or licensee shall maintain an inventory that includes records of:

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

6. The registrant or licensee shall make available to the regulatory body all such information from their inventory records of radiation generators and radioactive sources as may be required.

7. The registrant or licensee shall take measures to prevent loss or damage to radiation generators and radioactive sources and prevent unauthorized persons from taking actions specified in Article 7, by ensuring that:

   (a) Control over a radiation generator or radioactive source is relinquished only in compliance with all relevant requirements specified in the registration or licence;
   (b) The regulatory body is notified immediately if a radiation generator or radioactive source is lost, missing or no longer under control;
   (c) A radiation generator or radioactive source is transferred only if the recipient possesses the necessary authorization;
   (d) An inventory of radiation generators or radioactive sources (Article 36) is checked periodically to confirm that all regulated sources are in their assigned locations and remain under control.

8. The registrant or licensee shall categorize all sealed radioactive sources in accordance with the requirements of the regulatory body.

9. The manufacturer of a radioactive source or a device containing a radioactive source shall ensure that both source and its container are marked with the symbols recommended by the International Organization for Standardization (ISO).

10. The registrant or licensee, in cooperation with the manufacturer, shall ensure that sealed sources are identifiable and traceable in accordance with international standards and requirements.

11. The registrant or licensee shall ensure that radioactive sources not in use are stored in accordance with the requirements of these Regulations, and in the case when disused sealed radioactive sources are declared as radioactive waste in accordance with the

regulations for the safe management of radioactive waste, to ensure their security and radiation protection and safety.

12. The registrant or licensee shall promptly arrange for the safe management and continued control of radiation generators and disused radioactive sources, including appropriate financial provision in accordance with Article 11 or other national legislation.

Note (Radiation generators and radioactive sources)

Recommendations on the safety of radiation generators and radioactive sources in different practices are provided in:

(a) IAEA Safety Standards Series No. SSG-57, Radiation Safety in Well Logging [37];
(b) IAEA Safety Standards Series No.SSG-58, Radiation Safety in the Use of Nuclear Gauges [38];
(c) IAEA Safety Standards Series No.SSG-59, Radiation Safety of Accelerator Based Radioisotope Production Facilities [39];
(d) IAEA Safety Standards Series No. SSG-11, Radiation Safety in Industrial Radiography [40];
(e) IAEA Safety Standards Series No. SSG-8, Radiation Safety of Gamma, Electron and X Ray Irradiation Facilities [41];
(f) IAEA Safety Standards Series No. SSG-19, National Strategy for Regaining Control over Orphan Sources and Improving Control over Vulnerable Sources [42];
(g) IAEA Safety Standards Series No. SSG-17, Control of Orphan Sources and Other Radioactive Material in the Metal Recycling and Production Industries [43].

Article 40: Radiation Imaging of Humans for Non-Medical Purposes

1. Any practice involving human imaging in which radiation is used for purposes other than for medical diagnosis or treatment shall not be undertaken until authorized by the regulatory body (and as appropriate, other competent bodies).

2. The justification principle (Article 23) shall be applied to any practice involving human imaging in which radiation is used for purposes other than for medical diagnosis or medical treatment or other than as part of an authorized programme of biomedical research. The justification process for the practice shall include consideration of:

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

3. If determined by means of the process specified in paragraph 2, that a human imaging practice using radiation for non-clinical reasons is justified, then such a practice shall be subject to regulatory control.

4. The registrant or licensee shall ensure that appropriate optimization requirements are applied, including dose constraints (Article 25) where humans are exposed to radiation for employment related, legal or health insurance purposes. Furthermore, all such

exposures shall be performed using medical radiological equipment operated by medical personnel.

5. A practice by which an inspection imaging device is used to expose humans to radiation for the purpose of detection of concealed weapons, contraband or other objects on or within the body, shall be considered to give rise to public exposure. In such cases the registrant or licensee shall apply the requirements of the Regulations relating to public exposure in planned exposure situations.

6. The registrant or licensee shall ensure that for practices described in paragraph 5, optimization of protection and safety is subject to dose constraints for public exposure.

7. The registrant or licensee shall ensure that any inspection imaging device used for the detection of concealed objects on or within the human body, irrespective of the country of manufacture or supply, conforms to the applicable standards of the International Electrotechnical Commission or the International Organization for Standardization or to equivalent national standards.

8. Registrant or licensee shall ensure that all persons who are to undergo procedures with inspection imaging devices in which ionizing radiation is used are informed of the possibility of requesting the use of an alternative inspection technique that does not use ionizing radiation, where available.

Notes (radiation imaging of humans for non-medical purposes):

The purposes mentioned in paragraph 4 of Article 40 include assessment of fitness for employment (prior to employment or periodically during employment), assessment of physiological suitability for a career or a sport, determination of age for legal purposes, obtaining of evidence for legal purposes, detection of drugs concealed within the body, immigration or emigration requirements, pre- insurance checks and obtaining evidence for the purposes of a compensation claim.

Recommendations are provided in IAEA Safety Standards Series No. SSG-55, Radiation Safety of X Ray Generators and Other Radiation Sources Used for Inspection Purposes and for Non-medical Human Imaging [44].

PART 4: OCCUPATIONAL EXPOSURE

Article 41: General Responsibilities Specific to Occupational Exposure

1. The registrant or licensee shall be responsible for:
   (a) The radiation protection of workers engaged in activities in which they are, or could be subject to occupational exposure;
   (b) Ensuring that protection and safety is optimized, and that the dose limits for occupational exposure are complied with;
   (c) Compliance with the relevant requirements of these Regulations and authorization conditions.

2. For the protection and safety of workers in existing exposure situations, other than in the specific situations identified in Articles 53–55, requirements in respect of public exposure stated in Part 6 of these Regulations shall be applied.

3. An employer who is also a registrant or licensee shall have the responsibilities of both employer and registrant or licensee.

4. Nothing in these Regulations shall be construed as relieving an employer from the requirement to comply with applicable national and local legislation and regulations, or authorization conditions governing hazards in the workplace.

5. As part of the authorization process of a new or modified practice, the applicant shall, as appropriate, present for review by the regulatory body, among others, supporting documents that state:

    (a) Design criteria and design features relating to the exposure and potential exposure of workers in normal operation, anticipated operational occurrences and accident conditions;
    (b) Design criteria and design features of the appropriate systems and programmes for monitoring of workers for occupational exposure in normal operation, anticipated operational occurrences and accident conditions.

6. For workers who are, or could be subject to occupational exposure, the employer, the registrant or licensee shall ensure that:

    (a) Occupational exposure is controlled so that the relevant dose limits for occupational exposure specified in Article 27 are not exceeded;
    (b) Protection and safety are optimized in accordance with the requirements of these Regulations;
    (c) Decisions regarding measures for protection and safety are recorded and made available as appropriate and as specified by the regulatory body to relevant parties through their representatives;
    (d) Documented policies, procedures and organizational arrangements for occupational protection and safety are established to implement the relevant requirements of these Regulations, with priority given to design measures and technical measures for controlling occupational exposure;
    (e) Facilities, equipment and services for protection and safety are provided, the type and extent of which are commensurate with the expected likelihood and magnitude of the occupational exposure;
    (f) Workers' health surveillance and health services are provided;
    (g) Monitoring equipment and personal protective equipment are provided in accordance with the requirements of these Regulations and arrangements are made for its proper use, calibration, testing and maintenance;
    (h) Suitable and adequate human resources and training in protection and safety is provided, including periodic retraining to maintain the necessary levels of competence;
    (i) Records pertaining to occupational radiation protection are maintained in accordance with the requirements of these Regulations and authorization conditions;
    (j) Arrangements are made to facilitate consultation and cooperation with workers, through their representatives where appropriate, with regard to protection and safety and on all measures to achieve effective application of these Regulations;
    (k) Necessary conditions for promoting safety culture are provided (Article 29).

7. The employer and registrant or licensee shall:

   (a) Involve workers, through their representatives where appropriate, in optimization of protection and safety;
   (b) Establish and use dose constraints where applicable, as part of optimization of protection and safety.

8. Employers, registrants or licensees shall take measure to ensure that workers exposed to radiation from sources within a practice that are not required by or directly related to their work have the same level of protection against such exposure as members of the public.

9. The employer and registrant or licensee shall take such administrative actions as are necessary to ensure that workers are informed that protection and safety is an integral part of a general occupational health and safety programme in which they have specific obligations and responsibilities for their own protection and the protection of others against radiation exposure and for the safety of sources.

10. The employer and registrant or licensee shall record any report received from a worker that identifies circumstances that could affect safety conditions or compliance with the requirements of these Regulations and shall take appropriate action.

11. The employer and registrant or licensee shall facilitate compliance by workers (Article 42) with the requirements of these Regulations.

Article 42: Compliance by Workers

1. Workers engaged in activities in which they are, or could be subject to occupational exposure, shall:

   (a) Fulfil their obligations and carry out their duties for protection and safety;
   (b) Follow applicable rules and procedures for protection and safety as specified by the employer, registrant or licensee;
   (c) Properly use the monitoring equipment and personal protective equipment provided;
   (d) Cooperate with the employer and the registrant or licensee with regard to protection and safety and programmes for workers' health surveillance and dose assessment;
   (e) Provide the employer and registrant or licensee with sufficient information about their past and present work to ensure effective and comprehensive protection and safety for themselves and others;
   (f) Abstain from any wilful action that could put themselves or others in situations not in accordance with the requirements of these Regulations;
   (g) Accept such information, instruction and training in protection and safety to enable them to conduct their work in accordance with the requirements of these Regulations.

2. Workers engaged in activities in which they may be subject to occupational exposure shall at the earliest opportunity, report to the employer, registrant or licensee any circumstances that may adversely affect protection and safety.

Article 43: Cooperation between Employers, Registrant and Licensee

1. The employer and registrant or licensee shall cooperate to the extent necessary for ensuring compliance with the requirements of these Regulations by all responsible parties.

2. Where workers are engaged in work that could involve a source not under the control of their employer, the registrant or licensee responsible for the source shall cooperate with the employer to the extent necessary for compliance by both parties with the requirements of these Regulations.

3. Cooperation between the employer and registrant or licensee shall include, where appropriate:

    (a) Restrictions on exposure and other means of ensuring protection and safety of workers engaged in work that involves or could involve a source not under the control of their employer, such measures being the same or more stringent than for employees of the registrant or licensee;
    (b) Specific assessments of doses received by workers as specified in subparagraph (a);
    (c) Clear allocation and documentation of the respective protection and safety responsibilities of the employer and registrant or licensee.

4. To facilitate cooperation between parties, the registrant or licensee responsible for the source or for the exposure shall as appropriate:

    (a) Obtain from the employer, including self-employed persons, the occupational exposure history of workers as specified in Article 48 and any other necessary information;
    (b) Provide all such information to the employer as may be necessary to ensure compliance with the requirements of these Regulations;
    (c) Provide both workers and employer with the relevant exposure records.

Article 44: Radiation Protection Programme

1. The employer and registrant or licensee shall establish and maintain organizational, procedural and technical arrangements in a radiation protection programme for occupational exposure, including arrangements for the designation of controlled areas and supervised areas, for local rules and for the monitoring of the workplace.

2. The content of the radiation protection programme shall include the following, in accordance with the specific requirements of these Regulations:

    (a) Assignment of responsibilities for workers' protection and safety to the various specified management levels;
    (b) Designation and functions of qualified experts and of RPOs;
    (c) Integration of occupational radiation protection with other areas of health and safety, such as industrial hygiene, industrial safety and fire safety;
    (d) The system of accountability for control of radiation generators and radioactive sources;
    (e) Designation of controlled areas and supervised areas (paragraph 3);
    (f) Local rules for workers and the supervision of work (Article 45);
    (g) Provision of personal protective equipment where required (Article 45);

(h) Arrangements for monitoring workers and the workplace, including the acquisition and maintenance of suitable instruments (specified in Article 47);
(i) The system for recording and reporting information relating to control of exposures and decisions regarding measures for occupational radiation protection and safety and the monitoring of individuals;
(j) The education and training programme on the nature of radiation hazards and measures to ensure radiation protection and safety;
(k) A methodology for periodic review and audit of the performance of the radiation protection programme;
(l) The emergency plan, where the need for such a plan is indicated by the safety assessment;
(m) Workers' health surveillance programme;
(n) Requirements for assurance of quality and process improvement;
(o) Procedures needed for the implementation and control of the radiation protection programme.

3. The registrant or licensee shall clearly designate controlled areas and supervised areas based on operational experience and in accordance with the guidance of the regulatory body. The registrant or licensee shall:

(a) Designate as a controlled area any area in which specific measures for protection and safety are, or could be required for:
  (i) Controlling exposures or preventing the spread of contamination in normal operations;
  (ii) Preventing or limiting the likelihood and magnitude of exposures in anticipated operational occurrences and accident conditions;
(b) In defining the boundaries of any controlled area, consider the magnitude of exposures expected in normal operation, the likelihood and magnitude of exposures in anticipated operational occurrences and in accident conditions and the type and extent of procedures required for protection and safety;
(c) Delineate a controlled area by physical means or, where this is not reasonably practicable, by some other suitable means;
(d) Delineate a controlled area by appropriate means where a source is intermittently brought into operation, energized or moved from place to place and specify exposure times;
(e) Display the warning symbol recommended by the International Organization for Standardization and display instructions at access points to and at appropriate locations within controlled areas;
(f) Establish measures for occupational protection and safety, including, as appropriate, physical measures to control the spread of contamination and local rules and procedures for controlled areas;
(g) 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 likelihood and magnitude of exposures;
(h) Provide, as appropriate, at entrances to controlled areas:
  (i) Personal protective equipment;
  (ii) Equipment for individual monitoring and workplace monitoring;
  (iii) Suitable storage for personal clothing;
(i) 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 objects or material being removed from the area;
(iii) Washing or showering facilities and other personal decontamination facilities;
(iv) Suitable storage for contaminated personal protective equipment;

(j) Periodically assess the need for modifying protection and safety measures or to the boundaries of controlled areas;
(k) Provide information, instruction and training for persons working in controlled areas.

4. The registrant or licensee 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 protection measures and safety provisions are not normally needed.

