

# IAEA TECDOC SERIES

IAEA-TECDOC-1732

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

*Supplement to  
IAEA Safety Standards Series No. GS-G-1.5*



**IAEA**

International Atomic Energy Agency

# IAEA SAFETY STANDARDS AND RELATED PUBLICATIONS

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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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SUPPLEMENT TO IAEA SAFETY  
STANDARDS SERIES NO. GS-G-1.5

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## FOREWORD

IAEA Safety Standards Series No. GSR Part 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. The regulatory body has the authority and responsibility for promulgating regulations, and for preparing their implementation.

This publication provides advice on an appropriate set of regulations covering all aspects of the use of radiation sources and the safe management of the associated radioactive waste. The regulations provide the framework for the regulatory requirements and conditions to be incorporated into individual authorizations for the use of radiation sources in industry, medical facilities, research and education and agriculture. The regulations also establish criteria to be used for assessing compliance. This publication allows States to appraise the adequacy of their existing regulations and regulatory guides, and can be used as a reference for those States developing regulations for the first time. The regulations set out in this publication will need to be adapted to take account of local conditions, technical resources and the scale of facilities and activities in the State.

The set of regulations in this publication is based on the requirements established in the IAEA safety standards series, in particular in IAEA Safety Standards Series No. GSR Part 3 (Interim), Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, in IAEA Safety Standards Series No. GSR Part 5, Predisposal Management of Radioactive Waste, and in IAEA Safety Standards Series No. SSR-5, Disposal of Radioactive Waste. They are also derived from the Code of Conduct of the Safety and Security of Radiation Sources and the Guidance on the Import and Export of Radioactive Sources. This publication allows States to appraise the adequacy of their existing regulations and regulatory guides.

This publication is a supplement to the IAEA Safety Standards Series No. GS-G-1.5, Regulatory Control of Radiation Sources. The IAEA officer responsible for this publication was T. Boal of the Division of Radiation Transport and Waste Safety.

## EDITORIAL NOTE

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# 1. INTRODUCTION

## 1.1. BACKGROUND

The achievement and maintenance of a high level of safety in the use of radiation sources and in the management of radioactive waste depends on a sound legal and governmental infrastructure, including a regulatory body with well-defined responsibilities and functions. An appropriately organized and staffed regulatory body with access to adequate resources is a key element of such an infrastructure. The IAEA publication Fundamental Safety Principles [1] sets out safety principles that provide the bases for the IAEA Safety Standards. One of the principles is on the role of government and states: “An effective legal and governmental framework for safety, including an independent regulatory body, must be established and sustained”. The IAEA Safety Requirements publication Governmental, Legal and Regulatory Framework for Safety, GSR Part 1 [2] sets forth general requirements for an adequate legislative and regulatory framework for radiation and nuclear safety.

The IAEA Safety Requirements publication Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, GSR Part 3 [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 (hereinafter ‘radiation safety’ is the term used to cover both protection and safety). The way in which States apply GSR Part 3 will vary depending upon legal systems, technical resources, the scale of installations and related factors. National circumstances will determine whether radiation safety is handled in a separate law or not, but in no case should legislation on the management of radioactive waste precede that on radiation safety.

The Code of Conduct on the Safety and Security of Radioactive Sources (the Code of Conduct) [4] was approved by the Board of Governors in September 2003. Implementation of this Code of Conduct will help national authorities ensure that radioactive sources are used within an appropriate framework of radiation safety and security. Guidance on the Import and Export of Radioactive Sources [5] was approved by the Board of Governors in September 2004. The Guidance assists exporting and importing States on deciding whether to authorize exports and imports of Category 1 and 2 radioactive sources.

The generation of radioactive waste follows inevitably from the use of radioactive materials in medicine, industry, research, agriculture and education. The objective of safe management of radioactive waste is to deal with radioactive 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 that will ensure compliance with international safety standards on radiation safety and waste management. Requirements relating to the management of radioactive waste are set out in Predisposal Management of Radioactive Waste [6] and in Disposal of Radioactive Waste [7].

The Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste (the Joint Convention) [8] has introduced a comprehensive set of obligations that must be included in national legislations of States that ratify that Convention.

GSR Part 3 [3] can only be implemented through an effective radiation safety infrastructure that includes adequate laws and regulations, an efficient regulatory system, supporting experts and technical services, and a strong commitment to safety by the Government and all those with responsibilities for radiation safety. The IAEA Safety Guide on Regulatory

Control of Radiation Sources, GS-G-1.5 [9] gives detailed guidance for a national regulatory infrastructure to regulate any practice involving radiation sources used in medicine, industry, research, agriculture and education. The IAEA-TECDOC publications Notification and Authorization for the Possession and Use of Radiation Sources [10] and Inspection of Radiation Sources and Enforcement [11] provide complementary information.

A number of publications have been prepared by the IAEA related to the regulatory framework for radioactive waste management [12]. These publications have targeted different user groups, such as countries with small programmes using limited amounts of radioactive material and generating relatively small amounts of radioactive waste.

## 1.2. OBJECTIVE

This TECDOC aims at providing States with advice on an appropriate set of regulations covering all aspects of the use of radiation sources and the safe management of the associated radioactive waste. It also allows States to appraise the adequacy of their existing regulations and regulatory guides. The intent is to cover the whole range of circumstances related to facilities and activities using radiation sources.

This TECDOC provides guidance on matters to be addressed in national policy and strategy, and regulations. It includes examples of texts that could serve as reference to assist national authorities, regulatory bodies, technical and legal experts involved in the development or review of regulations for radiation safety.

The TECDOC supplements Safety Guide GS-G-1.5 [9] in providing practical advice 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 TECDOC is intended to provide States with model provisions for the regulations that need to be established for the control of radiation sources and the safe management of the associated radioactive waste. It is compatible with, and supplements, the Handbooks of Nuclear Law [13, 14] that provide provisions for the legislative framework.

## 1.3. SCOPE

The TECDOC contains advisory material related to matters that need to be addressed in policies, strategies, and regulations of a State, in relation to the use of radiation sources and for the management of the associated radioactive waste. It is an advisory publication and supplements the Safety Fundamentals [1], Safety Requirements GSR Part 1 [2], GSR Part 3 [3], GSR Part 5 [6] and SSR-5 [7], the Code of Conduct [4], the Handbooks of Nuclear Law [13, 14], Safety Guide GS-G-1.5 [9], the Joint Convention [8] as well as several Safety Guides of the Waste Safety Series [15, 16, 17, 18]. Those aspects of legislation that are needed in order to establish and operate a regulatory infrastructure in the areas of radiation safety and radioactive waste management are dealt with in the Handbooks on Nuclear Law [13, 14].

This TECDOC can be used by States where radiation sources are used in medicine, industry, research, agriculture and education. It also covers the safety of radioactive waste generated from the radioactive material in these areas. This TECDOC does not cover the safety of radioactive waste generated in research reactors, nuclear power plants or any other facility from the nuclear fuel cycle.

## 1.4. STRUCTURE

Section 2 of this TECDOC examines the various aspects of the legal framework for the establishment of regulations for protecting people against exposure to ionizing radiation, for the safety of radiation sources, for the safety of radioactive waste management, and for the protection of the environment. Section 3 provides advice for drafting or revising the law. Section 4 outlines issues to be considered in the regulatory process. Section 5 outlines issues to be considered in the development of regulations. Section 6 briefly summarizes the functions of the regulatory body. Section 7 sets out Model Regulations on radiation protection and safety and the safety of the management of radioactive waste.

## **2. LEGAL FRAMEWORK FOR THE SAFE MANAGEMENT OF RADIATION SOURCES AND RADIOACTIVE WASTE**

### 2.1. GENERAL

States are required to establish a legal framework to regulate the safety of facilities and activities involving radiation sources and the management of the associated radioactive waste, and to establish a regulatory body [1]. The fundamental safety objective of protecting people has to be achieved without unduly limiting the operations of facilities or the conduct of activities that give rise to radiation risks [1]. The number and types of radiation sources and amount and nature of radioactive waste present in the country, together with the types of activities planned for the future, will influence the content of the legislation, as well as the extent of the regulatory infrastructure that is needed to ensure safety. States are also required to develop national policies and implementation strategies for the safe management of radioactive waste [2]. These policies and strategies are required to take account of the diversity between types of radioactive waste and be commensurate with the radiological characteristics of the waste.

In establishing or amending elements of the national legal framework, the relevant requirements of the Safety Requirements publication Governmental, Legal and Regulatory Framework for Safety [2] are to be implemented. The requirements arising from the articles of Joint Convention [8] are also to be implemented in the national legal framework where appropriate.

The legal framework will also have to ensure that the adequate supporting infrastructure and appropriate supporting facilities and services such as training, personal dosimetry, environmental monitoring, calibration services and radioactive waste management are available. It will have to be ensured that sufficient human resources are available in the State to support the programme and that the necessary research and development work is being carried out.

The legal framework will ensure that a regulatory body is established, that is given the necessary authority and is effectively independent from organizations in charge of the utilization and promotion of radiation technologies.

The legal framework will need to cover in a comprehensive and integrated manner all aspects of safety, radiation protection, safeguards, physical protection, security and nuclear liability related to the control of radiation sources and to the management of radioactive waste. Further guidance on the legal framework and on the comprehensive legislation to regulate

nuclear energy based technologies can be found in [13, 14]. Further guidance on the regulatory independence of regulatory bodies can be found in [19].

## 2.2. NATIONAL LEGAL HIERARCHY

The legal structure for the control of radiation sources and for the control of radioactive waste is part of a State's general legal system. As such, it must respect the same rules that apply to other parts of that system. In spite of all 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 itself and secondary legislation. The latter is made up of regulations that are often technical in nature. Finally, numerous national legal systems recognize regulatory guides that specify performance expectations in fulfilling the requirements established by the primary or secondary legislation. More details on the national legal hierarchy are given in the Handbooks on Nuclear Law [13, 14]

## 2.3. NATIONAL POLICY

Even though some States apply a national policy that is indirectly reflected in diverse publications but not written up in a single publication, the common practice is that the policy is approved through a legal instrument as a statement of the government's intent.

National policy for safety shall express a long-term commitment to safety (para. 2.3, Ref. [2]). The national policy is required to be implemented in accordance with a graded approach, depending on national circumstances, to ensure that radiation risks associated with facilities and activities, including activities involving the use of radiation sources, receive appropriate attention by the government or by the regulatory body (para. 2.4, Ref. [2]).

A national policy in a particular field represents a comprehensive set of actions to be taken by the State. The national policy should define the responsibilities for the safe management of radiation sources and radioactive waste. It should consider the foreseen end points for radioactive waste and time frames, and should include a policy on gaining or regaining control over orphan and vulnerable radioactive sources.

A national policy should reflect national priorities, circumstances, structures, human and financial resources and should be reviewed and possibly updated from time to time. It should also be compatible with international instruments, such as Conventions and Codes recognized by the State. Publications relevant to the development of national policy are the IAEA Safety Requirements publications GSR Part 1 [2] and GSR Part 3 [3], the Joint Convention [8] as well as other international instruments such as Safeguards agreements and the Convention on Physical Protection of Nuclear Material [20].

The national policy will also indicate the system of the regulatory control that needs to be put in place and it will consider societal issues that affect the control of radiation sources and the management of radioactive waste.

Because a national policy should be based on a thorough knowledge of existing and foreseeable radiation sources and waste, the State or an organization appointed by it should undertake, as far as practicable, a complete analysis of the present and likely future inventory of radiation sources and radioactive waste, their nature, quantities, ways of generation of radioactive waste and possible locations.

Even if a formal notification system is not yet in place, work by a planning group or a designated technical staff should commence on establishing a national inventory of radiation sources and radioactive waste generated, in storage, and projected. An estimate of the variety and magnitude of radiation practices to be regulated in a country should be made. A risk-informed methodology for categorizing radioactive sources has been published in an IAEA Safety Guide [21]. This is based on five source categories – Category 1 sources have the largest potential to be dangerous; Category 5 sources have the lowest potential to be dangerous (if not managed properly). Identification of the location of radioactive sources of Categories 1 and 2 should be a high priority (such as those used in radiotherapy and in industrial radiography). Rough estimates of inventories of less hazardous sources, such as medical and dental diagnostic X ray units, as well as some industrial nuclear gauges, can be established with some knowledge of the numbers and types of potential users.

A national policy will incorporate the fundamental principles recognized by the international community. These include, for instance the top priority assigned to safety, the importance of the protection of human health, of society and of the environment, the involvement of stakeholders and the radioactive waste management options.