5. The registrant or licensee, taking into account of the nature, likelihood and magnitude of exposures or contamination in the supervised areas, shall:

(a) Delineate the supervised areas by appropriate means;
(b) Display approved signs, as appropriate, at access points to supervised areas;
(c) Periodically review conditions to assess the need for further measures for protection and safety or for changes to the boundaries of supervised areas.

Notes (Controlled and supervised areas):

Specific guidance can be given by the regulatory body on designation of controlled and supervised areas. Designation has to be based on operational experience and judgement.

Designated areas not at risk of contamination by unsealed radioactive substances may sometimes be defined in terms of dose rate at the boundary.

When defining the boundaries of controlled and supervised areas, to the extent feasible it is pragmatic to make use of existing physical boundaries such as the walls of rooms or buildings.

Article 45: Local Rules and Personal Protective Equipment

1. The employer and registrant or licensee shall not rely solely on administrative controls and personal protective equipment, but shall also provide well engineered controls and safe working conditions in accordance with the following hierarchy of preventive measures:

(a) Engineered controls;
(b) Administrative controls;
(c) Personal protective equipment.

Notes (Engineered and administrative controls):

Based on the type of facility and practices or activities, specific features of engineered controls may include shielding, ventilation, dust control, physical design for contamination control, monitoring of surface contamination, decontamination of equipment areas, floors and personnel.

The regulatory body may provide guidance for the various types of engineered controls by facility, based on a graded approach and regulatory experience.

Administrative controls may include protective clothing (including lead-equivalent shielding aprons or glasses) based on a graded approach to risk.

Job rotation may be considered as an administrative control to restrict the exposure of individual workers, provided all other options to restrict exposures have first been explored.

2. The employer and registrant or licensee, in consultation with workers through their representatives where appropriate, shall:

    (a) Establish the written local rules and procedures necessary for protection and safety of workers and other persons;
    (b) Include in the local rules and procedures, any relevant investigation level or authorized level and procedures to be followed in the event such a level is exceeded;
    (c) Ensure the local rules, procedures and measures for protection and safety are known to those workers to whom they apply and to other persons who may be affected by them;
    (d) Ensure that any work in which workers are, or could be subject to occupational exposure, is adequately supervised and take all reasonable steps to ensure that the rules, procedures and measures for protection and safety provisions are observed;
    (e) Designate as appropriate, an RPO in accordance with criteria established by the regulatory body.

3. The employer and registrant or licensee shall ensure that:

    (a) Workers are provided with suitable and adequate personal protective equipment that meets relevant standards or specifications, including as appropriate:
        (i) Protective clothing;
        (ii) Respiratory protective equipment, the characteristics of which are known to the users;
        (iii) Protective aprons, protective gloves and organ shields;
    (b) Where 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 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, tested at regular intervals recommended by the manufacturer or supplier and in accordance with the frequency of use of the equipment;
    (e) Account is taken of any additional exposure owing to time taken or inconvenience arising from the use of personal protective equipment and the non-radiological risks associated with performing a task using the personal protective equipment.

Article 46: Workplace Monitoring

1. The registrant or licensee, in cooperation with the employer where appropriate, shall establish, maintain and periodically review a programme of workplace monitoring commensurate with a graded approach under the supervision of a RPO or qualified expert.

2. The type and frequency of monitoring of workplaces shall be sufficient to enable:

   (a) Evaluation of the radiological conditions in all workplaces;
   (b) Assessment of exposures in controlled areas and supervised areas;
   (c) Review of the classification of controlled and supervised areas.

3. The type and frequency of monitoring of workplaces shall be based on dose rate, activity concentration in air and surface contamination and their expected fluctuations and on the likelihood and magnitude of exposures in anticipated operational occurrences and accident conditions.

4. The registrant or licensee, in cooperation with the employer where appropriate, shall maintain records of the workplace monitoring programme. The findings of the workplace monitoring programme shall be made available to workers, where appropriate through their representatives.

5. The programme for workplace monitoring shall specify:

   (a) The quantities to be measured;
   (b) Where and when the measurements are to be made and at what frequency;
   (c) The measurement methods and procedures;
   (d) Investigation levels and actions to be taken if the levels are exceeded.

Note (Workplace monitoring):

The regulatory body may provide guidance on selection and use of instruments for workplace monitoring to ensure their performance characteristics are appropriate for specific workplaces.

Recommendations on the acquisition, use, maintenance and testing of workplace monitoring instruments are provided in GSG-7 [21].

Article 47: Assessment of Occupational Exposure

1. The employer and registrant or licensee shall be responsible for making arrangements for the assessment and record of the occupational exposure of workers, with individual monitoring where appropriate. The registrant or licensee shall ensure that arrangements are made with authorized or approved dosimetry service providers that operate under a system of quality management in accordance with the requirements of these Regulations and with applicable national legislation.

2. Where feasible, individual monitoring shall be undertaken of any worker who routinely or occasionally works in a controlled area and may receive a significant occupational exposure dose. In cases where individual monitoring of the worker is inappropriate, inadequate or not feasible, the occupational exposure shall be assessed on the basis of workplace monitoring results together with information on the locations and durations of exposure of the worker.

Note (Direct reading dosimeters):

Direct reading dosimeters provide estimates of an individual's dose and information on dose rates. They are useful for optimization; however, it is noted that active dosimeters often perform poorly in pulsed radiation fields.

Notes (Personal dosimetry):

For the assessment of external exposure and individual monitoring, each worker has to be provided with an integrating personal dosimeter.

In most cases, a single dosimeter is adequate. The dosimeter is placed where the highest exposure at the surface of the trunk is expected. In an inhomogeneous radiation field, it may be useful for workers to wear additional dosimeters on other parts of the body to obtain a better assessment of the effective dose received.

A worker liable to receive an equivalent dose to the extremities, skin or lens of the eye that is a sizeable fraction of the relevant dose limit, is advised to be issued with dose monitoring devices capable of providing information to assess the equivalent dose to the tissue or organ concerned. Extremity dosimeters are worn in positions that measure dose to areas of the body expected to receive the highest dose.

Recommendations and guidance on the management system for dosimetry service providers can be given by the regulatory body (see also Article 19).

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

4. The employer and registrant or licensee shall clearly identify workers who could be subject to exposure due to contamination, including workers who use respiratory protective equipment. The employer shall arrange for appropriate monitoring of such workers to the extent necessary to demonstrate the effectiveness of the measures for protection and safety and to assess intakes of radionuclides and the committed effective doses.

5. Where accidental occupational exposure occurs, the registrant or licensee shall assess the doses and their distribution in the human body and record the results of the assessment. The registrant or licensee shall ensure that arrangements are in place to the extent possible for implementing an analysis system as appropriate and shall take remedial actions. Without delay, the registrant or licensee shall communicate the results of the dose assessment to both the workers affected and to the regulatory body.

Article 48: Records of Workers Exposure

1. The employer and registrant or licensee shall maintain records of occupational exposure for each worker for whom assessment of occupational exposure is required under Article 47.

2. The employer and registrant or licensee shall maintain records of occupational exposure for each worker during and after the worker's working life, at least until the worker attains or would have attained the age of 75 years and for not less than 30 years after cessation of the work in which the worker was subject to occupational exposure.

3. Records of occupational exposure shall include:

   (a) Information on the general nature of the work in which the worker was subject to occupational exposure;
   (b) Information on dose assessments, exposures and intakes at or above the relevant recording levels and the data upon which the dose assessments were based;

(c) Information on dates of employment with each employer of the worker's relevant career and on the doses, exposures and intakes in each such employment;
(d) Records of any assessment of doses, exposures and intakes due to actions taken in an emergency or due to accidents or other incidents, which shall be distinguished from doses, exposures and intakes due to normal conditions of work and which shall include references to reports of any relevant investigations.

4. The employer and registrant or licensee shall:

(a) Provide workers with access to records of their own occupational exposure;
(b) Provide the supervisor of the programme for workers' health surveillance, the regulatory body and the relevant employer, with access to workers' records of occupational exposure;
(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 for former workers by the employer or licensee, as appropriate.

5. In complying with paragraph 4, due care and attention shall be given to unauthorized modification or processing of data related to occupational exposure, or provision of these data to unauthorized persons. The registrant or licensee shall make arrangements for restricted access to records of occupational exposure with respect to confidentiality, availability and integrity of these records.

6. If the employer or registrant or licensee ceases to conduct activities in which workers are subject to occupational exposure, that party shall make arrangements for workers' records of occupational exposure to be retained by the regulatory body (or other state registry) or by the subsequent employer, registrant or licensee.

Note (Threshold value for recording worker dose):

Worker dose exposure or intake values are entered into individual exposure records when the values are equal or higher than the recording level established by the regulatory body.

Article 49: Workers' Health Surveillance

1. The employer and registrant or licensee, in accordance with the rules established by the regulatory body, shall make arrangements for appropriate health surveillance based on the general principles of occupational health and designed to assess the initial fitness and continuing fitness of workers for their intended tasks.

2. If one or more workers are to be engaged in work in which they are or could be exposed to radiation from a source not under the control of their employer, the registrant or licensee responsible for the source shall, as a precondition of engagement of such workers, agree with the employer any special arrangements for workers' health surveillance necessary to comply with the requirements of these Regulations or the requirements of any other relevant competent authority.

Notes (Further objectives of occupational health surveillance):

Further objectives of a workers' health surveillance programme are:

(a) To provide baseline information that may be useful in cases of accidental exposure to a hazardous agent or in the case of occupational disease and for counselling of workers with respect to occupational health risks (including radiation risks) to which they are, or might be, subjected;
(b) To support the ongoing care of overexposed workers.

Recommendations on medical examination of workers within health surveillance programmes are provided in GSG-7 [21].

Article 50: Information, Instructions and Training

The employer, in cooperation with the registrant or licensee, shall:

(a) Provide all workers with comprehensive information on health risks due to their occupational exposure in normal operation, anticipated operational occurrences and accident conditions;
(b) Provide all workers with appropriate instruction and training and periodic retraining in protection and safety in accordance with a graded approach based on the probability and potential magnitude of harm together with detailed information on the significance of their actions for protection and safety;
(c) Provide workers who could be involved in or affected by the response to an emergency, with appropriate information and specific instruction and training and periodic retraining, for protection and safety in emergency situations;
(d) Maintain records of all safety and radiation protection training provided to individual workers.

Notes (Training of workers subject to occupational exposure):
Training of workers subject to occupational exposure needs to address topics in a level of detail commensurate with the workers' job assignments and the potential hazard. Training typically covers topics such as the following:

(a) The main risks associated with ionizing radiation;
(b) Basic quantities and units used in radiation protection;
(c) Requirements for radiation protection (including optimization of protection and limitation of doses);
(d) The fundamentals of practical radiation protection (e.g. use of personal protective equipment, shielding and behaviour in designated areas);
(e) Specific task related issues;
(f) Responsibility to advise a designated person immediately if any unforeseen occurrence involving increased radiation risk arises;
(g) Where appropriate, actions that may need to be taken in the event of an accident.

Recommendations on worker education and training are provided in IAEA Safety Standards Series No. SSG-44, Establishing the Infrastructure for Radiation Safety [45].

Article 51: Workers' Conditions of Service

1. The conditions of service of workers shall be independent of whether they are or could be, subject to occupational exposure. Special compensatory arrangements or preferential consideration with respect to salary, special insurance coverage, working hours, length of vacation, additional holidays or retirement benefits shall neither be granted nor used as substitutes for measures for protection and safety in accordance with the requirements of these Regulations.

2. The employer shall make all reasonable efforts to provide workers with suitable alternative employment in circumstances for which it has been determined, either by the regulatory body or in the framework of the programme for workers' health surveillance in accordance with the requirements of these Regulations, that workers, for health reasons, may no longer continue in employment in which they are or could be, subject to occupational exposure.

Article 52: Specific Requirements for Female Workers and Trainees under 18 Years of Age

1. With the purpose of providing protection of the embryo or fetus and breastfed infants, the employer, in cooperation with the registrant or licensee, shall provide female workers, liable to enter controlled or supervised areas, or who may undertake emergency duties, with appropriate information on:
    (a) The risk to an embryo or fetus due to exposure of a pregnant woman;
    (b) The importance of notifying her employer as soon as possible if a female worker suspects she is pregnant or if she is breast-feeding;
    (c) The risk of health effects for a breastfed infant due to ingestion of radioactive substances.

2. Notification of the employer by a female worker who suspects she is pregnant or confirms she is breast-feeding shall not be a reason to exclude the female worker from work. The employer of a female worker, once notified of her suspected pregnancy or that she is breast-feeding, shall adapt the working conditions in respect of occupational exposure to ensure the embryo, fetus or infant is afforded the same level of protection as for members of the public.

3. The employer and registrant or licensee shall ensure no person under the age of 16 years is or could be, subject to occupational exposure.

4. The employer and registrant or licensee shall ensure that persons under the age of 18 years are allowed access to a controlled area only under supervision and only for the purpose of training for employment in which they are, or could be subject to occupational exposure, or for the purpose of academic studies in which sources are used.

Note (Notification of pregnancy or breast-feeding):

Notifying an employer of suspected pregnancy or of breast-feeding cannot be a requirement on a female worker in these Model Regulations. However, it is vital that female workers understand the importance of giving such notice so their working conditions may be modified accordingly.

Article 53: Exposure due to Radon in Workplaces

1. The reference level for ^{222}Rn in a workplace is set at a value that does not exceed an annual average activity concentration of ^{222}Rn of 1000 Bq/m^3 [*or other value to be decided by the State*], with account taken of the prevailing social and economic circumstances.

2. The reference level for annual average activity concentration of ^{222}Rn shall be set at 300 Bq/m^3 [*value to be decided by the State*] with account taken of the prevailing social and economic circumstances.

3. The employer and registrant or licensee shall ensure that activity concentrations of ^{222}Rn in the workplace are as low as reasonably achievable below the reference level established in accordance with paragraph 1 and shall ensure that protection is optimized.

4. If, despite all reasonable efforts by the employer to reduce it, the activity concentration of ^{222}Rn in the workplace remains above the reference level established in accordance with paragraph 1 the requirements for occupational exposure in planned exposure situations as stated in Part 4 of these Regulations shall apply.

Notes (Workplace exposure due to radon):

The regulatory body or other relevant authority are expected to develop and publish a strategy for protection against exposure due to radon in workplaces.

The regulatory body provides guidance on which requirements of Part 4 of these Regulations are applicable with regard to exposures due to radon.

The regulatory body provides guidance on how to calculate the reference level of ^{222}Rn in workplaces.

Article 54: Remediation of Areas with Residual Radioactive Material

1. The employer, registrant or licensee shall ensure that the exposure of workers undertaking remedial actions is controlled in accordance with the relevant requirements on occupational exposure in planned exposure situations as established in Part 4 of these Regulations.

2. The authorized party shall establish, an appropriate system for maintaining, retrieving and amending records that cover the nature and the extent of contamination; the decisions made before, during and after remediation; and information on verification of the results of remedial actions, including the results of all monitoring programmes after completion of the remedial actions.

3. The authorized party shall ensure that the remediation plan is consistent with the national policy and strategy for radioactive waste management.

Note (Article 54):

The regulatory body provides guidance on which requirements of Part 4 are applicable for this Article.

Article 55: Protection of Workers in Emergency Exposure Situations

1. In an emergency exposure situation, the relevant requirements for occupational exposure in planned exposure situations shall be applied for emergency workers, in accordance with a graded approach, except as described in paragraph 2.

2. Response organizations and employers shall ensure that no emergency worker is subject to an exposure in an emergency in excess of 50 mSv other than:

   (a) For the purposes of saving life or preventing serious injury;
   (b) When undertaking actions to prevent severe deterministic effects and actions to prevent the development of catastrophic conditions that could significantly affect people and the environment; or
   (c) When undertaking actions to avert a large collective dose.

   In these exceptional circumstances, response organizations and employers shall make all reasonable efforts to keep doses to emergency workers below the values set out in Table IV.2 of Annex IV. In addition, emergency workers undertaking actions as a result of which their doses could approach or exceed the values set out in Table IV.2 of Annex IV shall do so only when the expected benefits to others would clearly outweigh the risks to the emergency workers.

Note:

Annex IV of these Regulations can be taken directly from Table IV.2 of Schedule IV of GSR Part 3 [3]. However, it is recommended that the regulatory body considers the whole of GSR Part 3 [3] before considering the modification or transposition of this table into national regulations.

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3. Response organizations and employers shall ensure that:

   (a) Emergency workers who undertake actions in which the doses received might exceed 50 mSv do so voluntarily;
   (b) They have been clearly and comprehensively informed in advance of the associated health risks, and of available measures for protection and safety;
   (c) They are, to the extent possible, trained in the actions that they may be required to take.

4. Workers who receive doses in an emergency exposure situation shall not normally be precluded from incurring further occupational exposure. However, qualified medical advice shall be obtained before any further occupational exposure if such a worker has received a dose exceeding 200 mSv or at the request of the worker.

5. Response organizations and employers shall keep records of emergency occupational exposure that include the records of any assessments made of doses, exposures and intakes due to actions taken in the emergency or due to accidents or other incidents, which shall be distinguished from assessments of doses, exposures and intakes due to normal conditions of work and which shall include references to reports of any relevant investigations. Information on the doses received and information concerning the associated health risks shall be communicated to the workers involved.

Notes (emergency exposure situations):

The government ensures that protection strategies are developed, justified and optimized at the planning stage, by using scenarios based on the hazard assessment, for avoiding deterministic effects and reducing the likelihood of stochastic effects due to public exposure.

The government ensures that an emergency management system is established and maintained for the purposes of emergency response to protect human life, health and the environment in the event of a nuclear or radiological emergency. This emergency management system will:

(a) Be designed to be commensurate with the results of a hazard assessment and to enable an effective emergency response to reasonably foreseeable events (including very low probability events) in connection with facilities or activities;
(b) Be integrated, to the extent practicable, into an all-hazards emergency management system.
(c) Provide for essential elements at the scene, and at the local, national and international level, as appropriate.

The government ensures the coordination of its emergency arrangements and capabilities with the relevant international emergency arrangements.

Article 56: Radiation Exposure of Aircrew and Space Crew

1. When the regulatory body or other relevant authority determines that an assessment of the exposure of aircrew or space crew due to cosmic radiation is deemed to be warranted, a framework shall be established which shall include a reference level of dose and a methodology for the assessment and recording of doses received by aircrew from occupational exposure to cosmic radiation.

2. Where the exposure of aircrew or space crew is deemed justified and are likely to exceed the reference level, employers shall assess and keep records of doses and make the records of doses available to the aircrew or space crew.

3. The employer and registrant or licensee shall inform female aircrew or space crew of the risk to the embryo or fetus due to exposure to cosmic radiation and of the need for early notification of pregnancy.

4. Notification of the employer by a female aircrew or space crew who suspects she is pregnant shall not be considered a reason to exclude her from work. The employer of a female aircrew or space crew member, once notified of her suspected pregnancy, shall adapt the working conditions in respect of occupational exposure to ensure the embryo or fetus is afforded the same level of protection as for members of the public.

5. All reasonable efforts shall be made to optimize protection for individuals in air and space-based activities by restricting the doses received by such individuals while not unduly constraining such activities.

Notes (Article 56)

In IAEA GSG-7 [21], a reference level of about 5 mSv and a methodology for the assessment and recording of doses received by aircrew from occupational exposure to cosmic radiation are proposed.

Various computer codes have been developed for estimating doses received by aircrew and space crew for specific flight route parameters. See also the European Commission Publication 140 Ref. [46].

Recommendations are provided in GSG-7 [21].

PART 5: MEDICAL EXPOSURE

Article 57: General Responsibilities Specific to Medical Exposure

1. The registrant or licensee shall ensure that no patient, whether symptomatic or asymptomatic, undergoes a medical radiation exposure unless:

    (a) It is a radiological procedure requested by a referring medical practitioner and information on the clinical context has been provided, or it is part of an approved health screening programme;
    (b) The medical exposure has been justified by means of consultation between the radiological medical practitioner and the referring medical practitioner, or it is part of an approved health screening programme;
    (c) A radiological medical practitioner has assumed responsibility for protection and safety in the planning and delivery of the medical exposure as specified in paragraph 5(a);
    (d) The patient or patient's legal authorized representative has been informed of the expected diagnostic or therapeutic benefits of the procedure as well as the radiation risks.

2. The registrant or licensee shall ensure that no human incurs a medical exposure as part of a programme of biomedical research unless:

    (a) The exposure has been approved by an ethics committee (or other institutional body assigned similar functions by the relevant authority);
    (b) A radiological medical practitioner has assumed responsibility as specified in paragraph 5(a);
    (c) The requirements specified in paragraph 2 of Article 65 are met for optimization of protection and safety for persons subject to exposure as part of the programme of biomedical research.

3. The registrant or licensee shall ensure all necessary devices to limit patient movement are available during a radiological imaging procedure, with the objective of optimising image quality and avoiding, to the extent possible, the need for a carer or comforter to be present in the radiation area during exposure.

4. The registrant or licensee shall ensure that no carer or comforter incurs a medical exposure unless prior to providing essential care and comfort to an individual undergoing a radiological procedure, the carer or comforter has received and indicated understanding of information on radiation protection and the radiation risks. The registrant or licensee shall ensure that requirements specified in paragraph 1 of Article 65 are fulfilled for optimization of protection and safety of any radiological procedure in which an individual acts as a carer or comforter.

5. The registrant or licensee shall ensure that:

    (a) The radiological medical practitioner performing or overseeing the radiological procedure has assumed responsibility for the radiation protection and safety of patients in the planning and delivery of the medical exposure, including justification of the radiological procedure (Article 59) and optimization of protection and safety (Articles 60–65) in cooperation with

other clinical radiological professionals, such as the medical physicist and medical radiation technologists, as applicable;

(b) Radiological medical practitioners, medical physicists, medical radiation technologists and other health professionals with specific duties in relation to protection and safety for patients undergoing a given radiological procedure are specialized in the appropriate area;

(c) The requirements of these Regulations for calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiation equipment (Articles 61, 62 and 64) are conducted by or under the supervision or with the documented advice of a medical physicist whose degree of involvement is determined by the complexity of the radiological or oncological procedures and the associated radiation risks;

(d) Any delegation of responsibilities by a principal party is documented;

(e) Sufficient medical personnel and paramedical personnel are available as specified by the health authority.

Article 58: Education, Training and Competence

The registrant or licensee shall ensure that radiological medical practitioners, medical physicists, medical radiation technologists and other health professionals having duties in relation to the radiation protection of patients or medical exposure control:

(a) Are specialized in the appropriate area as prescribed by the relevant professional body, health authority or other appropriate organization;

(b) Meet the requirements of these Regulations for education, training and competence in radiation protection and, as applicable, the respective requirements of the professional body for each clinical discipline;

(c) Are named in a record of the qualifications, experience, continuous professional development, unique skills and competences of qualified clinical practitioners maintained by the registrant or licensee and/or the relevant State registration body as applicable.

Article 59: Justification of Medical Exposures

1. The justification principle (Article 23) shall be applied to any practice involving ionizing radiation for medical diagnosis or treatment. The justification process for all such practices shall include consideration of:

(a) The benefits and detriments of the imaging or treatment procedure;

(b) Legal or ethical issues associated with the procedure;

(c) The effectiveness and suitability of the procedure, including appropriateness of the radiation equipment for the intended use or the availability of alternative techniques that do not involve medical exposure;

(d) The availability of the necessary competences and experience to safely conduct the procedure throughout the intended period of the practice.

2. The registrant or licensee shall include with an application for authorization of a medical radiation practice or procedure, the basis of the conclusion that the medical benefits justify the radiation detriment the practice or procedure might cause, with account taken of the benefits and risks of available alternative techniques that do not involve medical exposure.

Note (Risk versus benefit):

The diagnostic or therapeutic benefit that justified medical exposures are expected to yield may not necessarily be only to the person exposed. For patients, this is clearly the case, but for exposures in biomedical research the benefit is also to the biomedical sciences and for future healthcare. Similarly, the benefit for carers and comforters might be the successful outcome of a diagnostic procedure on a child.

3. The registrant or licensee shall require in formal documentation that the justification of each medical exposure of a patient shall be a process of consultation between the radiological medical practitioner and referring medical practitioner, as appropriate, with account taken, in particular, for patients who are pregnant or breast-feeding or are paediatric, of:

    (a) The appropriateness of the request;
    (b) The urgency and necessity of the radiological procedure;
    (c) The characteristics of the medical exposure;
    (d) The characteristics of the individual patient;
    (e) Relevant information relating to the patient's previous radiological procedures.

4. The registrant or licensee shall ensure that national and international referral guidelines are taken into account for the justification of the medical exposure of individual patients.

5. The registrant or licensee shall ensure that before the performance of radiological procedures as part of a health screening programme for asymptomatic populations, justification is obtained from the health authority in conjunction with appropriate professional bodies.

6. The registrant or licensee shall require that any radiological procedure on an asymptomatic individual performed for the early detection of disease, but not as part of an approved health screening programme, is justified for that individual by the radiological medical practitioner and referring medical practitioner together and is in accordance with the guidelines of relevant professional bodies and the health authority. As part of this process, the individual shall be informed in advance of the expected benefits, risks and limitations of the radiological procedure.

7. Medical exposure of volunteers as part of a programme of biomedical research shall be subject to approval by an ethics committee (or other competent body assigned similar functions) and subject to any dose constraints that may be specified by the requirements of these Regulations and other relevant provisions of national legislation [*The State to insert the applicable legislation*].

Notes (Justification of medical exposures):

Applying the justification principle to medical exposure requires a three-level approach:

Level 1: As an overarching justification of medical exposure, it is accepted that the proper use of radiation in medicine does more good than harm.

Level 2: Generic justification of a given radiological procedure is carried out by the health authority in conjunction with appropriate professional bodies. This applies to justification of current technologies and techniques and new technologies and techniques as they evolve.

Level 3: Application of the radiological procedure to a given individual is considered whereby the specific objectives of the exposure, the clinical circumstances and characteristics of the individual involved are taken into account. National or international referral guidelines, developed by professional bodies together with health authorities are used at this level.

Recommendations on the application of the justification principle in medical exposures are provided in SSG-46 [22].

Article 60: Optimization of Protection and Safety in Medical Exposures

1. The registrant or licensee shall ensure through policy — and implement through procedures — that radiological medical practitioners in cooperation with medical physicists and medical radiation technologists optimize protection and safety for each medical exposure (Article 24).

2. The registrant or licensee shall, in cooperation with suppliers, ensure that medical radiological equipment and software that may influence medical exposure conforms to the applicable standards of the International Electrotechnical Commission (IEC), the International Organization for Standardization (ISO), applicable national standards and to the requirements of these Regulations (Article 39).

3. The registrant or licensee shall ensure through written protocols that for diagnostic radiology and image guided interventional procedures, the radiological medical practitioner, in cooperation with the in cooperation with the medical physicists and medical radiation technologists, medical physicist and radiopharmacist or radiochemist (as appropriate) use only the following:

    (a) Medical radiological equipment and software identified in the protocol, as appropriate for the procedure;
    (b) Nuclear medicine radiopharmaceuticals listed in the protocol, as appropriate for the procedure;
    (c) Appropriate techniques and parameters to deliver a patient exposure that is the minimum necessary for the clinical purpose of the radiological procedure, with account taken of relevant norms of acceptable image quality or diagnostic value established by relevant professional bodies and of relevant diagnostic reference levels established in accordance with Article 63.

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

5. For therapeutic radiological procedures in which radiopharmaceuticals are administered, the radiological medical practitioner in cooperation with the medical physicist and the medical radiation technologist, and if appropriate with the radiopharmacist or radiochemist shall ensure through written protocols, that the appropriate radiopharmaceutical with the appropriate activity is selected and administered to each patient such that radioactivity is primarily localized in the organ(s) of interest, while radioactivity in the rest of the body is kept as low as reasonably achievable.