In developing the national policy on the safety of radioactive waste management the application of the following fundamental principle is required: “People and the environment, present and future, must be protected against radiation risks”, Principle 7, Fundamental Safety Principles (SF-1) [1]. SF-1 states that “radioactive waste must be managed in such a way as to avoid imposing an undue burden on future generations; that is, the generations that produce the waste have to seek and apply safe, practicable and environmentally acceptable solutions for its long term management.” (para. 3.29, Ref. [1]).

“Radiation risks may transcend national borders and may persist for long periods of time. The possible consequences, now and in the future, of current actions have to be taken into account in judging the adequacy of measures to control radiation risks. In particular: safety standards apply not only to local populations but also to populations remote from facilities and activities; and where effects could span generations, subsequent generations have to be adequately protected without any need for them to take significant protective actions.” (para. 3.27, Ref. [1])

## 2.4. NATIONAL STRATEGIES

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 are adequately considered. Whereas the national policy indicates the preferred options the State intends to follow, the implementing strategy explains what coordinated actions are needed to put that policy into practice. Separation between policy and strategy is not always obvious. A comprehensive set of arrangements (set out for instance in the State’s legal framework) should be put into place to ensure that all sources are under control and that all radioactive waste is safely managed. In this regard, it will be important to specify in the national strategy to what extent and under which conditions, the control exercised by the regulatory body will be decentralized.

A strategy to safely manage radioactive waste will need to define the disposal routes for the different types of waste and the actions required to implement a disposal plan. It may also include for instance various options for decommissioning of facilities and for disposal. Siting

constraints, technical and economic considerations are also bound to limit the number of available options. Arrangements that need to be taken into account are for instance:

- planning for long-term management of radioactive waste;
- allocation of responsibilities to authorized users and to the regulatory body and provisions for independent regulatory functions;
- different disposal options for different types of waste;
- site selection procedures for disposal locations;
- ensuring that arrangements are in place to ensure the safety of facilities for radioactive waste management during their entire lifetime; and
- remediation of contaminated areas.

A strategy for gaining or regaining control over orphan and vulnerable radioactive sources should be developed. This should be based on a national assessment of the potential size of the problem and implemented according to a graded approach through a national action plan. The IAEA Specific Safety Guide: National Strategy for Regaining Control over Orphan Sources and Improving Control over Vulnerable Sources [22] describes how this could be done.

## 2.5. RELATED LEGISLATION

Radiation sources and radioactive waste are associated with complex technologies that create special risks to the health and safety of persons and to the environment. They therefore merit to be controlled from various perspectives. Examples of such cross-cutting relationships are to be found in the fields of environmental protection, health, industrial safety, medicine, and transportation, movement of goods or mining.

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 government agencies 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 in order to understand how the currently involved government 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.

The approach by States to the coordination and cooperation between government ministries and agencies on implementing its strategy on radiation protection and on radioactive waste management will depend on national measures and culture. It is critical that cross-cutting relationships be taken into account, and, specifically, that a strategy for radiation protection be properly related with that for radioactive waste management. Appropriate radiation protection legislation should exist before or at the latest at the same time as legislation on radioactive waste management is being established.

In summary, the establishment of an appropriate legal framework and regulatory infrastructure should proceed in steps. These steps will include:

- governmental commitment to radiation and waste safety; this is a pre-requisite to reach the desired objective;

- national inventory of radiation sources, radioactive waste and waste streams present or anticipated in the country, so as to establish the prioritization of operational activities;
- definition of a national policy on radiation safety and radioactive waste management at the government level;
- selection of appropriate strategies for the safe management of radioactive sources (including strategies to gain or regain control over orphan and vulnerable radioactive sources) and of radioactive waste ;
- involvement of agencies and technical experts with major interest in radiation safety and waste management ('stakeholders') to make an assessment of the required legislation and to establish or guide the drafting of the law;
- establishment of a regulatory body through the promulgation of a national law;
- development of regulations and supplementary guidance;
- development of import/export controls (at least for Category 1 and 2 radioactive sources);
- availability or development of supporting technical services to assure an efficient radiation safety and waste management;
- implementation of a regulatory system including requirements for notification; issuing of authorizations, conduct of inspections and enforcement of legislation.

### **3. THE LAW**

#### **3.1. LEGAL BASIS**

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

#### **3.2. BASIC REQUIREMENTS**

The regulatory system adopted in a particular State would have to conform to the legal practice of that State, but the objective is the same, whatever the system. Basic requirements and obligations would be decided upon by the legislature and the detail of how this would be achieved could be provided in subordinate legislation (regulations). The latter is easier to revise but the basic requirements and obligations are less likely to change. If they do, their implications would be of sufficient importance to require attention of the legislature.

## 4. THE REGULATORY PROCESS

### 4.1. EXTENT OF REGULATION

In most national legal systems, activities not specifically prohibited by law are free to undertake ('what is not forbidden is allowed'). However, in the case of activities that may represent a risk to individuals or to the environment, such as radiation and nuclear energy based technology, the law requires that prior permission be obtained ('what is not allowed is forbidden').

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 regulatory requirements apply, and the identity of persons who are responsible for applying, or complying with, the requirements.

As noted earlier, the legislation is required to specify facilities, activities and materials that are included in the scope of the legislation, and what is excluded from such legislation. The practices and interventions that may be included in the scope of the regulations are those that are specified in GSR Part 3 [3]. The regulations are also required to specify exclusions and determine under which conditions the regulatory body can exclude certain exposures considered un-amenable to control and when it may exempt certain practices or sources within practices from radiation safety requirements. Regulations will also need to establish which criteria are to be applied to allow for clearance of radioactive materials. The IAEA has developed a Safety Guide on the application of the concepts of exclusion, exemption and clearance [23].

The identification of persons responsible for radiation safety should be included as part of the requirements established in the regulations. GSR Part 3 [3] identifies the registrant and licensee as having prime responsibility for radiation safety.

The regulatory body needs to establish very clearly whom it will hold accountable for compliance with its regulations. The regulatory body in granting authorizations needs to confer prime responsibility on the registrant/licensee for occupational, patient and public radiation safety, and this person therefore should have legal accountability. In the case of employers who are not also authorized users, responsibility for occupational radiation safety is often part of broad responsibilities for occupational safety in general. If the employer is not the authorized user, sharing responsibility for occupational radiation safety can create problems for the regulatory body, particularly with enforcement.

Different national laws use different terms for the same concept, such as license, authorization, permit or certificate, for instance. In the present TECDOC the term of 'authorization' is the general concept covering license, registration.

A license is an explicit authorization issued by the regulatory body following an application and review process [13]. It is required for all activities deemed to represent a significant health or safety risk.

Where the risk created by an activity is less important, the operator may only be required by law to apply for a registration of that activity with the regulatory body.

Finally, where the risk is considered to be minimal, the operator will simply be asked to notify the regulatory body about engaging in this activity. In other words, the extent of the regulatory control applied is required to be commensurate with the potential magnitude and nature of the hazard.

#### 4.2. REGULATORY FLEXIBILITY

The functions and responsibilities of the regulatory body are listed in GSR Part 1 [2] and in GSR Part 3 [3], such as the authority to grant authorizations and to conduct inspections. Two powers conferred through the legislation which are particularly important are:

- the authority to impose 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; and
- the authority to grant exemptions from certain regulatory requirements (under specific conditions).

The authority to exempt a practice and/or a source within a practice from certain aspects of the regulations is also important. Exemption provisions relieve operators from applying the requirements of the regulations to the practice or source if certain exemption criteria are met. The provisions for exemption in GSR Part 3 [3] are based on the concept that the administrative burden to be imposed on persons engaging in certain practices or using certain sources is unnecessary and would achieve little. The Safety Standards for Radiation Protection and Safety of Radiation Sources do not specifically address exemptions from specific procedural requirements of regulations but such exemptions are important from a practical administrative standpoint. The reasons for granting each exemption should be documented.

The regulatory body has a clear obligation to apply its own regulations. Therefore, it should not grant an authorization when it is aware that some aspect of the proposed use does not conform to regulatory requirements. However, in some cases the applicant or operator may demonstrate to the satisfaction of the regulatory body that a prescriptive requirement does not seem appropriate and that there are alternative ways to achieve a satisfactory level of protection and safety. In these cases, regulatory flexibility should also be taken into account.

#### 4.3. OVERLAPPING JURISDICTIONS

As the management of radioactive sources is a broad field, involving numerous activities, it represents a multidisciplinary issue. For instance, the government agency that regulates safety in the workplace is often not the regulatory body governing radiation safety of practices. Besides being under the control of the regulatory body, the management of some radioactive waste may also fall under the control of many other regulatory authorities. Examples are:

- health and safety (dangerous chemicals, radiation protection);
- environment (discharges, environmental impact assessment of facilities);
- building codes (all facilities);
- transport (transportation regulations);
- customs and excise (import, export, transboundary movements);
- mining laws (radioactive waste from mining and milling activities);

In many States, regulatory authorities responsible for health and safety, environmental protection, mining etc. existed prior to the regulatory body responsible for radiation safety and the management of radioactive waste. The legislator should therefore pay much 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 should be clearly defined in the legislation establishing it.

Mechanisms to resolve juridical conflicts between national authorities should also be put in place. In such instances, a memorandum of understanding between authorities should 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, besides all legal precautions, good personal communication between members of the various regulatory authorities is probably the most efficient method to defuse potential conflicts before they arise.

#### 4.4. FRAMING OF REGULATORY REQUIREMENTS

There often options for the way in which the requirements of the Safety Standards for Radiation Protection and Safety of Radiation Sources and other IAEA Safety Standards are incorporated in regulations. The regulatory body, when preparing regulations, may identify options when practicable and weigh the advantages and disadvantages before selecting one as a regulatory requirement. Among other things the way in which a requirement is stated can make a difference in how burdensome or costly it will be for operators. Some poorly framed requirements can contribute little to safety and can be costly for operators.

### 5. REGULATIONS AND GUIDANCE

#### 5.1. REGULATIONS

Regulations or decrees according to the legal system of the country are issued by a government minister or other 'competent authority' such as the regulatory body as specified under the law. Whereas the law is giving the general framework within which a certain activity or type of activity may take place (for instance a law on environmental protection or a labour law), the regulations give specific explanations on how the law is to be applied in practice. They are of a general nature. However, they do not generally contain indications or specifications that would apply to one specific activity or to a specific installation. The requirements that apply to a specific installation or to a specific activity are given in the authorization or licence that is to be granted to that installation or activity before it starts, and are known as licence conditions. The authorization is therefore more detailed than the regulations and is so written that it only applies to one particular facility or activity.

The principal purpose for establishing regulations is to codify requirements of general applicability. The regulations need to 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 workers, members of the public and patients. By providing well-founded and clear statements of administrative and technical requirements, regulations serve to provide consistency and stability in the regulatory process.

Regulations are commonly more technical than the corresponding law but are part of the national legal system. Their purpose is to achieve safety through the establishment of detailed requirements regarding the application of the law and to provide a framework for more detailed conditions and requirements to be incorporated into individual licenses. By giving a general framework, they also contribute to avoiding arbitrary decisions that may otherwise be taken on a case by case basis and would make a uniform application of the law more difficult. In order to avoid misinterpretation, regulations should be clear, easy to understand, unambiguous and precise.

The principles and requirements in GSR Part 3 [3] and other IAEA Safety Requirement publications [6, 7 and 24] are intended to be incorporated in national regulations. However, they should be adapted to take account of local situations, technical resources, the scale of installations and other factors that will 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.

In developing regulations, the regulatory body is required to involve consultation with interested parties and the feedback of relevant experience. Particular care should be taken to cover all necessary aspects, to avoid conflicts with other national regulations or laws, and to avoid unrealistic authorization conditions. Due account is also to be taken of international conventions and internationally recognized standards e.g. standards published by International Standards Organization (ISO), International Electrotechnical Commission (IEC).

## 5.2. MODEL REGULATIONS

Section 7 of this TECDOC sets out Model Regulations that are primarily based on the IAEA Safety Requirements [2, 3, 6, 7] and on the Code of Conduct on the Safety and Security of Radioactive Sources [4]. They provide an example illustrating how regulations are commonly structured. They also give examples of the topics to be covered and of the way in which they should be covered. Given their nature, they cannot be simply copied into national regulations. They should rather be considered as a catalogue of examples from which national authorities could select what applies to their particular situation. National regulations need to be consistent with the text of the national law, but also the international agreements that the State is a party to. National regulations should always be closely linked to the law that they are implementing.