6. The registrant or licensee shall ensure through written protocols that particular aspects of medical exposures are considered in the optimization process for:

(a) Paediatric patients subject to medical exposure;
(b) Individuals subject to medical exposure as part of a health screening programme;
(c) Volunteers subject to medical exposure as part of a programme of biomedical research;
(d) Exposure of the embryo or fetus, in particular for radiological procedures in which the abdomen or pelvis of the pregnant female patient is exposed to the primary radiation beam or could otherwise receive a significant dose;
(e) Relatively high doses[3] to the patient ("high dose procedure");
(f) Exposure of a breastfed infant as a result of a female patient having undergone a radiological procedure with radiopharmaceuticals.

Article 61: Calibration of Equipment used in Medical Exposures

In accordance with Article 57, the medical physicist shall ensure that:

(a) All sources giving rise to medical exposure are calibrated in terms of appropriate quantities using internationally accepted 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 could affect the dosimetry and at intervals approved by the regulatory body;
(c) Calibrations of radiotherapy units are subject to independent verification prior to clinical use;
(d) Calibration of all dosimeters used for dosimetry of patients and for the calibration of sources is traceable to a standards dosimetry laboratory.

Note (Independent verification):

Ideally verification by another independent medical physicist using different dosimetry equipment. However, other options, such as verification by a second medical physicist or using a second set of dosimetry equipment or verification by postal thermoluminescence dosimetry, may be acceptable. In checking for compliance, the regulatory body needs to be aware of limitations on local resources and provide for solutions if there is a lack of options.

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[3] The term 'relatively high dose' is intended to apply in a given context. Clearly, doses from therapeutic radiological procedures are included in 'relatively high doses', as are image guided interventional procedures. In medical imaging, 'relatively high doses' would include doses from exposures in computed tomography and in radiological procedures in nuclear medicine with higher doses.

Article 62: Patient Dosimetry

The registrant or licensee shall ensure that patient dosimetry is performed and documented by or under the supervision of a medical physicist, using calibrated dosimeters and following internationally accepted or nationally accepted protocols, including dosimetry to determine the following:

(a) For diagnostic radiological procedures, typical doses to patients for common procedures;
(b) For image guided interventional procedures, typical doses to patients;
(c) For therapeutic radiological procedures, absorbed doses to the planning target volume for each patient treated with external beam therapy and/or brachytherapy and absorbed doses to relevant tissues or organs as determined by the radiological medical practitioner;
(d) For therapeutic radiological procedures with unsealed sources, typical absorbed doses to patients.

Article 63: Diagnostic Reference Levels

The registrant or licensee shall ensure that:

(a) Local assessments, on the basis of measurements required by Article 62, are made at approved intervals for those radiological procedures for which diagnostic reference levels (DRLs) have been established;
(b) A review is conducted to determine whether the optimization of protection and safety for patients is adequate, or whether corrective action is required if, for a given radiological procedure:
    (i) Typical doses or activities exceed the relevant diagnostic reference level; or
    (ii) Typical doses or activities 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.

Notes (Diagnostic Reference Levels, DRLs):

The government, in consultation with the health authority, relevant professional bodies and the regulatory body, ensures that DRLs be established for medical exposures, including image guided interventional procedures.

In setting DRLs, account is taken of the balance between required image quality and diagnostic result. DRLs are based to the extent possible, on wide scale surveys or published values appropriate for local circumstances.

Article 64: Quality Assurance for Medical Exposures

1. The registrant or licensee shall establish a comprehensive programme of quality assurance for medical exposures with the active participation of medical physicists, radiological medical practitioners, medical radiation technologists and for nuclear medicine facilities, radiopharmacists and radiochemists together with other health professionals, as appropriate.

2. The registrant or licensee shall ensure that a programme of quality assurance for medical exposures appropriate to the medical radiation facility, activity or practice includes:

    (a) Measurements of the physical parameters of medical radiological equipment made by or under the supervision of, a medical physicist:
        (i) At the time of acceptance and commissioning of the equipment prior to its clinical use on patients, and periodically thereafter;
        (iii) After any major maintenance procedure that could affect protection and safety of patients;
        (iv) After installation of new software or modification of existing software that could affect protection and safety of patients;
    (b) Prompt implementation of corrective actions if measured values of the physical parameters mentioned in subparagraph (a) are outside established tolerance limits;
    (c) Verification of appropriate physical and clinical factors used in radiological procedures;
    (d) Maintenance of records of relevant procedures and results;
    (e) Periodic checks of the calibration and conditions of operation of dosimetry equipment and monitoring equipment.

3. The registrant or licensee shall commission regular independent audits of the quality assurance programme for medical exposures at a frequency that reflects the complexity of radiological procedures performed and the associated risks.

Article 65: Dose Constraints for Carers and Comforters and Volunteers Participating in Biomedical Research Programmes

1. The registrant or licensee shall ensure that dose constraints (Article 25) are used in the optimization of protection and safety for any radiological procedure in which an individual acts as a carer or comforter.

2. The registrant or licensee shall ensure that dose constraints specified or approved by the ethics committee, or by another institutional body assigned similar functions, are used in the optimization of protection and safety for persons subject to exposure as part of a programme of biomedical research (Article 59).

Notes (Dose constraints):

For medical exposure, dose constraints are a radiation source-related value used in optimizing the protection of carers and comforters of patients undergoing radiological procedures and the protection of volunteers subject to exposure as part of a programme of biomedical research.

As typically required by the government and in line with international standards and international best practice, the health authority, relevant professional bodies and the regulatory body will consult and together, establish dose constraints for carers and comforters and volunteers participating in biomedical research.

The selection of dose constraints is a complex process in which numerous factors are taken into account, such as the age of the individual and the possibility of being pregnant.

Article 66: Protection of Pregnant or Breast-feeding Patients in Medical Exposures

1. The registrant or licensee shall have specific arrangements in place for radiation protection in cases where a female patient is or might be pregnant or is breast-feeding.

2. The registrant or licensee shall use all appropriate means of communication to alert female patients to the risks of radiation to the unborn baby or breastfed child. In particular, the registrant or licensee shall ensure that signs in appropriate languages are prominently visible in public places, patient waiting rooms, cubicles and other appropriate places to urge female patients to notify the radiological medical practitioner, medical radiation technologists or other clinical professional in the event that she is or might be pregnant, or that she is breast-feeding if the procedure includes administration of a radiopharmaceutical.

3. The registrant or licensee shall have arrangements in place for establishing that a female patient is not currently breast-feeding before commencing any radiological procedure involving administration of a radiopharmaceutical that could result in a significant dose to a breastfed infant and shall ensure this information is considered in the process of justification of the procedure (Article 59) and optimization of protection and safety (Article 60).

Notes (Pregnancy status and reproductive capacity):

Medical radiology facilities need to determine the pregnancy status of female patients of reproductive age before any procedure involving a radiation dose to a potential fetus. One approach is the '10-day-rule,' in which radiological examination of the lower abdomen and pelvis has to be confined to the ten-day interval following onset of menstruation. However, evidence suggests the 10-day-rule may be unnecessarily restrictive.

When the cells of the conceptus are few and not yet specialized, the most likely effect of exposure is failure to implant, or an undetectable termination. Malformations are very rare at this stage. Organogenesis starts 3 to 5 weeks post-conception; thus, it has been suggested a 28-day-rule can replace the 10-day-rule. Applying the 28-day-rule allows a radiological examination, if justified, to be performed throughout the cycle until a period is missed. The focus is shifted to a missed period and the possibility of pregnancy.

If there is a missed period, a female can be considered pregnant unless proven otherwise. In such a situation, available non-radiological imaging alternatives have to be considered.

A combined approach is to apply the 10-day rule only for high dose examinations of the lower abdomen and pelvis (such as CT) and to use the 28-day rule for all other examinations.

Article 67: Release of Patients after Radionuclide Therapy

1. The registrant or licensee shall have 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.

2. The registrant or licensee shall require through written protocols, that the radiological medical practitioner does not discharge a patient having undergone a therapeutic radiological procedure with sealed or unsealed sources until it has been established by a medical physicist or the facility's radiation protection officer that:

    (a) The activity of radionuclides in the patient is such that doses to the public and family members would be in compliance with the requirements of these Regulations;
    (b) The patient or legal guardian of the patient has been provided with:
        (i) Written instructions for keeping doses to persons in the vicinity of the patient as low as reasonably achievable;
        (ii) Advice on avoiding the spread of contamination;
        (iii) Information on the radiation risks.

Note (Article 67):

The government needs to ensure that, as a result of consultation between the health authority, relevant professional bodies and the regulatory body, criteria and guidelines for the release of patients who have undergone therapeutic radiological procedures using unsealed sources or patients who still retain implanted sealed sources are established.

Article 68: Unintended and Accidental Medical Exposures

1. In accordance with the requirements of Articles 37 and 38, the registrant or licensee shall take all practicable measures to reduce the likelihood of unintended or accidental medical exposures arising from design flaws and operational failures of medical radiological equipment; from failures of and errors in software; or from human error.

2. The registrant or licensee shall promptly investigate any unintended or accidental medical exposure, including:

    (a) Medical treatment delivered to the wrong individual or the wrong tissue or organ of the patient, or using the wrong radiopharmaceutical, or with an activity, dose or dose fractionation differing substantially from values prescribed by the radiological medical practitioner, or that could lead to significant secondary effects;
    (b) Any diagnostic radiological procedure or image guided interventional procedure in which the wrong individual or wrong tissue or organ of the patient is subject to exposure;
    (c) Any exposure for diagnostic purposes that is substantially greater than intended;
    (d) Any exposure arising from an image guided interventional procedure that is substantially greater than intended;
    (e) Inadvertent exposure of the embryo or fetus during a radiological procedure;
    (f) Failure of medical radiological equipment, failure of software or system failure, accident, error, mishap, or other unusual occurrence with the potential

for subjecting the patient to a medical exposure substantially different from that intended.

3. The registrant or licensee shall, as part of the investigation of any unintended or accidental medical exposure:

(a) Calculate or estimate doses received and dose distribution within the patient;
(b) Indicate the corrective actions required to prevent recurrence of the unintended or accidental exposure;
(c) Describe the strategy for implementation and implement of all corrective actions under their own responsibility;
(d) Ensure that the radiological medical practitioner promptly informs the referring medical practitioner and the patient or patient's legal authorized representative of the unintended or accidental medical exposure;
(e) Prepare a written report, as soon as possible after the investigation or as otherwise required by the regulatory body, of the apparent and root causes of the unintended or accidental medical exposure, incorporating the information and evidence of actions specified in subparagraphs (a)–(c), together with any other information as required by the regulatory body;
(f) For significant unintended or accidental medical exposures, submit the written report, as soon as possible to the regulatory body and to the relevant health authority.

Note:

The regulatory body determines in the guidance the meaning of "significant".

Article 69: Radiological Review of Medical Exposures

1. The registrant or licensee shall establish a process for periodic radiological review of the medical radiation facility. This review shall be conducted by a radiological medical practitioner in cooperation with the medical radiation technologists and the medical physicists.

2. The radiological review shall include an investigation and critical review of the current practical application of the radiation protection principles of justification and optimization for the radiological procedures that are performed in the medical radiation facility.

Article 70: Records Related to Medical Exposure

The registrant or licensee shall maintain the following records relating to medical exposure and shall make them available to the regulatory body on demand:

(a) Personnel:
  (i) Records of delegation by principal parties of the responsibilities for medical exposure, which shall be kept for [*insert period record to be maintained*];
  (ii) Records of personnel radiation protection training, which shall be kept for [*insert period record to be maintained*];
(b) Calibration, dosimetry and quality assurance:
  (i) Results of calibrations and periodic checks of relevant physical and clinical parameters selected during radiological examination or

treatment of patients, which shall be kept for [*insert period record to be maintained*];

(ii) Records of patient dosimetry, as required by Article 62, which shall be kept for [*insert period record to be maintained*];

(ii) Records of local assessments and reviews made with regard to diagnostic reference levels (DRLs) as required by Article 63, which shall be kept for [*insert period record to be maintained*];

(iv) Records associated with the quality assurance programme, as required by Article 64, which shall be kept for [*insert period record to be maintained*].

(c) Diagnostic radiology:

Information necessary for retrospective assessment of doses, including exposure parameters, number of exposures and duration of fluoroscopic exposure, which shall be kept for [*insert period record to be maintained*];

(d) Image guided interventional procedures:

Information for retrospective assessment of doses, including exposure parameters, duration of fluoroscopic exposure and number of images acquired, which shall be kept for [*insert period record to be maintained*];

(e) Nuclear medicine:

Details of radiopharmaceuticals administered and their activity, which shall be kept for [*insert period record to be maintained*];

(f) External beam radiation therapy or brachytherapy:

(i) A description of the planning target volume;

(ii) Absorbed dose at the centre of the planning target volume and maximum and minimum absorbed doses delivered to the planning target volume, or equivalent alternative information on absorbed doses to the planning target volume;

(iii) Absorbed doses to relevant tissues or organs as determined by the radiological medical practitioner;

(iv) For external beam radiation therapy, dose fractionation and overall treatment time, which together with the records listed in subparagraphs f(i), f(ii) and f(iii), shall be kept for [*insert period record to be maintained*];

(g) Exposure records of volunteers subject to medical exposure as part of a programme of biomedical research, which shall be kept for [*insert period record to be maintained*];

(h) Reports on investigations of unintended and accidental medical exposures (as required in Article 68, which shall be kept for [*insert period record to be maintained*].

Article 71: Medical Physicist

1. At a level commensurate with the complexity, dose and radiological risks of medical radiological procedures, the registrant or licensee shall involve a medical physicist having qualifications and competences in accordance with paragraph 3 of Article 5 and paragraph 1 of Article 33.

2. The registrant or licensee shall assign responsibility to a medical physicist for optimization of radiation protection and safety in medical exposures, including source calibration, clinical dosimetry, image quality and patient dose assessment, and physical

aspects of the programme of quality assurance, including medical radiological equipment acceptance and commissioning.

3. The registrant or licensee shall require through documented procedures, that the medical physicist actively participates in the investigation following any unintended or accidental medical exposure as described in Article 68.

4. The registrant or licensee shall require through procedures that the medical physicist communicates and cooperates with other qualified experts and health professionals in working towards establishing an integrated programme for radiation protection and safety at the medical radiation facility.

Notes (Involvement of medical physicists):

GSR Part 3 [3] defines the role and responsibilities of medical physicists.

The involvement of medical physicists needs to be clarified by the regulatory body and might be interpreted as "duties fulfilled by", "under the supervision of", "under the oversight of" or "with the documented advice".

The regulatory body can provide broad guidance on the level of involvement of a medical physicist and the respective radiological procedures. For example:

(a) Radiotherapeutic practices: A medical physicist has to be closely involved;
(b) High dose radiodiagnostic and interventional radiology procedures: A medical physicist has to be involved;
(c) Medical radiological practices other than (a) or (b): a medical physicist may be involved as appropriate, for consultation and advice on matters relating to radiation protection concerning medical exposure.

The medical physicist may have responsibilities in providing radiation protection and safety training for health professionals.

Articles 72: Specific Requirements for Radiation Protection and Safety in Diagnostic Radiology and Image Guided Interventional Procedures

*The provisions in Article 72 as presented in Appendix II of this TECDOC, are provided as **an example** of a prescriptive Article that includes specific requirements that apply to radiographic and fluoroscopic diagnostic procedures and image guided interventional procedures performed in a fixed location or mobile facilities, as well as X ray imaging as part of radiation therapy or nuclear medicine procedures. The specific technical requirements and values indicated are an example for consideration, in case the option of prescriptive regulations is promoted. However, the regulatory body is encouraged to introduce more generic requirements in the regulations and then define and publish more detailed guidance in a separate guidance document.*

Article 73: Specific Requirements for Radiation Protection and Safety in Nuclear Medicine

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Note (Article 73):

The following provisions apply to procedures in which unsealed radioactive material is administered to patients for diagnosis or treatment of disease, or for clinical or pre-clinical research.

Recommendations on the content of regulatory guides for nuclear medicine are provided in SSG-46 [22].

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1. The registrant or licensee shall ensure nuclear medicine facilities using unsealed sources have areas for the following:

   (a) Source storage and preparation;
   (b) Radiopharmaceutical administration to patients;
   (c) Uptake rooms;
   (d) Imaging (in vivo) and sample measurement (in vitro);
   (e) Separate waiting areas for patients before and after radiopharmaceutical administration;
   (f) Changing areas and toilets;
   (g) Radioactive waste storage and predisposal processing.

2. For nuclear medicine facilities at which therapy with radiopharmaceuticals is performed, the registrant or licensee shall ensure there are dedicated wards for patients undergoing such treatments.

3. The registrant or licensee shall ensure that adequate shielding is provided for workers, patients and other persons in the facility (e.g. visitors). Shielding calculations shall take into consideration the classification of areas within the facility, type of work to be performed, the radionuclides (and their activity) intended to be used, as well as the structural and ancillary protective barriers. The adequacy of the shielding shall be verified during construction and before the facility enters clinical use, and similarly after any structural modifications.

Note (Shielding in nuclear medicine facilities):

The regulatory body may provide guidance on methodologies and data for shielding calculations for nuclear medicine facilities.

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4. The registrant or licensee shall provide equipment for manipulation of unsealed radioactive material in radiopharmaceuticals, laboratories and other work areas.

5. During construction or prior to commissioning and operation of a medical radiation facility or rooms within a facility in which unsealed radioactive material is prepared, handled or administered to patients, the registrant or licensee shall ensure that the drainage system from such areas to the main building sewer is structured to prevent radionuclide contamination of non-controlled areas.

6. The registrant or licensee shall ensure floors and other surfaces of nuclear medicine facilities where manipulations of unsealed sources take place are covered with smooth, continuous, and non-absorbent materials that can be easily cleaned and decontaminated.

7. The registrant or licensee shall ensure radiopharmaceuticals are manufactured according to good manufacturing practice following relevant international standards for radionuclide purity, specific activity, radiochemical purity, chemical purity and pharmaceutical aspects, such as toxicity, sterility and pyrogenicity.

8. The registrant or licensee shall ensure that probes used for uptake measurements include design features for energy response, energy resolution, sensitivity, counting precision, linearity of count rate response and geometrical dependence.

9. The registrant or licensee shall ensure that probes used intra-operatively include design features for energy resolution, background count rate, sensitivity in scatter, sensitivity to

scatter radiation, shielding (side and back), counting precision, linearity of count rate response (with scatter radiation) and count rate recorded by visual display and by an audible sound, the intensity of which is proportional to the count rate.

10. The registrant or licensee shall ensure that gamma cameras (planar and SPECT systems) incorporate the following design features:

    (a) Detector: pulse height analysis; uniformity; spatial resolution and linearity; energy resolution; sensitivity; count rate performance; detector head shielding leakage;
    (b) Detector head motion;
    (c) Automatic patient–detector distance sensing;
    (d) Collision detection and emergency stops;
    (e) Collimators and collimator exchange mechanisms;
    (f) Imaging table and attachments;
    (g) Data acquisition: general acquisition features; static acquisition; dynamic acquisition; list mode acquisition; gated cardiac acquisition; whole body imaging; tomography;
    (h) Data processing system: Data display; image manipulation; region of interest generation and display; curve generation; display and arithmetic; quality control software; test data;
    (i) Accessories, such as features for physiological triggering, anatomical landmarking and phantoms.

11. The registrant or licensee shall ensure that PET scanners incorporate the following design features:

    (a) Detector: spatial resolution; sensitivity; scatter fraction, count losses and random measurements; energy resolution; image quality and accuracy of attenuation and scatter correction and quantitation; coincidence timing resolution for time-of-flight PET accuracy;
    (b) Time-of-flight capability;
    (c) Data acquisition: 2-D and 3-D whole body imaging and cardiac and respiratory gating;
    (d) Data processing system: image reconstruction algorithms, image manipulation and image correction;
    (e) Emergency stop.

12. The registrant or licensee shall develop procedures for safe receipt and movement of radioactive sources within the nuclear medicine facility and establish controls to prevent theft, loss and unauthorized withdrawal of radioactive material, or entrance of unauthorized personnel to controlled areas.

13. The registrant or licensee shall maintain an inventory of sources and have procedures to confirm that sources are in their assigned locations and are secure.

Article 74: Specific Requirements for Radiation Protection and Safety in Radiation Therapy

Note (Article 74):

The following provisions apply to radiation therapy (teletherapy and brachytherapy) by which radiation is used alone, or in combination with other modalities, for the treatment of cancer or other diseases.

A typical radiation therapy facility comprises six main functional areas: Reception, clinical consulting areas and areas for external beam radiation therapy, brachytherapy, imaging and treatment planning.

Detailed requirements for radiation therapy to be included in regulatory guides are given in SSG-46 [22].

1. The registrant or licensee shall ensure that regulatory siting and shielding requirements for a radiation therapy facility are met;

2. Siting and shielding calculations shall take into consideration inpatient and outpatient access, operational efficiencies, potential for future expansion, adjacent areas or rooms, occupancy factors and the physical weight of shielding;

3. Shielding adequacy shall be verified during construction and before the facility is placed in clinical use and similarly, after future structural modifications;

4. Radiation treatment room shielding shall be constructed such that its integrity as a radiation barrier is not compromised by joints, duct openings, pipes or other objects passing through the shielding, or by conduits, service boxes or other embedded structural elements.

   Notes (Shielding):

   The regulatory body may provide guidance on methodologies and data for shielding calculations for teletherapy and brachytherapy facilities.

   The regulatory body may require that licensees submit shielding specifications for review prior to granting an authorization for the construction phase.

5. The registrant or licensee shall ensure that within a single facility, external beam radiation therapy and High Dose Rate (HDR) brachytherapy are performed in treatment rooms designed for those radiotherapeutic procedures.

   Note (Dedicated rooms for radiotherapy and brachytherapy):

   HDR or Pulsed Dose Rate (PDR) brachytherapy and external beam radiation therapy are not undertaken in the same room for procedure flow and other efficiency reasons. Each requires unique equipment and operating conditions which would have to be re-established before every treatment unless these quite different procedures are performed in dedicated rooms.

6. The registrant or licensee shall ensure the radiotherapy Record and Verify System (RVS) interfaces with image and administrative data storage systems throughout the facility, including operational information systems such Picture Archiving and Communications (PACS) and the Radiology Information System (RIS)) or their equivalents.

7. The registrant or licensee shall ensure the RVS is subject to a comprehensive quality assurance (QA) programme.

8. In addition to power-off switches on the control panel outside a treatment room, there shall be additional power-off switches located within easy reach inside the treatment room, so that personnel can instantly shut down radiation generating equipment in an emergency.

9. The registrant or licensee shall provide communication systems and audio-visual devices or other means for clinical staff to be in continuous contact with and maintain a clear view of the patient.

10. The registrant or licensee shall ensure medical radiological equipment includes:

    (a) Provisions for selection, reliable indication and confirmation of operating parameters such as type of radiation, indication of energy, beam modifiers (such as filters and wedges), treatment distance, field size, beam orientation and either treatment time or pre-set dose;
    (b) Interruption mechanisms that stop irradiation when tolerance levels are exceeded;
    (c) A fail-safe mechanism in the event of a power interruption, that automatically retracts the source to its shielded position until the beam control mechanism is reactivated from the control panel;
    (d) Safety systems to prevent equipment operation by unauthorized personnel;
    (e) A device to manually return a source to the shielded position in the case of its failing to retract automatically.

11. The registrant or licensee shall ensure integrity and confidentiality of data, including patient information, is maintained throughout the facility's information networks.

12. The registrant or licensee shall ensure external beam radiotherapy equipment incorporates:

    (a) Safety interlocks or other means to prevent clinical use of the machine in conditions other than those selected at the control panel;
    (b) Means to permit interruption of treatment from the control panel;
    (c) Radiation beam control mechanisms, including devices that indicate in a clear and fail-safe manner, whether the radiation beam is on or off;
    (d) Means to keep the radiation field uniform within the treatment area in the absence of radiation beam modifiers, such as wedges or multileaf collimators;
    (e) Means to keep radiation leakage or scattering dose rates outside the treatment area as low as reasonably achievable;
    (f) Electrical or mechanical interlocks to prevent primary radiation being directed towards secondary barriers if primary shielding (where installed) is not intercepting the beam.

13. The registrant or licensee shall ensure the following regarding brachytherapy equipment and sources:

    (a) Low dose rate, high dose rate and pulsed dose rate brachytherapy sources are accompanied by a source certificate specifying the source strength in terms of reference air kerma rate in air or equivalent quantity at a specified distance, for a specified date;
    (b) The quality control tests are applied to the source include leakage and contamination tests;

(c) Applicators are manufactured specifically for the source and are compatible with it.

14. The registrant or licensee shall develop procedures for safe receipt and movement of radioactive sources within the radiotherapy and oncology facility and establish controls to prevent theft, loss and unauthorized withdrawal of radioactive material, or entrance of unauthorized personnel to controlled areas.

15. The registrant or licensee shall maintain an inventory of sources and have procedures to confirm that sources are in their assigned locations and are secure.

PART 6: PUBLIC EXPOSURE

Article 75: General Responsibilities for Public Exposure in Planned Exposure Situations

1. The registrant or licensee, in cooperation with suppliers and with providers of consumer products, shall apply the requirements of these Regulations and shall verify and demonstrate compliance with them, as specified by the regulatory body, in relation to any public exposure delivered by a source for which they have responsibility.

2. The registrant or licensee, in cooperation with suppliers, in applying the principle of optimization of protection and safety in the design, planning, operation and decommissioning of a source (or for closure and the post-closure period for waste disposal facilities), shall take into account:

   (a) Possible changes in conditions that could affect exposure of the public, such as changes in the characteristics and use of the source, changes in environmental dispersion conditions, changes in exposure pathways or changes in values of parameters used for the determination of the representative person (see note below);
   (b) Good practice in the operation of similar sources or the conduct of similar practices;
   (c) Possible accumulation in the environment of radioactive substances from discharges during the lifetime of the source;
   (d) Uncertainties in the assessment of doses, especially uncertainties in contributions to doses if the source and the representative person are separated in space or in time.

3. The registrant or licensee shall for all sources under their responsibility, establish, implement and maintain:

   (a) Policies, procedures and organizational arrangements for protection and safety in relation to public exposure, in accordance with the requirements of these Regulations. The extent of such arrangements shall be commensurate with the likelihood and magnitude of the exposures;
   (b) Measures for ensuring:
      (i) optimization of protection and safety;
      (ii) limitation of exposure of members of the public from such sources, in accordance with the authorization or such that the total exposure is not higher than the dose limits for members of the public (Article 27);
   (c) Measures for ensuring the safety of such sources;

(d) Provisions for suitable and adequate resources (including facilities, equipment and services) for the protection and safety of members of the public, commensurate with the likelihood and magnitude of the exposures;
(e) Programmes for appropriate training of personnel having functions relevant to the protection and safety of the public, as well as periodic retraining as required, to ensure the necessary level of competence;
(f) Provision for appropriate monitoring equipment, monitoring programmes and methods for assessing public exposure;
(g) Adequate records of monitoring programmes;
(h) Emergency plans, emergency procedures and emergency response arrangements, in accordance with the nature and magnitude of the radiation risks associated with the sources.

Note (Representative person):

Doses to the public are to be estimated using environmental concentrations and/or exposure rates and appropriate habit data. Therefore, for the purpose of protection of the public, it is necessary to define a person to be used for determining compliance with the dose constraint. This is the representative person. This individual, who will almost always be a hypothetical construct, receives a dose that is representative of the more highly exposed individuals in the population [21].

Article 76: Measures for Protection of Members of the Public and Visitors

1. The employer and registrant or licensee shall, where appropriate:

(a) Apply the relevant requirements of these Regulations in respect of public exposure for visitors to a controlled area or a supervised area;
(b) Ensure visitors are accompanied in any controlled area by a person who knows the measures for protection and safety for the controlled area;
(c) Provide adequate information and instructions to visitors before they enter a controlled area or supervised area, so as to provide for protection and safety of visitors and other individuals who could be affected by their actions;
(d) Ensure adequate control is maintained over the entry of visitors to a controlled area or a supervised area, including the use of signs for such areas.