## 5.3. ORGANIZATION OF REGULATIONS

The regulations are required to establish the necessary requirements to ensure the radiation safety in practices and interventions, safety of radiation sources, including the safety in the management of radioactive waste and the transport of radioactive material. All regulations are living documents that should be amended from time to time. Amendments should be driven by available scientific information, advances in nuclear energy based technology, feedback from users and operating experience within the regulatory body. Information obtained from national and international activities should be considered.

Regulations might be supported by practice-specific prescriptive requirements (i.e. codes of practice or guides) describing how to meet the specific regulatory expectations. These requirements might be produced as separate publications.

#### 5.4. PERFORMANCE VERSUS PRESCRIPTIVE REGULATIONS

The development of any particular regulation on the safe management of radiation sources and radioactive waste will involve 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’ 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-oriented or prescriptive-oriented. An example of a performance-oriented regulation would be one which 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 should be used and how and what records should be maintained.

Therefore, performance-oriented 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 do prescriptive regulations.

Prescriptive regulations are largely activity-specific, 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 requirements and how to do it in order to achieve an adequate level of safety. Prescriptive regulations in principle facilitate the performance of authorization reviews 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 drive to a simple ‘checking-of-compliance culture’ rather than to a ‘safety culture’ if positive steps are not 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. In particular, they are best suited to widespread practices where the equipment and procedures do not vary significantly among users.

In practice, national regulations will often combine performance-oriented 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. It also depends on the knowledge and experience of the licensees. The level of experience of a regulatory body will also have to be taken into account.

## 5.5. REGULATION OF NATURAL RADIOACTIVE MATERIAL

Because of the ubiquitous nature of natural radioactive material, regulatory bodies may be faced with the problem of deciding when and how to exercise regulatory control over such material. Terms often used in connection with these substances include ‘naturally occurring radioactive material (NORM)’, natural radioactive substances, natural sources and radioactive ores. The terminology is not defined in a way that is helpful for establishing what exposures should be subject to regulatory control as practices in planned exposure situations, and what exposures should be considered as requiring intervention as an existing exposure situation. Although radioactive ores are not defined in GSR Part 3 [3], the mining and milling of radioactive ores to recover uranium and thorium can be part of a nuclear fuel cycle and therefore they are subject to requirements for practices (see also Handbook of Nuclear Law Chapter 8 [13]).

The fundamental criterion for the regulation of natural sources is that regulatory measures should be applied only where dose reductions can be achieved at a reasonable cost. There is however no ‘best way’ to apply this criterion. Much will depend on national and local situations.

Except for relatively few practices involving natural sources (e.g. uranium and thorium mining and milling products), GSR Part 1 [2] leaves it to the regulatory body to specify what activities involving natural sources will be subject to the requirements for practices. In addition, other requirements dealing inter-alia with safeguards or physical protection need to be established. It is therefore incumbent upon the regulatory body to establish the scope and judiciously apply the concepts of exclusion and exemption as well as the requirements for planned exposure situations and for existing exposure situations to establish regulatory controls that are most appropriate for its State.

GSR Part 3 [3] includes activity concentration levels for natural radionuclides of greater than 1 Bq/g for uranium and thorium radionuclides or greater than 10 Bq/g for <sup>40</sup>K to be within the scope for planned exposure situations (para. 3.4(a), Ref. [3]). The regulatory body can identify candidate industries (e.g. production of phosphate fertilizers) and candidate sources of concentrated natural radioactive substances (e.g. in deposits or scale in the pipe work of oil rigs) where regulatory control may be required. For those industries or work activities that involve material in which the activity concentrations are greater than the levels described above, the regulatory needs to consider the need for regulatory control. In terms of the graded approach to regulation, the regulatory body may decide that the optimum option is not to apply regulatory requirements. The graded approach can include exempting the practice or work activity from regulatory control, requiring notification of the practice or work activity, or authorization of the practice or work activity through either registration or licensing. The IAEA Safety Report: Assessing the Need for Radiation Protection Measures in Work Involving Minerals and Raw Materials [25] provides information to assist Member States in identifying industrial activities that may require some form of regulatory supervision or control and for such activities, the most appropriate regulatory approach.

Those activities involving natural sources, that the regulatory body determines should be controlled under the requirements for practices, need to be clearly identified in the scope of its regulations governing practices. The model regulations in Section 7 do not cover natural sources.

## 5.6. REGULATORY GUIDANCE

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

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

The level of detail in regulatory guides may vary from one State to the next and is being 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 best applicable when only one or two similar facilities are subject to control.

## 6. THE FUNCTIONS OF THE REGULATORY BODY

The IAEA Safety Standards publication [2] lists the main responsibilities and functions of the regulatory body such as:

- development of requirements, regulations and regulatory guides;
- review and assessment of facilities and activities, and of information relevant to safety;
- authorization;
- inspection;
- enforcement.

For radiation sources, guidance on implementing these functions is set out in GS-G-1.5 [9]. For radioactive waste, guidance is set out in several publications of the Waste Safety Standards.

Regulatory bodies are also required to provide information on regulated activities to relevant stakeholders and to the public, and to coordinate their activities with those of international and national bodies in other States that are involved in radiation and radioactive waste management safety [2].

## 7. MODEL REGULATIONS

### 7.1. INTRODUCTION

These Model Regulations illustrate a way to incorporate the IAEA's requirements and guidance regarding radiation protection and safety of radiation sources found in GSR Part 1 [2], GSR Part 3 [3], the Code of Conduct [4] as well as References [5, 21, 27], and in Safety Requirement publications for the management of radioactive waste [6, 7] into the national regulatory infrastructure.

The fundamental safety objective of protecting people and the environment has to be achieved without unduly limiting the operations of facilities or the conduct of activities that give rise to radiation risks. Safety is concerned with radiation risks under normal circumstances and radiation risks as a consequence of incidents, as well as other possible direct consequences of a loss of control over radiation sources [2].

These Model Regulations are not the only way to adopt the IAEA's requirements and guidance in national regulations. The Model Regulations were chosen to be as clear and as simple as possible in view of the particular needs of the countries that might like to adopt this model. The types of practices generally used within most of countries are the most common uses of radiation sources. Most of these uses involve equipment and procedures for which there is a well-established operational experience, with the exclusion of complex nuclear facilities. The Model Regulations are designed to focus on the following objectives:

- (1) To establish and maintain regulatory control of radiation sources throughout their entire lifecycle;
- (2) To keep doses from normal operations as low as reasonably achievable and within prescribed limits;
- (3) To avoid accidents or incidents;
- (4) To achieve and maintain a high level of radiation safety for each radioactive source that is commensurate with the potential hazard posed by the radioactive source, while recognizing the need to ensure appropriate use of the radioactive source for beneficial purposes;
- (5) To prevent unauthorized access or damage to, and loss, theft or unauthorized transfer of, radioactive sources;
- (6) To mitigate or minimize the radiological consequences of any accidents or malicious act involving a radioactive source.

These objectives should be achieved through the establishment of an adequate system of regulatory control of radiation sources. For radioactive material including radioactive sources, this system of regulatory control is applicable from the stage of initial production to their final disposal, including provisions for the restoration of such control if it has been lost.

The Model Regulations apply to practices and the use of radiation sources within practices as well as to those situations to which the requirements for practices are applied, e.g. radon exposure control. Except to the extent that they cover emergency intervention by authorized users for accidents with their sources, the model Regulations do not cover intervention guidelines and criteria as provided by the GSR Part 3 [3]. Because of the multitude and varied nature of interventions and their social and economic complexities, intervention is not very amenable to a set of strict regulations implemented by a regulatory body. While the regulatory body may have an important role in intervention, other government agencies might have the lead role depending upon the particular situation. Because of the social and

economic implications of major decisions involving prolonged exposure and the post-acute phase of accidents, intervention decisions are often made at governmental policy levels higher than the regulatory body and other equivalent level agencies. It should be emphasized, however, that, regardless of who makes intervention decisions and who implements such decisions, intervention advice and criteria contained in the GSR Part 3 should be taken into account.

The notes in italics under the relevant section or article in the Model Regulations are explanatory and not necessarily part of the national regulations.

## 7.2. MODEL REGULATIONS

The regulatory body (name, address, telephone/facsimile/e-mail on the cover or at the beginning of the regulations).

*Note:*

*If useful, provide similar information about departments within the regulatory body, e.g. Licensing, Inspection, and Administration.*

These Regulations are issued under the following authority:

*Note:*

*Cite the legislation or other legal authority that provides the regulatory body the basis for the issuance of regulations on regulatory control of radiation sources.*

## PART 1 - GENERAL PROVISIONS

*Note:*

*The General Provisions are probably the most important part of the regulation because they provide the broad powers for the regulatory body to perform its functions and, in particular, to deal with situations that might not be contemplated by the more detailed regulatory requirements that follow.*

### **Article 1: Entry into Force**

These Regulations shall come into force on \_\_\_ (date) \_\_\_. Postponement in complying with specific articles in specific cases may be granted on receipt of a request in writing with proper justification. In particular, if a modification to an existing practice or radiation source is required by the regulatory body in order to comply with some requirement of these Regulations, such a requirement shall take effect within the period required for the modification or any other period as approved by the regulatory body.

### **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 prevent unauthorized access or damage to, and loss, theft or unauthorized transfer of, radioactive sources, so as to reduce the likelihood of accidental harmful exposure to such sources;
  - (c) To implement the Country's international commitments relevant to radiation safety.
2. They are not intended to relieve an authorized legal person from the duty to take any additional actions as may be appropriate and necessary to protect the health and safety of people.

### **Article 3: Scope**

1. These Regulations apply to the adoption, introduction, conduct, discontinuance, or cessation of a practice in a planned exposure situation and to the design, manufacture, construction or assembly, acquisition, import or export, distribution, selling, loaning or hiring, locating, commissioning, processing, possession, use and operation, maintenance or repair, transfer or decommissioning, disassembly, transport, storage and recycling or disposal of a radiation source within a practice other than in accordance with these Regulations.

2. In these Regulations:

- (a) Specific provisions for radiation protection and safety are those covered in Articles 22-71;
- (b) Specific provisions for radioactive waste are those covered in Articles 72-96;
- (c) Specific provisions for transport of radioactive material are covered in Article 97;
- (d) Specific provisions for emergency preparedness and response are covered in Articles 98-101.

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

- (a) The production, supply and transport of radioactive material and of devices that contain radioactive material, including sealed sources and unsealed sources, and of consumer products;
- (b) The production and supply of devices that generate radiation, including linear accelerators, cyclotrons, and fixed and mobile radiography equipment;
- (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 where such use could affect exposure to radiation;
- (d) The use of radiation or radioactive material for education, training or research, including any activities relating to such use that involve or could involve exposure to radiation or exposure due to radioactive material;
- (e) Any other practice as specified by the regulatory body.

4. The sources within any practice to which the requirements for practices of these Regulations shall apply include:

*Note:*

*Text to be adjusted to local circumstances*

- (a) Facilities that contain radioactive material and facilities that contain radiation generators, including medical radiation facilities and irradiation facilities;
- (b) Individual sources of radiation, including sources within the types of facility mentioned in para. (a), as appropriate, in accordance with the requirements of the regulatory body;

- (c) Exposure due to material in any practice where the activity concentration in the material of any radionuclide in the uranium decay chain or thorium decay chain is greater than 1 Bq/g or the activity concentration of  $^{40}\text{K}$  is greater than 10 Bq/g;

*Note:*

*A situation of exposure due to radionuclides of natural origin in food, feed, drinking water, agricultural fertilizer and soil amendments, construction material and existing residues in the environment is treated as an existing exposure situation (see Part 17 of these Regulations) regardless of the activity concentrations of the radionuclides concerned.*

- (d) Radioactive waste resulting from applications and to radioactive waste management facilities and activities including:
- (i) Effluent discharges;
  - (ii) Waste that contains only naturally occurring materials, whatever the origin of that waste;
  - (iii) Disused radioactive sources.
- (e) Any other radiation source specified by the regulatory body, including sources in the environment such as radon.

*Note:*

*GSR Part 3 [3] includes the following exposures to radon in the scope for planned exposure situations: (a) Exposure due to  $^{222}\text{Rn}$  and to  $^{222}\text{Rn}$  progeny and due to  $^{220}\text{Rn}$  and to  $^{220}\text{Rn}$  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; and (b) Exposure due to  $^{222}\text{Rn}$  and to  $^{222}\text{Rn}$  progeny where the annual average activity concentration of  $^{222}\text{Rn}$  in air in the workplace remains above the reference level established in accordance with para. 5.27 of GSR Part 3 after the fulfilment of the requirement in para. 5.28 of GSR Part 3 [3].*

- (f) The specific radioactive waste provisions apply only to waste arising from medical, agricultural, industrial, research and education applications, mining and milling activities, including associated radioactive waste management activities such as collection, segregation, characterization, classification, treatment, conditioning, and storage.
- (g) These Regulations shall apply to intervention by legal persons authorized to possess radiation sources in the event of radiological emergencies involving their sources.