2. Where a source may give rise to external exposure of members of the public the registrant or licensee shall ensure that:

(a) Floor plans and arrangements of equipment for all installations utilizing such sources, as well as all significant modifications to existing installations, are subject, as appropriate to review and approval by the regulatory body prior to commissioning;
(b) Shielding and other measures for protection and safety, 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. The registrant or licensee shall ensure, as appropriate, that:

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

(b) Measures for protection and safety are implemented for restricting public exposure due to contamination in areas within a facility that are publicly accessible.

Article 77: Radioactive Waste and Discharges

1. The registrant or licensee shall in cooperation with suppliers, as appropriate:
   (a) Develop and implement a strategy for radioactive waste management and shall include appropriate evidence that protection and safety is optimized;
   (b) Ensure that any radioactive waste generated is kept to the minimum practicable in terms of both activity and volume;
   (c) Maintain an inventory of all radioactive waste that is generated, stored, transferred or disposed of;
   (d) Manage radioactive waste in accordance with the requirements of these Regulations and with the relevant limits, conditions and controls established in the authorization;
   (e) Ensure that there is separate processing of radioactive waste of different types, where warranted by differences in factors such as radionuclide content, half-life, activity concentration, volume, and physical and chemical properties, taking into account the available options for storage and disposal of radioactive waste, without precluding the mixing of radioactive waste for purposes of protection and safety;
   (f) Ensure activities for predisposal management and disposal of radioactive waste are conducted in accordance with the requirements of applicable regulations, and in accordance with the authorization.

2. On making an application for the authorization of discharges, the registrant or licensee shall, in cooperation with suppliers and as appropriate:
   (a) Determine the characteristics and activity of material to be discharged, and possible points and methods of discharge;
   (b) Perform a pre-operational study to determine all significant exposure pathways by which discharged radionuclides could give rise to exposure of members of the public;
   (c) Assess the doses to the representative person (Article 75) due to the planned discharges;
   (d) Consider the radiological environmental impact in an integrated manner with the system for protection and safety, as required by these Regulations and the limits, conditions and control established in the authorization;
   (e) Submit to the regulatory body the findings of (a)–(d) above to facilitate establishment by the regulatory body of authorized limits on discharges and conditions for their implementation.

3. The registrant or licensee shall ensure that radioactive waste and discharges of radioactive material to the environment are managed in accordance with the limits, conditions and controls established in the authorization.

Notes (Discharges):

The regulatory body establishes operational limits and conditions relating to public exposure, including authorized limits for discharges. These operational limits and conditions:

(a) Are criteria with which registrant and licensee are expected to comply before commencement of operation and during operation thereafter;
(b) Correspond to doses below dose limits with account taken of the results of optimization of protection and safety;
(c) Reflect the registrant or licensee's adoption of good practice in the operation of similar facilities or activities;
(d) Have to allow for operational flexibility;
(e) Take into account the results of the prospective assessment for radiological environmental impacts.

When a source within a practice could cause public exposure outside the territory or other area under the jurisdiction or control of the State in which the source is located, the government or the regulatory body:

(a) Ensure the assessment for radiological impacts includes those impacts outside the territory or other area under the jurisdiction or control of the State;
(b) Establish requirements for control of discharges to the extent possible;
(c) Arrange with the affected State means for exchange of information and consultation, as appropriate.

Recommendations on the regulatory control of radioactive discharges to the environment are provided in IAEA Safety Standards Series No GSG-9, Regulatory Control of Radioactive Discharges to the Environment [47]. More on discharges can be found in IAEA-TECDOC-1714, "Management of Discharge of Low level Liquid Radioactive Waste Generated in Medical, Educational, Research and Industrial Facilities [48].

4. The registrant or licensee shall, at a frequency determined by the regulatory body, review and as necessary modify discharge control measures with the agreement of the regulatory body, taking into account:

    (a) Operating experience;
    (b) Any changes in exposure pathways or in the characteristics of the representative person affecting assessment of doses due to discharges.

Article 78: Monitoring and Reporting

1. The registrant or licensee, when required by the regulatory body, shall establish and implement a monitoring programme to ensure public exposure due to sources under their responsibility is assessed in a manner sufficient to verify and demonstrate compliance with the authorization. Monitoring shall include the following, as appropriate:

    (a) External exposure due to such sources;
    (b) Discharges;
    (c) Radioactivity in the environment;
    (d) Other parameters important for the assessment of public exposure.

2. The registrant or licensee shall maintain monitoring programme records, which shall be forwarded to the regulatory body at intervals defined in the authorization and include at least the following:

   (a) Estimated doses to members of the public;
   (b) Levels and composition of discharges;
   (c) Dose rates at site boundaries and in premises open to the public;
   (d) Results of environmental monitoring;
   (e) Retrospective assessments of doses to the representative person.

3. The registrant or licensee shall report promptly [*depending on the regulatory approach, a prescribed duration may be inserted here*] to the regulatory body:

   (a) Any levels exceeding operational limits and conditions relating to public exposure, including authorized limits on discharges;
   (b) Any significant increase in dose rate or concentrations of radionuclides in the environment that could be attributed to the registrant or licensee.

4. The registrant or licensee shall establish and maintain a capability to conduct monitoring in an emergency in the event of unexpected increases in radiation levels or in concentrations of radionuclides in the environment due to an accident or other unusual event attributed to the authorized source or facility.

5. The registrant or licensee shall verify the adequacy of assumptions made for assessment of public exposure and assessment of radiological environmental impacts.

6. The registrant or licensee shall publish or make available on request, as appropriate, the results of source monitoring and environmental monitoring programmes and assessments of doses from public exposure on a communications platform accessible by the public.

Article 79: Consumer Products

1. Consumer products (as defined in Article 4) shall not be provided to the public unless such provision is justified in accordance with the requirements of these Regulations (Article 23) and either their use has been exempted on the basis of the criteria specified in Annex I of these Regulations or their provision to the public has been otherwise authorized.

2. Suppliers proposing to provide consumer products to the public shall apply to the regulatory body for an authorization in accordance with paragraph 1 of Article 11.

3. Aspects of consumer product design and manufacture that could affect exposure during normal handling, transport and use, as well as in the event of mishandling, misuse, accident or disposal, shall be in compliance with the optimization of protection and safety requirements of these Regulations (Article 24).

4. Applicants seeking authorization to manufacture, import, supply or otherwise handle such consumer products shall duly account for the following:

   (a) The radionuclides used in the consumer products and their radiation types, energies, activities and half-lives;

(b) The chemical and physical forms of the radionuclides used in the consumer products and their significance for protection and safety in normal and abnormal conditions;
(c) The containment and shielding of radioactive substances in the consumer products and the physical constraints on access to these radioactive substances in normal conditions and abnormal conditions;
(d) Specifications for the scope and frequency of servicing or repair of the consumer products and the manner in which this would be done, taking account of the protection and safety requirements of these Regulations;
(e) Relevant experience with similar consumer products.

5. The registrant or licensee authorized to provide consumer products to the public shall:

(a) Comply with the conditions of the authorization to provide consumer products to the public;
(b) Ensure the consumer products comply with the requirements of these Regulations;
(c) Have appropriate arrangements for the servicing, maintenance, recycling or disposal of such consumer products, in accordance with the requirements of these Regulations;
(d) By means of legible labels attached where feasible to a visible surface of each consumer product and to the retail packaging, indicate the following:
(i) That the consumer product contains radioactive substances;
(ii) Information that clearly identifies the radionuclides in the manner required by these Regulations;
(iii) That the provision of the consumer product to the public has been authorized by the regulatory body;
(iv) Information on required or recommended options for recycling or disposal.

6. The registrant or licensee authorized to provide consumer products to the public shall provide with the consumer product, clear and appropriate information and instructions on the following:

(a) Correct installation, use and maintenance of the consumer product;
(b) Servicing and repair;
(c) The radionuclides and their activities at a specified date;
(d) Dose rates in normal operation and during servicing and repair;
(e) Required or recommended options for recycling or disposal.

7. The registrant or licensee authorized to provide consumer products shall provide consumer product retailers with appropriate information on safety and instructions on the transport and storage of the consumer products.

Article 80: Responsibilities for Remediation of Areas with Residual Radioactive Material

1. Persons or organizations responsible for planning, implementation and verification of the remediation of areas with residual radioactive material shall prepare and submit for regulatory body approval, a remedial action plan supported by a safety assessment.

2. The objective of the remedial action plan shall be to reduce the existing radiation risk in a timely and progressive manner until restrictions on the use of, or access to the area can be eased or lifted, to the extent possible.

3. The remedial action plan submitted for regulatory body approval shall identify the legal person having prime responsibility for implementing the actions set out in the plan.

4. The remedial action plan submitted for regulatory body approval shall consider:

    (a) That proposed remedial actions potentially causing additional doses to members of the public shall be justified in accordance with the requirements of these Regulations (Article 23) on the basis of the resulting net benefit, including consideration of the consequent reduction of the annual dose;
    (b) That both the radiological and non-radiological impacts on people and the environment are considered together, taking into account technical, societal and economic factors;
    (c) That the costs of the transport and management of radioactive waste, the radiation exposure and other health risks of workers managing the radioactive waste and any subsequent public exposure associated with its disposal are taken into account.

5. The remedial action plan submitted for regulatory body approval shall include:

    (a) A mechanism for public information;
    (b) Mechanisms to involve interested parties in the planning, implementation and verification of the remedial actions, including any monitoring following remediation;
    (c) Monitoring programmes for the impact of the remediation actions serving also as a tool for imposing or lifting site restrictions;
    (d) A system for maintaining adequate records relating to the existing exposure situation and to actions taken for protection and safety and their outcomes;
    (e) Procedures for reporting to the regulatory body or other relevant authority on any abnormal conditions relevant to protection and safety.

6. The person or organization having prime responsibility for the remedial action plan shall establish and implement the following:

    (a) Post-remediation control measures, for as long as required by the regulatory body or other relevant authority;
    (b) A programme, including provision for monitoring, to verify the long term effectiveness of the completed remedial actions for areas in which controls are required after remediation.

7. The person or organization having prime responsibility for carrying out the remedial actions shall:

    (a) Ensure that the work, including management of the radioactive waste arising, is conducted in accordance with the remedial action plan;
    (b) Take responsibility for all aspects of protection and safety, including the conduct of a safety assessment;
    (c) Ensure that the area is monitored regularly during the remediation so as to verify levels of contamination, to verify compliance with the requirements for radioactive 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) Ensure the performance of a radiological survey after completion of remedial actions to demonstrate that the end point conditions, as established in the remedial action plan, have been met;

(e) Provide for the final remediation report and submits a copy to the regulatory body or other relevant authority.

8. The person or organization responsible for 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 provision for monitoring, to verify the long term effectiveness of the completed remedial actions for areas in which controls are required after remediation.

Notes (Remediation of areas with residual radioactive material):

Where areas with residual radioactive material deriving from past activities or from a nuclear or radiological emergency have been identified, the government needs to establish provision within the protection and safety framework for:

(a) Identification of those persons or organizations responsible for the contamination of areas and those responsible for financing the remediation programme and determination of appropriate arrangements for alternative sources of funding if such persons or organizations are no longer present or unable to meet their liabilities;

(b) Designation of persons or organizations responsible for planning, implementing and verifying the results of remedial actions;

(c) Establishment of restrictions on the use of or access to the areas concerned before, during and if necessary, after remediation;

(d) Maintaining, retrieving and amending of records that cover the nature and extent of contamination; the decisions made before, during and after remediation;

(e) Providing and archiving information on verification of the results of remedial actions, including the results of monitoring programmes after completion of the remedial actions.

The government needs to establish a strategy for radioactive waste management including mechanisms to deal with waste arising from remedial actions.

For areas with long lasting residual radioactive material, where the State has permitted habitation and resumption of social and economic activities, the government, in consultation with interested parties, have to ensure that arrangements are in place for continuing control of exposure with the aim of establishing conditions for sustainable living, including establishment of:

(a) Reference levels for protection and safety consistent with day-to-day life;

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

The regulatory body has particular responsibility for:

(a) Review of the safety assessment submitted by the responsible person or organization, approval of the remedial action plan and of any subsequent changes to the remedial action plan and granting 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 to procedures or equipment that may have radiological environmental impacts or that may alter the exposure conditions for workers taking remedial actions or for members of the public;

(e) Establishment of regulatory requirements for control measures following remediation (where necessary).

After remedial actions have been completed, the regulatory body needs to:

(a) Review, amend as necessary and formalize the type, extent and duration of any post-remediation control measures identified in the remedial action plan, with due consideration of the residual radiation risks;

(b) Identify the person or organization responsible for any post-remediation control measures;

(c) Impose specific restrictions where necessary, for the remediated area to control:

(i) Access by unauthorized persons;

(ii) Removal of radioactive material or use of such material, including its use in commodities;

(iii) Future use, including use of water resources from the area, use of the area for food or feed production and consumption of food from the area;

(d) Periodically review conditions in the remediated area and amend or remove any restrictions if appropriate.

If the regulatory body or other relevant authority has not imposed ongoing restrictions or controls, conditions prevailing after completion of the remedial actions have to be considered the background conditions for any new facilities and activities or for habitation on the land. Recommendations on remediation strategies can be found IAEA Safety Standards Series No. GSG-15, Remediation Strategy and Process for Areas Affected by Past Activities or Events [49].

Article 81: Public Exposure Due to Radon Indoors

1. Having taken account of prevailing social and economic circumstances, the reference level for ^{222}Rn for public dwellings and other buildings with high human occupancy factors, shall be an annual average activity concentration of 300 Bq/m^3 [*or other value as determined by the State*].

2. In areas where activity concentrations of radon give concern for public health the requirements of the national radon action plan shall apply.

3. A person or organization providing technical services for the measurement of radon shall meet the requirements of Article 19.

Notes (Public exposure due to radon):

The government requires that activity concentrations of radon in dwellings and other buildings with high occupancy factors by members of the public are monitored and have to also require that the public and interested parties are informed about radon exposure and the associated health risks, including the increased risks relating to smoking.

The government establishes a radon action plan in line with national regulations for radiation protection and safety, to address at least the following:

(a) Strategies for performing surveys of ^{222}Rn concentrations;

(b) Protocols for measurement of ^{222}Rn;

(c) *Strategies for reducing activity concentrations of ^{222}Rn and consequent exposures, to levels at which protection is optimized;*
(d) *Strategies to prevent radon exposure in new buildings;*
(e) *Requirements for new construction or improvement of dwellings and on the type of dwellings and other buildings in specific areas, where radon measurements are performed;*
(f) *Establishment of responsibilities and resources for implementing the radon action plan;*
(g) *Communication strategies to increase awareness of local authorities, employers and the public about the risks of ^{222}Rn;*
(h) *Strategies for performing surveys on ^{222}Rn concentrations.*

The government assigns responsibility for implementing the action plan for controlling public exposure due to ^{222}Rn indoors and determine the circumstances under which actions are mandatory or voluntary, with account taken of the prevailing social and economic circumstances.

The government establishes a reference level for ^{222}Rn for dwellings and other buildings with high occupancy factors for members of the public, with account taken of the prevailing social and economic circumstances, that in general will not exceed an annual average activity concentration due to ^{222}Rn of 300 Bq/m^3.

Recommendations on protection of the public from exposures due to radon are provided in SSG-32 [29].

Article 82: Exposure due to Radionuclides in Commodities

The specific reference level for exposure due to radionuclides in commodities such as construction materials, food and feed and in drinking water shall be an annual effective dose of 1 mSv to the representative person [*or other value as determined by the State*].

Notes:

The regulatory body might consider guideline levels for radionuclides in food traded internationally that could contain radioactive substances as a result of a nuclear or radiological emergency, published by the Joint Food and Agriculture Organization of the United Nations/World Health Organization Codex Alimentarius Commission.

The regulatory body might also consider the guideline levels for radionuclides contained in drinking water published by the World Health Organization.

Recommendations and guidance on public exposure can be found in GSG-8 [30], RS-G-1.8 [36] and Refs [31, 32].

PART 7: MANAGEMENT OF RADIOACTIVE WASTE

Notes: National policy and strategy for the management of radioactive waste:

Legal and regulatory framework

The government has to provide for a national legal and regulatory framework within which radioactive waste management activities can be planned and safely carried out. This has to include the allocation of responsibilities, the securing of financial and other resources relating to radioactive waste and the provision of independent regulatory functions (see paragraph 2.5 of GSR Part 1 (Rev. 1) [2].

National policy and strategy on radioactive waste management

To ensure effective management and control of radioactive waste, the government establishes a national policy and strategy appropriate for the nature and amount of radioactive waste in the State. The radioactive waste management policy and strategy indicates the manner and extent of regulatory control and consider relevant societal factors. It needs to be compatible with the IAEA fundamental safety principles and with international instruments, conventions and codes ratified by the State. The policy and strategy form the basis for decision making with respect to management of radioactive waste and establish the preferred options for radioactive waste management.

Notes: Principles for the management of radioactive waste:

Siting and design of facilities

Predisposal radioactive waste management facilities are located and designed to ensure safety for the expected operating lifetime under both normal and possible accident conditions, and for their decommissioning.

Construction and commissioning of the facilities

Predisposal radioactive waste management facilities have to be constructed in accordance with the design described in the safety case and approved by the regulatory body. Commissioning of the facility needs to be performed to verify that the equipment, structures, systems and components, and the facility as a whole, perform as planned.

System of accounting for and control of nuclear material

Facilities subject to agreements on nuclear material accounting in the design and operation of predisposal radioactive waste management facilities need to have a system of accounting for and control of nuclear material implemented so as not to compromise the safety of the facility.

Taking account of interdependencies

Interdependences among all steps in the predisposal management of radioactive waste, as well as the impact of anticipated disposal options, need to be appropriately taken into account in the national policy and strategy and have to be reflected in national requirements for protection and safety and the security of waste management facilities.

Radioactive waste generation and control

All radioactive waste have to be identified and controlled. Radioactive waste arisings have to be kept to the minimum practicable, in terms of both activity and volume.

See IAEA Safety Standards Series No. SSG-45, Predisposal Management of Radioactive Waste from the Use of Radioactive Material in Medicine, Industry, Agriculture, Research and Education, [50].

Processing of radioactive waste

Radioactive material for which no further use is foreseen, and with characteristics that make it unsuitable for authorized discharge, authorized use or clearance from regulatory control, have to be

processed as radioactive waste. The processing of radioactive waste has to be based on appropriate consideration of the characteristics of the waste and of the demands imposed by the different steps in its management (pre-treatment, treatment, conditioning, transport, storage and disposal).

Waste packages need to be designed and produced so that the radioactive material is appropriately contained both during normal operation and in accident conditions that could occur in the handling, storage, transport and disposal of waste.

Requirements for predisposal management of waste are established in GSR Part 5 [7] and supporting recommendations are provided in IAEA Safety Standards Series Nos. SSG-45 Predisposal Management of Radioactive Waste from the Use of Radioactive Material in Medicine, Industry, Agriculture, Research and Education, [50] and GSG-16, Leadership, Management and Culture for Safety in Radioactive Waste Management, [51].

Article 83: Responsibilities of Licensees for Radioactive Waste Management

1. A facility or activity involving generation and/or management of radioactive waste shall be authorized by licensing in accordance with the requirements of these Regulations (Article 12).

2. Licensees shall ensure an adequate level of protection and safety by various means, including:
    (a) Demonstration of safety by means of the safety case and for an existing facility or activity, by means of periodic safety reviews;
    (b) Preparation and implementation of appropriate operating procedures, including monitoring;
    (c) Application of good engineering practice;
    (d) Establishment and implementation of a management system;
    (e) Ensuring that staff are trained, qualified and competent;
    (f) Establishing and implementing the overall strategy for managing radioactive waste that is generated, including waste that has arisen from past practices, and for providing financial securities, taking into account interdependencies among all steps in waste management, the available options and the national radioactive waste management policy;
    (g) Ensuring that generation of the activity and volume of radioactive waste are kept to the minimum practicable;
    (h) Ensuring that radioactive waste is managed by appropriate classification, segregation, treatment, conditioning, storage and disposal, and maintaining records of such activities;
    (i) Ensuring that disposal of radioactive waste is not unnecessarily delayed;
    (j) Using relevant international experience to ensure operations are as safe as practicable;
    (k) Reporting to the regulatory body of required information at intervals as may be specified in the licence, including any changes, including those related to the ownership of waste.

3. The licensee of a facility or activity involving generation and/or management of radioactive waste shall be responsible for the safety of predisposal radioactive waste management facilities or activities.

4. The licensee shall review safety at existing facilities to verify compliance with requirements. Safety related upgrades shall be made by the licensee in accordance with

the national policy and strategy for management of radioactive waste and with the requirements of these Regulations.

Article 84: Safety Case and Safety Assessment for Radioactive Waste

1. An application for a licence shall include a safety case, supporting safety assessment and, as appropriate, an environmental impact assessment. In the case of a step-by-step development, or in the event of modification of the facility or activity, the safety case and its supporting safety assessment shall be reviewed and updated as necessary.

2. The primary aim of the safety case is to ensure that the safety objectives and criteria set by the regulatory body are met. The safety case shall include considerations for reducing hazards posed to workers, members of the public and the environment during normal operation, anticipated operational occurrences and accident conditions. The safety case shall address operational safety and all safety aspects of the facility or activity. The information that is supplied shall reflect the requirements of the regulatory body and be commensurate with the complexity of the facility and its potential impacts.

3. The safety case and its supporting safety assessment shall be documented at a level of detail and to a quality sufficient to demonstrate safety, to support the decision at each stage and to allow for independent review and approval of the safety case and safety assessment. The documentation shall be clearly written and shall include arguments justifying the approaches taken in the safety case on the basis of traceable information.

4. The safety case for a predisposal radioactive waste management facility shall include a description of how all the safety aspects of the site, the design, operation, shutdown and decommissioning of the facility and managerial controls satisfy the regulatory requirements. The safety case and its supporting safety assessment shall demonstrate the level of protection provided and shall provide assurance to the regulatory body that safety requirements will be met.

Article 85: Emergency Preparedness and Response for Radioactive Waste Management

The licensee shall establish and maintain emergency plans commensurate with the hazards associated with the radioactive waste facilities and activities, and report incidents significant to safety in a timely manner to the regulatory body and other interested parties.

Article 86: Control of the Generation of Radioactive Waste

Licensees generating radioactive waste shall ensure that appropriate measures are taken to keep generation of radioactive waste to the minimum practicable. This can be accomplished by:

(a) Minimizing the activity and volume of waste by using the minimum quantity of radioactive material needed;
(b) Applying careful planning to the design, construction, administration, operation and decommissioning planning of facilities so that the generation of radioactive waste is kept to the minimum practicable in terms of activity and volume;
(c) Applying, to the extent possible, the reuse and recycling of materials;
(d) The authorized discharge of effluent and clearance of materials from regulatory control, after some appropriate processing and/or a sufficiently long period of storage, to reduce the amount of radioactive waste that needs

further processing or storage;

(e) Wherever possible, when purchasing sealed sources, establishing contractual arrangements for the return of sources to the manufacturer or predetermined waste manager following use;

(f) Implementing a comprehensive management system for all activities potentially generating radioactive waste;

(g) Maintaining consistency with the radioactive management policy and strategy.

Notes (recycle and reuse):

Whenever the option of recycle and reuse of radioactive material or radioactive sources requires the transfer of ownership of the radioactive material or radioactive source to another organization, the licensee needs to ensure compliance with national regulations.

The applicant for a radioactive waste management license demonstrates that the option of reuse and recycling of radioactive material has been considered.

Recycling and reuse can involve the following activities:

(a) Before declaring the radioactive material as waste, consider whether the licensee or any other organization can make use of the material;

(b) Return of sealed radioactive sources to the manufacturer/supplier, when the latter would accept these;

(c) Decontamination and/or reuse of material such as equipment and protective clothing;

(d) Unconditional or conditional clearance of material that fulfils the conditions for the removal of control from material as defined by the regulatory body.

The licensee adopts provisions for possible reuse and recycling of materials as part of the radioactive waste management programme, whenever feasible.

Recycling and reuse often involve transfer of equipment and materials from one organization to another. Such transfer of radioactive material needs to be carried out according to the national radiation safety legislation and regulation. In this case the licensee ensures that all information, radiological and non-radiological, concerning the transferred materials is available to the receiving organization and that this organization is licensed to accept these materials.

Note:

Further information on recycling can be found in IAEA-TECDOC-1130 Recycle and Reuse of Materials and Components from Waste Streams of Nuclear Fuel Cycle Facilities [52].

Article 87: Classification, Management and Storage of Radioactive Waste

1. The licensee shall ensure an integrated approach to safety and security, commensurate with the level of radiological hazard and the nature of the waste, in the predisposal management of radioactive waste.

2. The licensee shall ensure that waste is stored such that it can be inspected, monitored, retrieved and preserved in a condition suitable for its subsequent management. Due account shall be taken of the expected period of storage and to the extent possible, passive safety features shall be applied. For long term storage, measures shall be taken to prevent degradation of the waste containment. Provision shall be made for the regular monitoring, inspection and maintenance of the waste and of the storage facility to ensure their continued integrity.

Note:

Recommendations are provided in IAEA Safety Standards Series No. WS-G-6.1, Storage of Radioactive Waste [53].

3. The licensee shall ensure that waste packages and unpackaged waste accepted for processing, storage and/or disposal shall conform to criteria that are consistent with the safety case by which the authorization was granted.

4. The licensee shall carry out periodic safety reviews and implement any safety upgrades required by the regulatory body further to the review. The results of the periodic safety review shall be reflected in the updated version of the safety case for the facility.

Article 88: Decommissioning of Radioactive Waste Management Facilities

1. The licensee shall develop, in the design stage, an initial plan for the shutdown and decommissioning of the predisposal radioactive waste management facility and shall periodically update it throughout the operational period.

2. Decommissioning of the facility shall be carried out on the basis of the final decommissioning plan, as approved by the regulatory body. In addition, assurance shall be provided that sufficient funds will be available to carry out shutdown and decommissioning.

Note:

Requirements are established in IAEA Safety Standards Series No. GSR Part 6, Decommissioning of Facilities [54] and supporting recommendations are provided in IAEA Safety Standards Series No. SSG-49, Decommissioning of Medical, Industrial and Research Facilities [55].

IAEA-TECDOC-1816, Model Regulations for Decommissioning of Facilities [56] presents an example of regulations dedicated to the decommissioning of facilities.

Article 89: Management System, Records and Reporting for Radioactive Waste Management

1. The licensee shall establish and implement a management system, commensurate with the hazard of the waste management activities.

2. The licensee shall promote and maintain a strong safety culture.

3. The licensee shall develop a suitable and comprehensive recording system for radioactive waste management activities under its responsibility. That recording system shall include discharges and clearance of radioactive material and shall allow for traceability of radioactive waste from the point of its collection through to its long term storage and its disposal.

4. All records related to the radioactive waste inventory (including disused sealed radioactive sources) and radioactive waste management activities shall be:

   (a) Maintained up to date (such as changes to waste characteristics during processing);
   (b) Retained in such a way as to ensure that relevant information is accessible in the future, as necessary.

5. When waste is being transferred, associated records shall be provided to the licensee of the subsequent step.

6. The licensee shall provide reports on its radioactive waste management activities to the regulatory body, upon demand.

Article 90: Disposal of Radioactive Waste from Radioactive Sources

1. The licensee of a disposal facility for radioactive waste from radioactive sources shall be responsible for its safety.

2. The licensee shall carry out safety assessment and develop and maintain a safety case and shall carry out all the necessary activities for site selection and evaluation, design, construction, operation, closure and, if necessary, surveillance after closure, in accordance with national strategy, in compliance with the regulatory requirements and within the legal and regulatory infrastructure.

3. The licensee shall evaluate the site and shall design, construct, operate and close the disposal facility in such a way that safety is ensured by passive means to the fullest extent possible and the need for actions to be taken after closure of the facility is minimized.

4. The licensee of a disposal facility shall develop an adequate understanding of the features of the facility and its host environment and of the factors that influence its safety after closure over suitably long time periods, so that a sufficient level of confidence in safety can be achieved.