#### **Article 4: Definitions**

Terms shall be interpreted as defined below. Where noted, the definitions have been adjusted from the original source publication to be consistent with the scope of this regulation.

**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 design, manufacture, construction, import, export, distribution, sale, loan, commissioning, use, operation, maintenance, repair, transfer, decommissioning or possession of radiation sources for industrial, education, research, agriculture and medical purposes; the transport of radioactive material; the mining and processing of radioactive ores; the closing down of associated facilities; the clean-up of sites affected by residues from past activities; and radioactive waste management activities such as the discharge of effluents.

**Authorization:** A permission granted by the regulatory body to a person, natural or juridical, who has submitted an application to carry out an activity or practice. An authorization may take the form of a licence or registration.

*Note:*

*For activities that pose little or no health risk, the applicant may only be required to submit an appropriate notification.*

**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.

**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 its presence is unintended or undesirable, or the process giving rise to its 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.

**Defence in depth:** The application of more than a single protective measure for a given safety objective, such that the objective is achieved even if one of the protective measures fails.

**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 is unusually high or unusually low for that procedure.

**Disposal:** The emplacement of radioactive material in an appropriate facility without the intention of retrieval (slight modification from [4]).

**Disused radioactive source:** See radiation source.

**Dose constraint:** A prospective and source related value of individual dose (dose constraint) or risk (risk constraint) 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.

*Notes:*

- 1) *For occupational exposure, a constraint on individual dose to workers established and used by licensees to set the range of options in optimizing protection and safety for the source;*
- 2) *For public exposure, the dose constraint is a source related value established or approved by the government or the regulatory body, with account taken of the doses from planned operations of all sources under control. The dose constraint for each particular source is intended, among other things, to ensure that the sum of doses from planned operations for all sources under control remains within the dose limit;*

- 3) *The risk constraint is a source related value that provides a basic level of protection for the individuals most at risk from a source. This risk is a function of the probability of an unintended event causing a dose, and the probability of the detriment due to the dose. Risk constraints correspond to dose constraints but apply to potential exposure;*
- 4) *For medical exposure, the dose constraint is a 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.*

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

**Emergency exposure situation:** An emergency exposure situation is a situation of exposure that arises as a result of an accident, a malicious act, or any other unexpected event, and requires prompt action in order to avoid or reduce adverse consequences.

*Note:*

*Emergency exposures 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:*

*Protection of the environment includes the protection and conservation of: non-human species, both animal and plant, and their biodiversity; environmental goods and services such as the production of food and feed; resources used in agriculture, forestry, fisheries and tourism; amenities used in spiritual, cultural and recreational activities; media such as soil, water and air; and natural processes such as carbon, nitrogen and water cycles.*

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

**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 (slight modification from [5]).

**Facility:** Irradiation installations, mining and milling facilities, waste management facilities and any other place where radioactive materials are produced, processed, used, handled, stored or disposed of — or where radiation generators are installed — on such a scale that consideration of protection and safety is required;

**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 a health test or medical examination is performed for the purpose of the early detection of disease.

**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.

*Note:*

*In some types of inspection imaging device ionizing radiation is used to produce images by backscatter, transmission or both. Other types of inspection imaging device utilize imaging by means of electrical and magnetic fields, ultrasound and sonar waves, nuclear magnetic resonance, microwaves, terahertz rays, millimetre waves, infrared radiation or visible light.*

**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 (slight modification from [5]).

**Legal person:** Any organization, corporation, partnership, firm, association, trust, estate, public or private institution, group, political or administrative entity or other persons designated in accordance with national legislation, who or which has responsibility and authority for any action taken under these Regulations. This includes natural persons (slight modification from [3]).

**Licence:** An authorization granted by the regulatory body on the basis of a safety assessment and accompanied by specific requirements and conditions to be completed by the licensee.

**Licensee:** The holder of a current licence granted for an activity or practice, which has recognized rights and duties for the activity or practice, particularly in relation to protection and safety.

**Management:** The administrative and operational activities that are involved in the manufacture, supply, receipt, possession, storage, use, transfer, import, export, transport, maintenance, recycling or disposal of radioactive sources [4].

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

*Note:*

*A patient is an individual who is a recipient of services of health care professionals and/or their agents that are directed at (1) health promotion; (2) prevention of illness and injury; (3) monitoring health; (4) maintaining health; and (5) medical treatment of diseases, disorders and injuries in order to achieve a cure or, failing that, optimum comfort and function. Some asymptomatic individuals are included. For the purpose of these Regulations, the term 'patient' refers only to those individuals undergoing radiological procedures.*

**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.

*Note:*

*Competence of persons is normally assessed by the State by having a formal mechanism for registration, accreditation or certification of medical physicists in the various specialties (e.g. diagnostic radiology, radiation therapy, nuclear medicine). States that have yet to develop such a mechanism would need to assess the education, training and competence of any individual proposed by the licensee to act as a medical physicist and to decide, on the basis either of international accreditation standards or standards of a State where such an accreditation system exists, whether such an individual could undertake the functions of a medical physicist, within the required specialty.*

**Medical radiation facility:** A medical facility in which radiological procedures are carried out.

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

*Note:*

*Competence of persons is normally assessed by the State by having a formal mechanism for registration, accreditation or certification of medical radiation technologists in the various specialties (e.g. diagnostic radiology, radiation therapy, nuclear medicine). States that have yet to develop such a mechanism would need to assess the education, training and competence of any individual proposed by the licensee to act as a medical radiation technologist and to decide, on the basis either of international standards or standards of a State where such a system exists, whether such an individual could undertake the functions of a medical radiation technologist, within the required specialty.*

**Medical radiological equipment:** 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 cobalt-60 teletherapy units; and to devices used in medical imaging to capture images, such as a gamma camera, image intensifier, flat panel detector or positron emission tomography scanner.

**Member of the public:** For protection and safety purposes, in a general sense, any individual in the population except when subject to occupational exposure or medical exposure. For the purpose of verifying compliance with the annual dose limit for public exposure, this is the representative person.

**Notification:** A document submitted to the regulatory body by the legal person to notify an intention to carry out an activity or practice.

**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.

*Note:*

*'protection and safety is optimized' means that optimization of protection and safety has been applied and the result of that process has been implemented*

**Orphan radioactive source:** See radiation source.

**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 from a source.

**Practice:** Any human activity that introduces additional sources of exposure or exposure pathways or extends exposure to additional people or modifies the network of exposure pathways from existing sources, so as to increase the exposure or the likelihood of exposure of people or the number of people [3].

**Principal parties:** The persons having the main responsibilities for the application of these Regulations. These are: (a) registrants or licensees; and (b) employers (slight modification from [3]).

**Protection and safety:** The protection of people against exposure to ionizing radiation or 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.

**Radiation source:** Anything that may cause radiation exposure, such as by emitting ionizing radiation or releasing radioactive substances or materials. When used in this TECDOC, the term includes all of the following:

1. **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.
2. **Radioactive material:** Material designated in national law or by a regulatory body as being subject to regulatory control because of its radioactivity.
3. **Radioactive source:** Radioactive material that is permanently sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It also means any radioactive material released if the radioactive source is leaking or broken, but does not mean material encapsulated for disposal, or nuclear material within the nuclear fuel cycles of research and power reactors [4]. The Categorization of Radioactive Sources (Category 1, Category 2, Category 3, Category 4 and Category 5) is presented in GSR Part 3 [3] and RS-G-1.9 [21].
  - (a) **Disused radioactive source:** A radioactive source which is no longer used, and is not intended to be used, for the practice for which an authorization has been granted [4].
  - (b) **Orphan radioactive source:** A radioactive source which is not under regulatory control because it has never been under regulatory control, or because it has been abandoned, lost, misplaced, stolen, or transferred without proper authorization [4].
  - (c) **Spent radioactive source:** A radioactive source that is no longer suitable for its intended purpose as a result of radioactive decay.

Notes:

- 1) *A spent source may still present a radiological hazard.*
- 2) *Many spent sources may no longer be suitable for use because their encapsulation is past its recommended working life, or the equipment that it is in, is no longer of use.*

(d) **Vulnerable radioactive source:** A radioactive source for which the control is inadequate to provide assurance of long term safety and security, such that it could relatively easily be acquired by unauthorized persons or could relatively easily become orphaned.

4. **Radioactive waste:** 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 procedures involving medical exposure in a given specialty.

Note:

*Competence of persons is normally assessed by the State by having a formal mechanism for registration, accreditation or certification of radiological medical practitioners in the given specialty (e.g. radiology, radiation therapy, nuclear medicine, dentistry, cardiology, etc.). States that have yet to develop such a mechanism need to assess the education, training and competence of any individual proposed by the licensee to act as a radiological medical practitioner and to decide, on the basis either of international standards or standards of a State where such a system exists, whether such an individual can undertake the functions of a radiological medical practitioner, within the required specialty.*

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

**Reference level:** In 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:

*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.

**Registration:** A form of authorization for practices of low or moderate risks whereby the legal person responsible for the practice has, as appropriate, prepared and submitted a safety assessment of the facility and equipment to the regulatory body. The practice or use is authorized with conditions or limitations as appropriate. The requirements for safety assessment and the conditions or limitations applied to the practice should be less severe than those for licensing.

**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 [2].

**Regulatory control:** Any form of control or regulation applied to facilities or activities by a regulatory body for reasons related to radiation protection or to the safety of radiation sources [4].

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

*Note:*

*ICRP Publication 101 indicates that the dose to the representative person 'is the equivalent of, and replaces, the mean dose in the 'critical group'', and provides guidance on assessing doses to the representative person. The concept of critical group remains valid.*

**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.

**Spent radioactive source:** See radiation source.

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

**Supervised area:** A defined area not designated as a controlled area but for which occupational exposure conditions are kept under review, even though no specific protection measures or safety provisions are not normally needed.

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

*Note:*

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

## **Article 5: Exposures**

The exposures to which the safety requirements of these Regulations apply are any occupational exposure, medical exposure or public exposure due to any relevant practice or radiation source within the practice, as specified in Articles 3 (3) and 3 (4).

## **Article 6: Exclusions**

The following exposures are excluded from the scope of these Regulations:

- (a) Exposures from natural radioactivity in the body;
- (b) Cosmic radiation (see note 3);
- (c) Any other radiation sources that is essentially unamenable to control as may be determined by the regulatory body.

*Notes:*

- 1) *Identification of excluded exposure is not a substitute for a clearly stated scope. This is particularly important when regulatory body responsibilities are divided among two or more government agencies and each has its own regulations. Statements about excluded exposure should only be made when they add to the clarity of what is covered in the scope;*
- 2) *Unamenability to control implies recognition of the cost of exercising control over the exposure and the benefit to be gained by the control. It is more than feasibility as it incorporates the idea of reasonableness;*
- 3) *The regulatory body or other relevant authority shall determine whether assessment of the exposures of aircrew to cosmic radiation is warranted.*

## **Article 7: Responsible Parties**

*Notes:*

*Text to be adapted to local circumstances;*

*The regulatory body shall be responsible for the enforcement of these Regulations.*

1. The person or organization 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 having the main responsibilities for the application of these Regulations shall be:
  - (a) Registrants or licensees, or persons or organizations responsible for notified or authorized practices or sources within practices;
  - (b) Employers of workers, in relation to occupational exposure;
  - (c) Radiological medical practitioners, in relation to medical exposure;
  - (d) Those persons or organizations designated to deal with emergency exposure situations or existing exposure situations.

*Note:*

*The term persons or organizations are used here so that persons who are subject to notification only are also included. While requirements applicable to notification only may be minor, they are still requirements.*

3. Other parties shall have specified responsibilities for the application of these Regulations. These parties may include, as appropriate:
  - (a) Suppliers of sources, providers of equipment and software, and providers of consumer products;
  - (b) Radiation protection officers;
  - (c) Referring medical practitioners;
  - (d) Medical physicists;

- (e) Medical radiation technologists;
  - (f) Qualified experts or any other party to whom a principal party has assigned specific responsibilities;
  - (g) Workers other than workers listed in (a)-(f);
  - (h) Ethics committees.
4. The general responsibilities of the principal parties include the following:
- (a) To establish radiation protection and safety objectives in conformity with the relevant requirements of these Regulations;
  - (b) To develop, implement and document a protection and safety programme commensurate with the radiation risks associated with the exposure situation under their responsibility (graded approach) and sufficient to ensure compliance with the requirements of these Regulations. In particular, this programme shall include the following actions:
    - (i) To determine and keep continually under review the measures needed to achieve the radiation safety objectives, to ensure that the resources needed for their implementation are provided and regularly to verify that the radiation safety objectives are being achieved;
    - (ii) To identify and prevent, or promptly correct, any failures or shortcomings in the radiation safety measures;
    - (iii) To facilitate consultation and co-operation among all relevant parties with respect to radiation safety;
    - (iv) To keep appropriate records regarding the discharge of their responsibilities.
  - (c) To ensure that:
    - (i) Radioactive sources are managed in accordance with the authorization;
    - (ii) When radioactive sources are not in use, they are promptly stored;
    - (iii) A radiation generator or radioactive source is transferred only if the recipient possesses the necessary authorization;
    - (iv) Arrangements are made for the safe management of radioactive sources (minimum Category 1, 2 and 3), including financial provisions where appropriate, once they have become disused;
    - (v) The import and export of Category 1 and 2 radioactive sources is done in accordance with these Regulations;
    - (vi) Sources are shipped and received in accordance with regulatory requirements;
    - (vii) Assistance is provided to State authorities or local law enforcement authorities in recovering any lost or stolen source.
  - (d) The relevant principal parties and other parties having specified responsibilities in relation to protection and safety shall ensure that all personnel engaged in activities relevant to protection and safety have appropriate education, training and qualification so that they understand their responsibilities and can perform their duties competently, with appropriate judgement and in accordance with procedures.

#### **Article 8: Regulatory Inspection of Premises and Information**

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

*Note:*

*The extent to which inspection is performed by the regulatory body will depend on the potential magnitude and nature of the hazard associated with the practice or source within*

*practice. The regulatory body's inspection programme should include a system for prioritizing inspections based on a categorization system. For the more hazardous type of facilities, the regulatory body may carry out inspections every year (frequency), while for facilities that are suitable for registration, the regulatory body may carry out a regulatory inspection every 3- 5 years. In addition, this inspection frequency should take into account the availability of qualified inspectors. Further information on regulatory inspections can be found in [2, 9, and 11].*

#### **Article 9: Non-Compliance and Accidents**

1. In the event of a breach of any applicable requirement of these Regulations, principal parties shall, as appropriate:
  - (a) Investigate the breach and its causes, circumstances and consequences;
  - (b) Take appropriate action to remedy the circumstances and to prevent a recurrence of similar situations;
  - (c) Report to the regulatory body within 24 hours, or as required, on the causes of the breach, its circumstances and consequences, and on the corrective or preventive actions taken or to be taken (see Article 19);
  - (d) Take whatever other actions are necessary as required by these Regulations.
2. The communication of such a breach to the regulatory body shall be timely and it shall be immediate whenever an emergency exposure situation has developed or is developing.
3. Whenever a situation involving the loss of control (e.g. loss, theft) of a Category 1, 2 or 3 radioactive source has occurred, or is occurring (see Article 19) the regulatory body shall be informed as soon as practicable.
4. Failure to take corrective or preventive actions within a reasonable time in accordance with these Regulations shall be grounds for enforcement in accordance with Article 10.

#### **Article 10: Enforcement**

An authorization to use a radiation source may be revoked, suspended or modified, or the possession of a radiation source may be prohibited upon finding an undue threat to health and safety or non-compliance with applicable regulatory requirements. Legal persons responsible for notified or authorized practices or sources within practices are subject to fines for non-compliance with applicable regulations and regulatory requirements commensurate with the nature of the infraction. Willful violations or attempted violations of the regulations or requirements may be referred to (*National Justice Authority*) for prosecution under national criminal statutes and codes.

*Notes:*

- 1) *Sanctions should be included in this Article 10 if provided for in the legislation.*
- 2) *The enforcement action shall be commensurate with the seriousness of the non-compliance. Further information on enforcement actions can be found in [2], [9], and [11].*

#### **Article 11: Applicability of other Regulations and Requirements, and Resolution of Conflicts**

1. The requirements of these Regulations are in addition to, and not in place of, other applicable national and local laws and regulations. Nothing in these Regulations shall be construed as relieving employers from complying with applicable national and local laws and

regulations governing safety. If a conflict exists between requirements contained herein and other laws or regulations, the regulatory body shall be notified of such conflict in order to initiate steps towards resolution.

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

### **Article 12: Additional Requirements**

The licensee shall comply with additional requirements imposed by the regulatory body by regulation, order, or conditions of an authorization, in addition to those established in these Regulations, as deemed appropriate or necessary to:

- (a) Protect health;
- (b) Protect the environment; or
- (c) Minimize risk from radiation hazards.

### **Article 13: Interpretation**

Except as specifically authorized, no official interpretation of these Regulations binding on the regulatory body can be made by any officer or employee of the regulatory body other than a written interpretation by (*identify who in the regulatory body is authorized to make the official interpretation that will be binding*).

## **PART 2: ADMINISTRATIVE REQUIREMENTS**

### **Article 14: General Obligations**

No person shall engage in activities, which involve practices, radiation sources, or radioactive waste, as specified in Article 3 of these Regulations, unless the requirements of these Regulations, including requirements of notification and authorization, are met.

### **Article 15: Requirements for Notification**

1. Unless exempt from notification as provided for in Article 16 paragraph 1 or 3, any legal person:

- (a) Who, on the effective date of these Regulations specified in Article 1, is responsible for a practice or in possession of a radioactive source referred to in Article 3, shall submit a notification to the regulatory body within 90 days of the effective date specified in Article 1. Annex I (see section 7.3 of this TECDOC) of these Regulations specifies the information to be provided in the notification;
- (b) Who intends to initiate a practice or to possess a radiation source referred to in Article 3 shall submit a prior notification to the regulatory body of such an intention.

2. Sources and practices requiring notification only are: (if this provision is to be used, the list is to be established by the regulatory body: see Note 2 regarding possible reasons for notification only).

3. After notification, each legal person who is required to apply to the regulatory body for an authorization (registration or licence) and who submits such an application in accordance with Article 17 is permitted to continue existing activities specified in the

notification, in conformance with the applicable requirements of these Regulations, until such time as the regulatory body revokes such permission or grants the authorization.

*Notes:*

- 1) *The regulatory body may specify sources or practices for which notification only is sufficient and an authorization is not required. For other sources or practices, an application for authorization is deemed to include a notification [9].*
- 2) *For sources requiring notification only, the regulatory body should identify the applicable safety requirements for the practice in which the source is used; e.g. a requirement to dispose of the source in an authorized radioactive waste disposal facility, limitations on the purpose for which the sources may be used or minimum age of persons using the sources, i.e. over 18 years.*

## **Article 16: Exemption of Practices and Sources**

1. Practices and sources within a practice may be exempted from the specific safety requirements (see Article 3 (2)) of these Regulations provided that they comply with criteria for exemption or any exemption levels defined by the regulatory body.

*Notes:*

- 1) *Exemption criteria are provided in Schedule I of GSR Part 3 [3]. Exemption levels specified as activity concentration levels for moderate amounts of material are published in Table I-1 of Schedule I of the GSR Part 3 and for bulk amounts of solid material are published in Table I-2 of Schedule I of the GSR Part 3.*
- 2) *For radionuclides of natural origin, exemption of bulk amounts of material is necessarily considered on a case by case basis<sup>1</sup> by using a dose criterion of the order of 1 mSv in a year, commensurate with typical doses due to natural background levels of radiation.*
- 3) *The release of sources from regulatory control through both the exemption and clearance (Article 21) provisions is a process that is subject to regulatory control. As a minimum, the regulatory body needs to determine that adequate control mechanisms are in place to ensure that the radioactive materials to be released are within the prescribed limits for activity or activity concentration. This can frequently involve the use of sophisticated measurement and control systems.*

2. Exemptions shall not be granted for practices deemed not to be justified as specified in Articles 22 and 47.

3. The following practices and sources within a practice are automatically exempted from the specific safety requirements (see Article 3.2) of these Regulations, including the requirements for notification, registration or licensing (see Articles 15 and 17):

- (a) Radioactive materials in a moderate amount for which the total activity of a given nuclide present on the premises at any one time or its activity concentration does not exceed the applicable exemption levels;
- (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 Table I-2 of Schedule I of GSR Part 3;
- (c) Equipment containing radioactive material exceeding the quantities or concentrations specified above, provided that:

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<sup>1</sup> Material containing radionuclides of natural origin at an activity concentration of less than 1 Bq/g for any radionuclide in the uranium and thorium decay chains and of less than 10 Bq/g for <sup>40</sup>K is outside the scope of planned exposure situations (para. 3.4(a) of [3]); hence the concept of exemption does not apply for such material.

- (i) The equipment containing radioactive material is of a type approved by the regulatory body;
  - (ii) It is in the form of a sealed source that effectively prevents any contact with the radioactive material and prevents its leakage;
  - (iii) It is in the form of an unsealed source in a small amount such as sources used for radioimmunoassay;
  - (iv) In normal operating conditions the equipment does not cause an ambient dose equivalent rate or a directional dose equivalent rate, as appropriate, exceeding 1  $\mu\text{Sv/h}$  at a distance of 0.1 m from any accessible surface of the apparatus; or
  - (v) Necessary conditions for disposal of the equipment have been specified by the regulatory body.
- (d) Radiation generators of a type approved by the regulatory body, or in the form of an electronic tube, such as a cathode ray tube for the display of visual images, provided that:
- (i) They do not in normal operating conditions cause an ambient dose equivalent rate or a directional dose equivalent rate, as appropriate, exceeding 1  $\mu\text{Sv/h}$  at a distance of 0.1 m from any accessible surface of the equipment; or
  - (ii) The maximum energy of the radiation generated is no greater than 5 keV.

### **Article 17: Requirements for Authorization by Registration or Licence**

*Notes:*

- 1) *As the nature and level of risk or complexity associated with a practice or source within a practice, the regulatory body needs to develop a categorization system that covers all practices and sources within practices that are regulated. The regulatory body will apply a graded approach to regulatory control of the activities, practices and sources within practices based on the categorization system. Such a graded approach may include notification, registration and licensing. Notification would be applied to the lowest level of risk and licence to the highest.*
- 2) *GSR Part 3 [3] and RS-G-1.9 [21] provide categories for sealed sources used in common practices. This categorization scheme does not include X ray generators such as dental and medical X ray apparatus, and it does not include unsealed radioactive sources, such as those used in nuclear medicine practices.*
- 3) *GS-G-1.5 [9] provides examples of practices or sources within practices that may be candidates for registration: industrial gauges in permanent locations, dental diagnostic X ray units, radio-immunoanalysis and diffractometry apparatus.*
- 4) *The regulatory body is to decide on which categories of radiation sources are to be registered and which categories are to be licensed. It is considered that radioactive sources in categories 1, 2 and 3 must be licensed. The regulatory body may decide that some category 4 or 5 sources are amenable to registration, which would be consistent with GS-G-1.5 [9].*
- 5) *The regulatory body may decide to have only one type of authorization without distinguishing between 'registration' and 'licence'. In such a case, the wording of this article shall be adapted accordingly.*

1. Except as provided in Article 15 and Article 16 of these Regulations, any person or organization intending to engage in a practice or possess a radiation source referred to in Article 3 shall apply to the regulatory body for an authorization which shall take the form of either a registration or a licence.

2. In the case of existing practices or sources for which notification is made in accordance with Article 15, paragraph 1(a), such application shall be submitted within

90 days of the effective date specified in Article 1. If the application refers to an industrial irradiation installation, an installation processing radioactive materials, a medical or industrial radiography facility, or for any use of source that the regulatory body has not designated as suitable for registration, the authorization shall take the form of a licence.

3. Any legal person applying for an authorization shall:

- (a) Submit to the regulatory body relevant information necessary to support the application, including:
  - (i) An evaluation of the nature, likelihood and magnitude of the exposures attributed to the practice and sources within the practice;
  - (ii) A safety assessment in cases where this is prescribed by the regulatory body, to be submitted as part of the application;
  - (iii) An appropriate prospective assessment made for radiological environmental impact, commensurate with the radiation risks associated with the facility or activity, where prescribed by the regulatory body;
  - (iv) An emergency plan, if applicable;
  - (v) A determination of the characteristics and activity of any radioactive material to be discharged to the environment with an assessment of the resulting doses to the critical group;
  - (vi) A final disposal solution for generated radioactive waste and disused sealed sources according to the agreed national policy and strategy;
- (b) Take all necessary steps for the protection and safety of:
  - (i) Workers;
  - (ii) Members of the public;
  - (iii) Patients;
- (c) Ensure the availability of human and financial resources for decommissioning of the facility and the management of radioactive waste.