Note:

Requirements are established in SSR-5 [8], and supporting recommendations are provided in:

(a) IAEA Safety Standards Series No. SSG-23, The Safety Case and Safety Assessment for the Disposal of Radioactive Waste [57];
(b) IAEA Safety Standards Series No. SSG-1 (Rev. 1), Borehole Disposal Facilities for Radioactive Waste [58];
(c) IAEA Safety Standards Series No. SSG-14, Geological Disposal Facilities for Radioactive Waste [59].

Article 91: Management of Waste Generated during Remediation of Areas with Residual Radioactive Material

The management of radioactive waste from remediation activities shall as a planned exposure situation, comply with the requirements of these Regulations and international standards for protection and safety from ionizing radiation. Such wastes shall be managed in accordance with the national arrangements for predisposal management and disposal of radioactive waste.

PART 8: IMPORT AND EXPORT OF

CATEGORY 1 AND 2 RADIOACTIVE SOURCES

Article 92: Export of Category 1 or Category 2 Radioactive Sources

1. Licensees intending to export Category 1 or Category 2 radioactive sources shall apply to the regulatory body for an export authorization.

Note:

Guidance to States on the evaluation of requests to export Category 1 or Category 2 radioactive sources is provided in Ref. [5].

2. The application for authorization to export a source or sources shall include a copy of the recipient authorization to receive and possess the source or sources to be exported that includes at least the following information:

   (a) Name of the recipient;
   (b) Recipient location and legal address or principal place of business;
   (c) Relevant radionuclide(s) and activity;
   (d) Uses of the source, if appropriate;
   (e) Recipient authorization expiration date (if any).

3. Other information to be submitted as part of the application for authorization to export may include, as applicable:

   (a) Copies of relevant parts of any contractual agreements to re-import the source;
   (b) Justification or explanation of any need to use the 'exceptional circumstances' provisions in Ref. [5].

4. After receiving authorization to export the source(s), licensees shall ensure that:

   (a) The export of the source(s) is conducted in compliance with all applicable requirements of SSR-6 (Rev. 1) [18];
   (b) The importing State is notified in advance (at least 7 days, to the extent practicable) of each shipment with the following information in writing:
      (i) The estimated date of export;
      (ii) Exporting facility;
      (iii) Recipient;
      (iv) Radionuclide(s) and activity;
      (v) Aggregate activity level;
      (vi) The number of radioactive sources and, if available, their unique identifiers;
   (c) For Category 1 sources only, the notification described above shall be accompanied by a copy of the importing States consent to import the sources, if applicable.

Note:

This notification may originate from the exporting State or the exporting facility. If the exporting State agrees that the notification can be made by the exporting facility, the exporting facility have to provide a copy of the notification to the exporting State.

Article 93: Import of Category 1 or Category 2 Radioactive Sources

1. Licensees intending to import Category 1 or Category 2 radioactive sources shall apply to the regulatory body for an import authorization.

Note:

Guidance to States on the evaluation of requests to import Category 1 and 2 radioactive sources is provided in Ref. [5].

2. The application for authorization to import a source or sources shall include the following information:

   (a) Name of the exporter;
   (b) Exporter location and legal address or principal place of business;
   (c) Name of the recipient;
   (d) Recipient location and legal address or principal place of business;
   (e) Relevant radionuclide(s) and activity;
   (f) Uses of the source(s), if appropriate;
   (g) Details of the arrangements for the safe management of the source(s), including financial provisions where appropriate, once they have become disused, and copies of any contractual agreements;
   (h) Justification or explanation of any need to use the 'exceptional circumstances' provisions, if applicable.

3. After receiving authorization to import the source(s), licensees shall, to the extent possible, ensure that the import of the source(s) is in compliance with all the requirements of SSR-6 (Rev. 1) [18].

PART 9: TRANSPORT OF RADIOACTIVE MATERIAL

Article 94: Transport Requirements

Transport of radioactive material (radioactive sources, radioactive waste or any other radioactive material), by all modes on land or water, or in the air, including transport that is incidental to the use of the radioactive material, either national or international, shall be done in compliance with the requirements of SSR-6 (Rev. 1) [18].

Note:

This Article will require modification if the country has transport safety regulations in place that can be cited.

Recommendations on measures applied by competent authority aimed at assuring compliance with the transport regulations are provided in IAEA Safety Standards Series No. SSG-78, Compliance Assurance for the Safe Transport of Radioactive Material [60].

Recommendations on radiation protection are provided in IAEA Safety Standards Series No. SSG-86, Radiation Protection Programmes for the Transport of Radioactive Material, [61].

PART 10: SPECIFIC CASES, ADDITIONAL PROVISIONS

Article 95: Nuclear Security

The licensee shall ensure an integrated approach to safety and security, commensurate with the level of radiological hazard.

Article 96: Nuclear Safeguards

The licensee shall consider nuclear safeguards requirements in the design and the operation of facilities or conduct of activities to which nuclear safeguards apply. These requirements shall be implemented in such a way as not to compromise the safety of the facility.

PART 11: MISCELLANEOUS, FINAL AND TRANSITIONAL PROVISIONS

Article 97: Use of International Safety Standards and other Publications

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Notes:

In the absence of national prescriptive regulations, the regulatory body may include a provision by which international requirements and recommendations can be applied.

Applicants for authorizations may propose to apply recommendations regarding facilities and activities, equipment, procedures, qualifications and training of personnel, maintenance and management system contained in safety and good practice publications issued by the International Atomic Energy Agency, World Health Organization, Pan American Health Organization or other international bodies as methods by which performance requirements in these Regulations will be met. In such instances, the applicant shall:

(a) Identify the publication(s);
(b) Identify both the particular recommendation or part of the publication being adopted and the performance requirement in these Regulations it is intended to implement.

The applicant for a licence may adopt by reference any of the publications listed under References to the extent that they are relevant to the particular practice. Applicants may propose to use other relevant publications that are not listed under References provided that the publications are clearly identified and copies of the relevant parts of the publications are included with the application.

The regulatory body on its own initiative or upon request will revise and update the list under References from time to time.

Article 98: Entry into Force

1. These Regulations shall enter into force on [*insert date*].

Article 99: Transitional Provisions

1. On entry into force of these Regulations, its provisions shall be applied to all pending applications for authorization.

2. Any authorizations (by registration or licences) granted pursuant to [*cite previous Regulations or article*] shall [*continue to be in valid legal force/be considered to have*

been granted under these Regulations]. However, they shall expire, at the latest, [*specify time period*] after the entry into force of these Regulations.

3. The regulatory body may, on written notice, revoke any authorization condition granted under [*paragraph xx of Article xx*], to the extent that it is inconsistent with the terms of these Regulations.

4. If, when granting an authorization (licence) under [*cite previous Regulations or article*], the authorization is considered to include operations requiring a construction or operating authorization under these Regulations, and if such an operation referred to in the authorization is started, at the latest, within [*specify time period*] after the entry into force of these Regulations, the construction or operation authorization in accordance with these Regulations is considered to be included in the authorization granted under [*cite applicable Regulations or Article*].

Note - Alternative version for Article 99:

Persons conducting activities pursuant to authorizations (registrations or licences) granted under [name of previous Regulations] shall, within [specify time period] following entry into force of these Regulations, submit a report to the [name of regulatory body] detailing practices or activities being conducted pursuant to the relevant authorization (registration or licence).

Article 100: Repeal

Upon entry into force of these Regulations, the following provisions of [*name of previous Regulations*] are hereby repealed: [*list of regulations or provisions in previous regulations to be repealed in whole or in part*].

PART 12: ANNEXES

Annex I: Exemption and clearance levels

Note (Annex I): Consider using Schedule I of GSR Part 3 [3])

Annex II: Categories for sealed sources used in common practice.

Note (Annex II): Consider using the information in Schedule II of GSR Part 3 [3])

Annex III: List of national legislation, requirements or standards specifying engineering, performance and functional specifications for equipment.

Note (Annex III): It is upon the State to form the list of national legislation, requirements or standards specifying engineering, performance and functional specifications for equipment.

Annex IV: Guidance values for restricting exposure of emergency workers.

Note (Annex IV): Consider using Table IV.2 of Schedule IV of GSR Part 3 [3])

APPENDIX II

EXAMPLE OF ARTICLE 72: SPECIFIC REGULATORY REQUIREMENTS FOR RADIATION PROTECTION AND SAFETY IN DIAGNOSTIC RADIOLOGY AND IMAGE GUIDED INTERVENTIONAL PROCEDURES

The following provisions in Article 72 are presented as an example of a prescriptive article that includes specific requirements that apply to radiographic and fluoroscopic diagnostic procedures and image guided interventional procedures performed in either a fixed location or using mobile equipment, as well as X ray imaging as part of radiation therapy or nuclear medicine procedures.

The specific technical requirements and values indicated are an example for consideration, in case the option of prescriptive regulations is promoted. However, the regulatory body is encouraged to introduce more performance based requirements in the regulations and then define and publish more detailed guidance documents.

Recommendations on regulatory guides for Diagnostic Radiology and Image Guided Interventional Procedures are provided in SSG-46 [22].

Articles 72: Specific Requirements for Radiation Protection and Safety in Diagnostic Radiology and Image Guided Interventional Procedures

Note (Article 72):

The following provisions apply to radiographic and fluoroscopic diagnostic procedures and image guided interventional procedures performed in a fixed location or mobile facilities, as well as X ray imaging as part of radiation therapy or nuclear medicine procedures.

1. The registrant or licensee shall ensure for every diagnostic radiology examination or treatment room, that the shielding requirements of the regulatory body are met. The adequacy of shielding shall be verified during construction and before first clinical use of a room and similarly after any structural modifications.

   Notes:

   Shielding calculations are based on conservative assumptions, with some allowance for future changes in use.

   Special attention has to be given to wall shielding height, shielding of doors and viewing windows in walls.

   Close attention has to be given to hybrid imaging systems, where shielding has to be calculated for each modality and combined as appropriate.

   Consideration has to be given in the design stage to shielding requirements for radiosensitive equipment and consumables.

2. The registrant or licensee shall ensure that equipment for diagnostic radiology and image guided interventional procedures which can affect radiation exposure includes design features for:

   (a) Immediate detection of any malfunction of a component of the system leading to unplanned exposure of the patient or staff;
   (b) Minimizing the potential for human error;

(c) Displaying the radiation generator operating parameters;
(d) Controlling the radiation beam;
(e) Ensuring adequate filtration (inherent and added) to remove low energy components of the X ray beam;
(f) Collimation to define the primary radiation beam;
(g) Ensuring that X ray tube assembly radiation leakage is as low as reasonably achievable and less than 1 mGy in an hour measured at 1 metre from the focal spot;
(h) Automatic termination of exposure after a pre-set time or when the 'dead man' exposure button is released;
(i) Tube current/time product (mAs) or automatic exposure control (AEC) detection;
(j) Indication of air kerma/area product and/or incident air kerma.

Note (diagnostic radiological equipment safety design):

Depending on the approach of the regulatory body, broad, more general requirements may be stated for the design and operating safety of equipment and the more prescriptive requirements above would then be provided in regulatory guidance.

Recommendations on design features are provided in SSG-46 [22].

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3. The registrant or licensee shall ensure dental imaging equipment includes the following operating and radiation safety design features:

(a) A minimum tube potential of 50 kVp;
(b) For intraoral dental systems, an open-ended collimator providing a tube focus to skin distance (FSD) of at least 20cm and a field size at the collimator not exceeding 4cm x 5cm if rectangular, or 6cm diameter if cylindrical and limitation of field size to the dimensions of the image receptor;
(c) For panoramic dental systems, limitation of field size to the area required for diagnosis by means of programmed field size trimming, including specific exposure and beam collimation settings for paediatric patients;
(d) For dental cone beam computed tomography (CBCT) adjustable X ray tube potential (kVp) and current/time product (mAs) with a choice of volume sizes and voxel sizes.

4. The registrant or licensee shall ensure computed tomography (CT) devices include the following operating and radiation safety design features:

(a) Console display of all CT parameters that directly influence image acquisition;
(b) Console display of estimated volume CT air kerma index and CT air kerma/length product for the procedure or image acquisition;
(c) Operator alert if exposure factors are set too high (usually expressed in terms of the volume CT air kerma index and/or the CT air kerma/length product);
(d) A means of dose modulation (rotational and z-axis) and means for selection of noise index or equivalent;
(e) A comprehensive range of beam widths and pitches and other ancillary devices such dynamic collimation to ensure 'over ranging' in CT is kept as low as reasonably achievable by facilitating the appropriate choice of beam width and pitch to limit patient dose while maintaining diagnostic image quality;
(f) Reconstruction algorithms that result in dose reduction without compromising image quality (e.g. iterative reconstruction algorithms).

5. The registrant or licensee shall ensure mammography equipment includes the following operating and radiation safety design features:

   (a) Various anode and filter combinations;
   (b) Compression and immobilization capabilities;
   (c) Magnification views;
   (d) Console display of dose index (incident air kerma or mean glandular dose);
   (e) Image receptors to accommodate all breast sizes.

6. The registrant or licensee shall ensure medical fluoroscopy devices include the following operating and radiation safety design features:

   (a) A device that energizes the X ray tube only when continuously depressed (e.g. exposure footswitch or 'dead man' switch);
   (b) Indications both at the control console and on monitors, of elapsed time, air kerma/area product and cumulative reference air kerma;
   c) Automatic brightness control (ABC) or automatic dose rate control (ADRC);
   (d) Pulsed fluoroscopy and pulsed image acquisition modes;
   (e) The capture and display of the last acquired frame (last image hold);
   (f) Interlocks to prevent inadvertent energizing of the X ray beam when the image detector is removed from the imaging chain;
   (g) Capability to deactivate the exposure footswitch between cases;
   (h) A timer with alarm sound after a pre-set period of continuous fluoroscopy.

7. The registrant or licensee shall ensure that equipment for paediatric diagnostic and interventional radiology procedures include design features specific to children, such as restraints and exposure controls, imaging field and other elements specific to facilitate the imaging of very small patients.

Note (Radiological equipment for paediatric procedures):

Additional features for paediatric examinations may include:

(a) Option of very short imaging exposure times (high maximum mA);
(b) Specifically designed AEC systems;
(c) Paediatric settings for fluoroscopy and image guided interventional equipment brightness and dose-rate control;
(d) Paediatric protocols for CT;
(e) Child imaging mode for dental panoramic and CBCT equipment.

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