4. Applications for authorizations involving Category 1, 2 or 3 radioactive sources shall include a description of the arrangements for the safe management of the source(s), including financial provisions where appropriate, once they have become disused.

5. Information in the application that needs to be kept confidential (see Article 28) must be clearly identified by the applicant.

6. Any legal person responsible for a source to be used for medical exposure shall include in the application for a licence the qualifications in radiation protection of the medical practitioners who are to be so designated by name or by qualification credentials in the licence as the only individuals permitted to prescribe medical exposure by means of the authorized source.

*Notes:*

- 1) *The regulatory body should require other information, as set out in paragraph 3.33 of GS-G-1.5 [9] be submitted in addition to that listed in paragraph 3 of this Article. The level of detail to be submitted by the applicant for registration or licence is related to the risk associated with the practice or source within the practice.*
- 2) *For some practices, particularly those that involve construction of facilities that are later difficult to modify, such as commercial product irradiators and radiotherapy facilities, a two stage licensing process is desirable. The regulatory body should issue an authorization to construct before construction begins. This reduces the chance of large financial investments in designs or practices that for other reasons cannot be licensed to operate. A good way to implement a two-stage process is for the regulatory body to get an almost complete picture in the initial application; facility design, equipment*

*description, general operating procedures and qualifications of personnel, etc. The regulatory body may also wish to prohibit procurement of radiation sources (including import) until a particular stage of construction has been completed, and safe and secure storage of the sources can be ensured. The licence can be granted for the entire operation with a licence condition which requires the licensee to notify the regulatory body when construction is completed and relevant acceptance tests made, but before operations begin. The licence condition should prohibit operation by the licensee until notified by the regulatory body that it is satisfied with the facility as constructed. The regulatory body will normally conduct a pre-operational inspection at this stage. Also, because of elapsed time and modifications during construction, there may be adjustments to the operating procedures and qualifications or identification of key personnel before permission is granted to operate.*

- 3) The regulatory body should, as part of its assessment of applications for authorization, also consider the financial capability of the applicant to comply with these Regulations, particularly with respect to the decommissioning of facilities, the disposal of radioactive waste and the prompt disposal of radioactive sources once they become disused.*
- 4) With the possible exception of gauging devices used on process or manufacturing lines and some types of medical diagnostic X ray sources, the Member States are not likely to have many sources and practices that meet the criteria to be good candidates for registrations. For this reason, the model regulations from this point forward refer to licensees only; however, if registration is to be included, the requirements placed on licensees in the statements that follow also apply to registrants.*
- 5) The regulatory body may provide that the authorization is granted for a certain period of time and those licensees should seek re-approval after the time decided by the regulatory body or when any significant change to the practice or source is proposed. The period of time for the authorization would be based an assessment of the nature and level of risk or complexity associated with the practice or source within the practice. The period of time for authorization is not directly comparable to time intervals between inspections. Further information on the authorization process can be found in [2], [9], and [10].*
- 6) The regulatory body may attach conditions to an authorization and may suspend or revoke it 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.*
- 7) Requirements for safety assessment can be found in General Safety Requirements [26].*

### **Article 18: Responsibilities of Licensees**

1. Licensees shall bear the responsibility for establishing and implementing the technical and organizational measures that are needed for ensuring protection, and safety for the practices and sources for which they are authorized and for compliance with all applicable requirements of these Regulations. Licensees may designate suitably qualified persons to carry out actions and tasks related to these responsibilities, but they shall retain the prime responsibility for protection and safety. Licensees shall document the names and responsibilities of persons designated.

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

3. Licensees shall establish clear lines of responsibility and accountability for protection and safety for the sources for which they are authorized, and shall establish organizational arrangements for protection and safety.
4. Licensees shall ensure that any delegation of responsibilities by a principal party is documented.
5. Licensees shall ensure that the relevant principal parties and other parties having specified responsibilities in relation to protection and safety shall ensure that all personnel engaged in activities relevant to protection and safety have appropriate education, training and qualification so that they understand their responsibilities and can perform their duties competently, with appropriate judgement and in accordance with procedures.
6. Licensees shall have in place operating procedures and arrangements for protection and safety that are subject to periodic review and updating under a management system.
7. Licensees shall establish procedures for reporting on and learning from accidents and other incidents.
8. Licensees shall ensure safe management of and control over all radioactive waste that is generated, and shall dispose of such waste in accordance with the regulatory requirements.
9. During the entire lifecycle of radiation sources, from the moment of their manufacturing up to their final disposal, the respective licensees shall ensure that the appropriate safety measures are taken.
10. For this purpose, licensees shall ensure that a multilevel (defence in depth) system of sequential, independent provisions for protection and safety that is commensurate with the likelihood and the magnitude of the potential exposures is applied to sources for which the licensees are authorized. Licensees 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 accidents that do occur;
  - (c) Restoring the sources to safe conditions after any such accidents.
11. Licensees shall ensure that structures, systems and components, including software, that are related to protection and safety for facilities and activities are designed, constructed, commissioned, operated and maintained so as to prevent accidents as far as reasonably practicable.
12. The licensee for any facility or activity shall make suitable arrangements:
  - (a) To prevent reasonably foreseeable accidents in the facility or the activity;
  - (b) To mitigate the consequences of those accidents that do occur;
  - (c) To provide workers with the information, instruction, training and equipment necessary to restrict potential exposures;
  - (d) To ensure that there are adequate procedures for the control of the facility and for the management of any reasonably foreseeable accidents;
  - (e) To ensure that safety significant structures, systems and components, including software, and other equipment can be inspected and tested regularly for any degradation that could lead to abnormal conditions or inadequate performance;
  - (f) To ensure that maintenance, inspection and testing appropriate to the preservation of the provisions for protection and safety can be carried out without undue occupational exposure;

- (g) To provide, wherever appropriate, automatic systems for safely shutting off or reducing the release of radiation from facilities in the event that operating conditions are outside the stipulated ranges;
- (h) To ensure that abnormal operating conditions that could significantly affect protection and safety are detected by systems that respond quickly enough to allow for corrective action to be taken in a timely manner;
- (i) To ensure that all relevant safety documentation is available in the appropriate languages.

13. The licensee shall ensure that the safety of the facility or of the waste shall not be jeopardized by any provision made for the purpose of complying with national or international requirements concerning safeguards of the material.

*Note:*

*The regulatory body should decide whether the licences would have a defined period of validity and, if so, establish appropriate licence renewal procedures.*

### **Article 19: Requirements for Reporting to the Regulatory Body**

*Note:*

*Requirements for reporting to the regulatory body, which are found throughout these Regulations, are summarized here for convenience.*

1. Licensees shall:
  - (a) Notify the regulatory body by *{telephone or other method e.g. facsimile, e-mail, etc. as determined by the regulatory body}* facsimile immediately of any event in which a dose limit is exceeded;
  - (b) Notify the regulatory body by telephone or facsimile as soon as practicable, but not later than 24 hours after discovery, of any significant unintended or accidental medical exposures (see Article 58);
  - (c) Submit to the regulatory body, within 30 days after discovery of any significant unintended or accidental medical exposures, a written report which states the cause of the any significant unintended or accidental medical exposures and includes information on the doses, corrective measures and any other relevant information;
  - (d) Report a summary of the public exposure monitoring results to the regulatory body at approved intervals and promptly inform the regulatory body of any abnormal results which lead or could lead to an increase of public exposure (see Article 60);
  - (e) Report discharges of radioactive waste to the environment to the regulatory body at intervals as may be specified in the licence and promptly report any discharges exceeding the authorized limits (see Article 89);
  - (f) Report promptly and within 30 days submit a written report to the regulatory body any releases of radioactive material to the environment above the clearance criteria established by the regulatory body.
2. In addition to the radiation safety related reports above, licensees shall make the following reports to the regulatory body:
  - (a) Radioactive source inventory data (see Article 33) and subsequent changes to those data, except for routine movements of the source allowed in the authorization;
  - (b) Unusual events or incidents, such as:
    - (i) Loss of control over a radioactive source;
    - (ii) Unauthorized access to, or unauthorized use of, a source;

- (iii) Discovery of any orphan sources;
  - (c) Any intentions to introduce modifications to any practice with a radioactive source whenever the modifications could have significant implications for safety;
  - (d) A copy of relevant parts of any contract or acceptance document relating to the return of radioactive sources intending to be imported (see Articles 69, 70 and 71);
3. Breaches of these Regulations shall be communicated to the regulatory body within 24 hours, and shall include the information required by Article 9;
4. For radioactive sources in Category 1, 2 and 3, the local law enforcement agency shall be informed immediately and the regulatory body shall be informed as soon as practicable for:
- (a) Lost sources;
  - (b) Actual or attempted theft of sources;
5. Additional reports regarding radioactive waste shall be made in accordance with Articles 76, 89 and 90.
6. Unless otherwise specified, all reports required by this Article shall be made in writing within 30 days.

#### **Article 20: Investigations and Feedback of Operating Experience**

1. Licensees shall ensure that information on normal operation performance as well as abnormal conditions and events significant to radiation safety is disseminated or made available, as appropriate, to the regulatory body and other relevant parties, including other users, as specified by the regulatory body.
2. In addition, and where applicable, licensees shall make suitable arrangements with suppliers of sources to establish and maintain mechanisms for transfer from licensees to suppliers of any information on the use, maintenance, disposal and malfunctioning that may be relevant for future improvements in the design and fabrication of the sources they have supplied.
3. Licensees 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 or is outside the stipulated range of operating conditions; or
  - (b) Any equipment failure, accident, error, mishap or other unusual event or condition occurs that has the potential for causing a quantity to exceed any relevant limit or operating restriction.
4. The licensee shall conduct an investigation as soon as possible after an event and shall prepare a written record of its causes, or suspected causes, including a verification or determination of any doses received or committed and recommendations for preventing the recurrence of the event and the occurrence of similar events.
5. The licensee shall communicate to the regulatory body and to any other relevant parties, as appropriate, a written report of any formal investigation relating to events prescribed by the regulatory body, including exposures giving rise to doses exceeding a dose limit. The licensee also shall immediately report to the regulatory body any event in which a dose limit is exceeded

## **Article 21: Clearance**

Radiation sources, including substances, materials, radioactive waste and objects within authorized practices can be released from further compliance with the radiation protection and safety requirements (see Article 3 (2)) of these Regulations provided that they comply with criteria for clearance or clearance levels established by the regulatory body.

*Note:*

*Criteria for clearance are established in the GSR Part 3 [3]. Clearance levels specified as activity concentration of radionuclides of artificial origin for clearance of solid material are published in Table I-2 of Schedule I of the GSR Part 3 [3]. Activity concentration of radionuclides of natural origin for clearance of material are published in Table I-3 of Schedule I of the GSR Part 3[3].*

## **PART 3: REQUIREMENTS FOR RADIATION PROTECTION**

*Note:*

*The radiation protection requirements as well as management requirements and technical requirements that follow are stated in very broad terms, very similar to the way they are in GSR Part 3. Many of these requirements would need to be supplemented with prescriptive requirements as may be appropriate for ensuring adequate radiation safety. These prescriptive requirements and additional other regulatory actions to ensure radiation safety must be tailored to the specific conditions and needs of each individual country.*

## **Article 22: Justification of Practices**

1. No practice shall be authorized unless it is likely to produce sufficient benefit to the exposed individuals or to society to offset the radiation harm that it might cause, taking into account social, economic and other relevant factors. If requested by the regulatory body, the applicant for an authorization shall provide sufficient information and evidence on the benefits and the harm to support the justification of the practice or source. The regulatory body may deny authorization of the proposal in the application on the basis that it is not justified.

2. The following practices are deemed to be not justified:

- (a) Practices, except for justified practices involving medical exposure, that result in an increase in activity, by the deliberate addition of radioactive substances or by activation<sup>2</sup>, in food, feed, beverages, cosmetics or any other commodity or product intended for ingestion, inhalation or percutaneous intake by, or application to, a person;
- (b) Practices involving the frivolous use of radiation or radioactive substances in commodities or in 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.

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<sup>2</sup> This requirement is not intended to prohibit those practices that may involve the short term activation of commodities or products, for which there is no increase in radioactivity in the commodity or product as supplied.

3. Human imaging using radiation that is performed for occupational, legal or health insurance purposes, and is undertaken without reference to clinical indication, shall normally be deemed to be not justified. If, in exceptional circumstances, the government or the regulatory body decides that the justification of such human imaging for specific practices is to be considered, Articles 34(1), 34(2), 35(1) and 35(3) shall apply.

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

5. Human imaging using radiation for the detection of concealed objects for anti-smuggling purposes shall normally be deemed to be not justified. If, in exceptional circumstances, the government or the regulatory body decides that the justification of such human imaging is to be considered, Articles 34 and 35 shall apply.

6. Human imaging using radiation for the detection of concealed objects that can be used for criminal acts or to pose a national security threat shall be justified only by the government. If the government decides that the justification of such human imaging is to be considered, Articles 34 and 35 shall apply.

*Notes:*

- 1) *It is usually unnecessary for an applicant to justify an authorization for use of a source within a well-established practice since use of radiation sources is broadly justified by legislation. Therefore, the wording of the regulatory requirement is such that the applicant provides justification information only if requested by the regulatory body. Also, the wording of the requirement is such that the regulatory body retains the authority to deny unjustified applications. However, this does place a burden on the regulatory body to identify potentially unjustified proposals.*
- 2) *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.*
- 3) *For justification of medical exposures, see Article 48.*
- 4) *Article 2(b) is not intended to prohibit those practices that may involve the short term activation of commodities or products, for which there is no increase in radioactivity in the commodity or product as supplied*

### **Article 23: Optimization of Protection and Safety**

1. Licensees shall ensure that protection and safety is optimized.

2. For occupational exposure and public exposure<sup>3</sup>, licensees shall ensure that all relevant factors are taken into account in a coherent way in the optimization of protection and safety to contribute to achieving the following objectives:

- (a) To determine measures for protection and safety that are optimized for the prevailing circumstances, with account taken of the available options for protection and safety as well as the nature, likelihood and magnitude of exposures;
- (b) To establish criteria, on the basis of the results of the optimization, for the restriction of the likelihood and magnitudes of exposures by means of measures for preventing accidents and for mitigating the consequences of those that do occur.

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<sup>3</sup> Requirements for the optimization of medical exposure are specified in Articles 47-60.

## **Article 24: Dose Constraints**

1. For occupational exposure and public exposure, licensees shall ensure, as appropriate, that relevant constraints are used in the optimization of protection and safety for any particular source within a practice.
2. In case of any source that can release radioactive material to the environment, the dose constraints shall be established so that the prospective annual doses to members of the public, including people distant from the source and people of future generations, summed over all exposure pathways, including contributions by other practices and sources, are unlikely to exceed the dose limits specified in Annex II or any lower values established by the regulatory body.

## **Article 25: Dose Limits**

Licensees shall ensure that the exposures of individuals due to the practices for which the licensees are authorized are restricted so that neither the effective dose nor the equivalent dose to tissues or organs exceeds any relevant dose limit specified in Annex II.

## **Article 26: Management Requirements**

1. The principal parties shall ensure that protection and safety is effectively integrated into the overall management system of the organizations for which they are responsible.
2. The principal parties shall demonstrate commitment to protection and safety at the highest levels within the organizations for which they are responsible.
3. Licensees shall establish a management system, commensurate with the size and nature of the authorized activity, which ensures that:
  - (a) Policies and procedures are established that identify safety as being of the highest priority;
  - (b) Problems affecting protection and safety are promptly identified and corrected in a manner commensurate with their importance;
  - (c) The responsibilities of each individual for safety are clearly identified and each individual is suitably trained and qualified;
  - (d) Clear lines of authority for decisions on safety are defined;
  - (e) Organizational arrangements and lines of communications are established that result in an appropriate flow of information on safety at and between the various levels in the entire organization of the licensee.
4. The principal parties shall ensure that the management system is designed and implemented to enhance protection and safety by:
  - (a) Applying the requirements for protection and safety coherently with other requirements including requirements for operational performance, and coherently with guidelines for security;
  - (b) Describing the planned and systematic actions necessary to provide adequate confidence that the requirements for protection and safety are fulfilled;
  - (c) Ensuring that protection and safety is not compromised by other requirements;
  - (d) Providing for the regular assessment of performance for protection and safety and the application of lessons learned from experience;
  - (e) Promoting safety culture.

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

### **Article 27: Safety Culture**

The principal parties shall promote and maintain a safety culture by:

- (a) Promoting individual and collective commitment to protection and safety at all levels of the organization;
- (b) Ensuring a common understanding of the key aspects of safety culture within the organization;
- (c) Providing the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, with account taken of the interactions between individuals, technology and the organization;
- (d) Encouraging the participation of workers and their representatives and other relevant persons in the development and implementation of policies, rules and procedures dealing with protection and safety;
- (e) Ensuring accountability of the organization and of individuals at all levels for protection and safety;
- (f) Encouraging open communication with regard to protection and safety within the organization and with relevant parties, as appropriate;
- (g) Encouraging a questioning and learning attitude and discouraging complacency with regard to protection and safety;
- (h) Providing means by which the organization continually seeks to develop and strengthen its safety culture.

### **Article 28: Confidentiality of Information**

Licensees shall establish information management systems, commensurate with the size and nature of the authorized activity, which ensure:

- (a) That the confidentiality of information that it receives in confidence from another party is protected;
- (b) That information received in confidence from another party is only provided to a third party with the consent of the first party;

### **Article 29: Human Factors**

1. The principal parties and other parties having specified responsibilities in relation to protection and safety, as appropriate, shall take into account human factors and shall support good performance and good practices to prevent human and organizational failures, by ensuring that:

- (a) Sound ergonomic principles are followed in the design of equipment and the development of operating procedures, so as to facilitate the safe operation and use of equipment, to minimize the possibility that operator errors will lead to accidents, and to reduce the possibility that indications of normal conditions and abnormal conditions will be misinterpreted;
- (b) Appropriate equipment, safety systems and procedural requirements are provided and other necessary provisions are made:

- (i) To reduce, as far as practicable, the possibility that human error or inadvertent action could give rise to accidents or other incidents leading to the exposure of any person;
  - (ii) To provide means for detecting human errors and for correcting them or compensating for them;
  - (iii) To facilitate protective actions and corrective actions in the event of failures of safety systems or failures of measures for protection and safety.
2. All employees shall be informed at least annually of the importance of effective measures for protection and safety and be trained in their implementation as appropriate.
  3. Training programmes shall be routinely evaluated and updated as necessary.

### **Article 30: Radiation Protection Officers and Qualified Experts**

1. Licensees shall arrange for qualified experts to be identified and made available for providing advice on the observance of these Regulations when so required by the regulatory body.
2. The qualifications of qualified experts in radiation safety shall include a level of academic knowledge and of professional experience compatible with the levels of risks associated with the authorized practices or sources within a practice.
3. A radiation protection officer shall be technically competent in radiation protection matters relevant to a given type of practice. The radiation protection officer oversees the application of the requirements of these Regulations to that practice.
4. An applicant may propose to use a radiation protection officer in place of a qualified expert in radiation safety on the basis of the relatively low risk of the practice.
5. Licensees shall keep the regulatory body informed of the arrangements made with respect to paragraphs 1 and 2 above.

## **PART 4: VERIFICATION OF SAFETY**

### **Article 31: Safety Assessment**

1. When so required by the regulatory body (*regulatory body should specify applicability e.g. include radioactive sources in Category 1, 2 and 3*), or to meet management system requirements, the licensee shall prepare safety assessments that are either generic or specific to the practices or sources for which they are responsible, including radioactive waste management activities, so as:
  - (a) To identify the ways in which exposures could 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 reasonable and practicable, make an assessment of potential exposures;
  - (c) To assess the adequacy of the provisions for protection and safety.

2. The safety assessment shall include, as appropriate, a systematic critical review of:
  - (a) The operational limits and conditions for the operation of a facility;
  - (b) The ways in which structures, systems and components, 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.
3. The 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 to 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.
4. Licensees shall ensure that the safety assessment is documented and, where appropriate, that it is independently reviewed under the relevant management system.
5. Licensees shall perform additional reviews of the safety assessment as necessary to ensure that the 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.
6. If as a result of a safety assessment, or for any other reason, opportunities to improve protection and safety appear to be available and improvement seems desirable, any consequential modifications shall be made cautiously and only after favourable assessment of all the implications for protection and safety. The implementation of all improvements shall be prioritized so as to optimize protection and safety.

### **Article 32: Monitoring, Testing and Verification of Compliance**

Licensees 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 licence conditions;
- (b) Suitable 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, as required by the regulatory body, including records of the tests and calibrations carried out in accordance with regulations and licence conditions;
- (e) The results of monitoring and verification of compliance are shared with the regulatory body as required.

### **Article 33: Inventory and Records**

1. Licensees shall establish, maintain and be able to retrieve records relating to:

- (a) Inventory of sealed sources and radiation generators;
- (b) Records of doses from occupational exposures;
- (c) Records relating to facilities and activities;
- (d) Inventory of radioactive waste;
- (e) Records of events, including non-routine release of radioactive material to the environment;
- (f) Records that might be necessary for decommissioning or closure of facilities;
- (g) The transfer of radioactive sources;
- (h) The testing of instruments and safety systems, and calibrations carried out in accordance with the requirements of the Regulations.

2. Individual sealed source records shall include the:

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

3. Licensees shall provide the regulatory body as required with appropriate information from their inventory records of radiation generators and radioactive sources. Licensees shall check inventory periodically to confirm that radiation generators are in their assigned locations and are under control.

## **PART 5: HUMAN IMAGING FOR PURPOSES OTHER THAN MEDICAL DIAGNOSIS, MEDICAL TREATMENT OR BIOMEDICAL RESEARCH**

### **Article 34: Justification of practices of any type of human imaging using radiation**

1. The justification process applied to the practice of any type of human imaging procedure in which radiation is used for purposes other than for medical diagnosis or medical treatment or as part of a programme of biomedical research shall include the consideration of:

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

2. If it has been determined through the process specified in (1) that a particular practice of human imaging using radiation is justified, then, such a practice shall be subject to regulatory control.

*Notes:*

- 1) *The government is to ensure that the regulations covering justification of practices (Article 22) is applied to the practice of any type of human imaging procedure in which radiation is used for purposes other than for medical diagnosis or medical treatment or as part of a programme of biomedical research;*
- 2) *The regulatory body, in cooperation with other relevant authorities, agencies and professional bodies, as appropriate, shall establish the requirements for regulatory control of the practice, and for review of the justification*

### **Article 35: Optimization of protection and safety**

1. For human imaging using radiation conducted by medical personnel using medical radiological equipment, which exposes humans to radiation for employment related, legal or health insurance<sup>4</sup> purposes without reference to clinical indications, the licensee shall ensure that the appropriate optimization requirements for medical exposure in Article 49 of these Regulations are applied, with dose constraints (*to be established by Government in consultation with relevant authorities, professional bodies, and regulatory body*) used instead of diagnostic reference levels.

2. Procedures with inspection imaging devices in which radiation is used to expose persons 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. Licensees shall apply the requirements for public exposure (Articles 61-65). In particular, licensees shall ensure that optimization of protection and safety is subject to any dose constraints for public exposure set by the government or the regulatory body.

3. Licensees shall ensure that all persons who are to undergo procedures with inspection

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<sup>4</sup> Such purposes include assessment of fitness for employment (prior to employment or periodically during employment), assessment of physiological suitability for a career or a sport, assessment of athletes before a selection or transfer, 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.

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.

4. The licensee shall ensure that any inspection imaging device used for the detection of concealed objects on or within the body, whether it is manufactured in or imported into the State in which it is used, conforms to applicable standards of the International Electrotechnical Commission (IEC) or the International Organization for Standardization (ISO) or to equivalent national standards.

## **PART 6: OCCUPATIONAL EXPOSURE**

### **Article 36: General Responsibilities**

1. For workers who are engaged in activities in which they are or could be subject to occupational exposure in planned exposure situations, licensees and employers shall be responsible for:

- (a) Protection of workers against occupational exposure;
- (b) Compliance with relevant requirements of regulations and licence conditions.

2. Licensees and employers shall ensure, for all workers engaged in activities in which they are or could be subject to occupational exposure, that:

- (a) Occupational exposures is controlled so that the relevant dose limits for occupational exposure specified in Annex II are not exceeded;
- (b) Protection and safety is optimized in accordance with Articles 24 and 25;
- (c) Decisions with regard to measures for protection and safety are recorded and made available to relevant parties, through their representatives where appropriate, as specified by the regulatory body;
- (d) 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) Suitable and adequate 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) Necessary workers' health surveillance and health services for workers are provided;
- (g) Appropriate monitoring equipment and personal protective equipment are provided and arrangements are made for its proper use, calibration, testing and maintenance;
- (h) Suitable and adequate human resources and appropriate training in protection and safety are provided, as well as periodic retraining as required to ensure the necessary level of competence;
- (i) Adequate records are maintained in accordance with the requirements of regulations and licence conditions;
- (j) Arrangements are made to facilitate consultation and cooperation with workers, with regard to protection and safety, through their representatives where appropriate, on all measures to achieve effective application of these Regulations;
- (k) Necessary conditions for promoting a safety culture are provided.

3. Licensees and employers shall:
  - (a) Involve workers, through their representatives where appropriate, in optimization of protection and safety;
  - (b) Establish and use, as appropriate, constraints as part of optimization of protection and safety.
4. Licensees and employers shall 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.
5. Licensees and employers shall take such administrative actions as are necessary to ensure that workers are informed that ensuring 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.
6. Licensees and employers shall record any report received from a worker that identifies any circumstances that could affect safety conditions or compliance with the requirements of these Regulations, and shall take appropriate remedial actions.
7. Employers and licensees shall facilitate compliance by workers with the requirements of these Regulations.

### **Article 37: Cooperation between Employers and Licensees**

1. Employers and licensees shall cooperate to the extent necessary for compliance by all responsible parties with the requirements of the Regulations.
2. If workers are engaged in work that involves or that could involve a source that is not under the control of their employer, the licensee responsible for the source and the employer shall cooperate to the extent necessary for compliance by both parties with the requirements of these Standards.
3. Cooperation between the employer and the licensee shall include, where appropriate:
  - (a) The development and use of specific restrictions on exposure and other means of ensuring that the measures for protection and safety for workers who are engaged in work that involves or could involve a source that is not under the control of their employer are at least as good as those for employees of the licensee;
  - (b) Specific assessments of the doses received by workers as specified in (a);
  - (c) A clear allocation and documentation of the responsibilities of the employer and those of the licensee for protection and safety.
4. As part of the cooperation between parties, the licensee responsible for the source or for the exposure shall, as appropriate:
  - (a) Obtain from the employers, including self-employed individuals, the previous occupational exposure history of workers as specified in Article 42(1), and any other necessary information;

- (b) Provide appropriate information to the employer, including any available information relevant for compliance with the requirements of these Standards that the employer requests;
- (c) Provide both the worker and the employer with the relevant exposure records

**Article 38: Classification of Areas**

1. Controlled Areas

- (a) Licensees shall 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) Licensees shall:
  - (i) Determine the boundaries of any controlled area on the basis of the likelihood and magnitude of expected exposures and the type and extent of the procedures required for protection and safety;
  - (ii) Delineate controlled areas by physical means or, where this is not reasonably practicable, by some other suitable means;
  - (iii) Where a source is only intermittently brought into operation or energized or is moved from place to place, delineate an appropriate controlled area by means that are appropriate under the prevailing circumstances and specify exposure times;
  - (iv) Display a warning symbol, recommended by the ISO, and display instructions at access points to and at appropriate locations within controlled areas;
  - (v) 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;
  - (vi) 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;
  - (vii) Provide, as appropriate, at entrances to controlled areas:
    - a. Personal protective equipment;
    - b. Equipment for individual monitoring and workplace monitoring;
    - c. Suitable storage for personal clothing;
  - (viii) Provide, as appropriate, at exits from controlled areas:
    - a. Equipment for monitoring for contamination of skin and clothing;
    - b. Equipment for monitoring for contamination of any objects or material being removed from the area;
    - c. Washing or showering facilities and other personal decontamination facilities;
    - d. Suitable storage for contaminated personal protective equipment;
  - (ix) Periodically review conditions to assess whether there is any need to modify the measures for protection and safety or the boundaries of controlled areas;
  - (i) Provide appropriate information, instruction and training for persons working in controlled areas.

## 2. Supervised Areas

- (a) Licensees shall designate as a supervised area any area not already designated as a controlled area, but where occupational exposure conditions need to be kept under review even though specific protection measures and safety provisions are not normally needed;
- (b) Licensees, taking into account the nature, likelihood and magnitude of exposures or contamination in the supervised areas, shall:
  - (i) Delineate the supervised areas by appropriate means;
  - (ii) Display approved signs, as appropriate, at access points to supervised areas;
  - (iii) Shall periodically review conditions to assess whether there is any need for further measures for protection and safety or any need for changes to the boundaries of supervised areas.

### **Article 39: Local Rules and Procedures and Personal Protective Equipment**

1. Employers and licensees shall minimize the need to rely on administrative controls and personal protective equipment for protection and safety by providing well engineered controls and satisfactory working conditions, in accordance with the following hierarchy:

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

2. Licensees and employers shall, in consultation with workers, through their representatives, in a language appropriate to the audience addressed:

- (a) Establish in writing local rules and procedures that are necessary for protection and safety for workers and other persons;

*Note:*

*In some cases it will be appropriate to have the local rules and procedures in both the official language and in a local dialect.*

- (b) Include in the local rules and procedures any relevant investigation level or authorized level, and the procedures to be followed in the event that any such level is exceeded;
- (c) Make the local rules and procedures and the measures for protection and safety 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, measures for protection and safety provisions are observed;
- (e) Designate, as appropriate, a radiation protection officer in accordance with criteria established by the regulatory body.

3. Licensees and employers shall ensure that:

- (a) If necessary, 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 the basis of medical advice are capable of safely sustaining the extra effort necessary;
- (d) All personal protective equipment, including equipment for use in an emergency, is maintained in proper condition and, if appropriate, is tested at regular intervals;
- (e) If the use of personal protective equipment is considered for any given task, account is taken of any additional exposure that could result owing to the additional time taken or the inconvenience, and of any non-radiological risks that might be associated with using personal protective equipment while performing the task.

#### **Article 40: Monitoring of Workplace**

1. Licensees, in cooperation with employers if appropriate, shall establish, maintain and keep under review a programme for the monitoring at the workplace under the supervision of a radiation protection officer or qualified expert, commensurate with the graded approach.
2. The type and frequency of monitoring of workplaces shall:
  - (a) Be sufficient to enable:
    - (i) Evaluation of the radiological conditions in all workplaces;
    - (ii) Assessment of the exposure of workers in controlled areas and supervised areas;
    - (iii) Review of the classification of controlled and supervised areas;
  - (b) 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.
3. Licensees, in cooperation with employers where appropriate, shall maintain records of the findings of the workplace monitoring programme. The findings of the workplace monitoring programme shall be made available to workers, where appropriate through their representatives.
4. The programmes for monitoring of the workplace shall specify:
  - (a) The quantities to be measured;
  - (b) Where and when the measurements are to be made and at what frequency;
  - (c) The most appropriate measurement methods and procedures;
  - (d) Investigation levels and the actions to be taken if they are exceeded.

#### **Article 41: Occupational Exposure Assessment**

1. Licensees and employers shall be responsible for making arrangements for the assessment of the occupational exposure of workers, on the basis of individual monitoring where appropriate, and shall ensure that arrangements are made with appropriate or approved dosimetry service providers that operate under a quality management system.
2. For any worker who usually works in a controlled area, or who occasionally works in a controlled area and may receive a significant dose from occupational exposure, individual monitoring shall be undertaken where appropriate, adequate and feasible. In cases where individual monitoring of the worker is inappropriate, inadequate or not feasible, the occupational exposure shall be assessed on the basis of the results of workplace monitoring and information on the locations and duration of exposure of the worker.
3. For any worker who regularly works in a supervised area or who enters a controlled area only occasionally, the occupational exposure shall be assessed on the basis of the results of workplace monitoring or of individual monitoring, as appropriate.

4. Employers shall ensure that workers who could be subject to exposure due to contamination are identified, including workers who use respiratory protective equipment. Employers shall arrange for appropriate monitoring 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.

#### **Article 42: Records of Worker Exposure**

1. Employers and licensees shall maintain records of occupational exposure for each worker for whom assessment of occupational exposure is required under Article 41.

2. Records of occupational exposure for each worker shall be maintained 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) When a worker is or has been exposed while in the employ of more than one employer, information on the dates of employment with each employer 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. Employers and licensees 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;
- (e) In complying with (a)–(d) above, give due care and attention to maintaining the confidentiality of records.

5. If employers and licensees cease to conduct activities in which workers are subject to occupational exposure, they shall make arrangements for the retention of workers' records of occupational exposure by the regulatory body (*or other designated organization*) or by relevant employer or licensee.

#### **Article 43: Workers' Health Surveillance**

1. Employers and licensees, in accordance with the rules established by the regulatory body (*specify or reference them here*), 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 that is not under the control of their employer, the licensee responsible for the source shall, as a precondition for the engagement of such workers, make with the employer any special arrangements for workers' health surveillance that are needed to comply with the rules established by the regulatory body or other relevant authority.

#### **Article 44: Information, Instructions and Training**

Employers, in cooperation with licensees:

- (a) Shall 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) Shall provide those workers who could be involved in or affected by the response to an emergency with appropriate information, and adequate instruction and training and periodic retraining, for protection and safety;
- (c) Shall maintain records of the training provided to individual workers.

#### **Article 45: 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 be used as substitutes for measures for protection and safety in accordance with the requirements of these Regulations.

2. Employers 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 46: Special Arrangements for female workers and for persons under 18 years of age undergoing training**

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

- (a) The risk to the embryo or fetus due to exposure of a pregnant woman;
- (b) The importance for a female worker of notifying her employer as soon as possible if she suspects that she is pregnant or if she is breast-feeding;
- (c) The risk of health effects for a breast-fed infant due to ingestion of radioactive substances.

*Note:*

*Notification of an employer of a suspected pregnancy or of breast-feeding cannot be a requirement on a female worker in these standards. However, it is important that all female*

*workers understand the importance of making such notifications so that their working conditions may be modified accordingly.*

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

3. Employers and licensees shall ensure that no person under the age of 16 years is or could be subject to occupational exposure.

4. Employers and licensees 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 studies in which sources are used.

## **PART 7: MEDICAL EXPOSURE**

### **Article 47: General Responsibilities of Licensees**

1. Licensees shall ensure that no patient, whether symptomatic or asymptomatic, undergoes a medical exposure unless:

- (a) It is a radiological procedure that has been 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, as appropriate, 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 para. 4(a) of this Article;
- (d) The patient or the patient's legal authorized representative has been informed, as appropriate, of the expected diagnostic or therapeutic benefits of the radiological procedure as well as the radiation risks.

2. Licensees shall ensure that no individual incurs a medical exposure as part of a programme of biomedical research unless the exposure has been approved by an ethics committee (or other institutional body that has been assigned functions similar to those of an ethics committee by the relevant authority) as required in para. 5 of this Article and a radiological medical practitioner has assumed responsibility as specified in para. 4(a) of this Article. Licensees shall ensure that the requirements are met for the optimization of protection and safety for persons subject to exposure as part of a programme of biomedical research.

3. Licensees shall ensure that no individual incurs a medical exposure as a carer or comforter unless he or she has received, and has indicated an understanding of, relevant information on radiation protection and information on the radiation risks prior to providing care and comfort to an individual undergoing a radiological procedure. Licensees shall ensure

that the requirements specified in Article 54(1) are fulfilled for the optimization of protection and safety for any radiological procedure in which an individual acts as a carer or comforter.

4. Licensees shall ensure that

- (a) The radiological medical practitioner performing or overseeing the radiological procedure has assumed responsibility for ensuring overall protection and safety for patients in the planning and delivery of the medical exposure, including the justification of the radiological procedure as required in Article 48 and the optimization of protection and safety, in cooperation with the medical physicist and the medical radiation technologist;
- (b) Radiological medical practitioners, medical physicists, medical radiation technologists and other health professionals with specific duties in relation to protection and safety for patients in a given radiological procedure are specialized in the appropriate area;
- (c) Sufficient medical personnel and paramedical personnel are available as specified by the health authority;
- (d) Medical personnel and paramedical personnel are specialized in the appropriate area and meet the respective requirements for education, training and competence in radiation protection (*as specified by the regulatory body*);
- (e) The names of all medical and paramedical personnel are named in a list maintained up-to-date;
- (f) For therapeutic radiological procedures, the requirements of these Regulations for calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological equipment, as specified in Articles 50, 51(c), 53(1) and 52(2), are conducted by or under the supervision of a medical physicist;
- (g) For diagnostic radiological procedures and image guided interventional procedures, the requirements of these Standards for medical imaging, calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological equipment, as specified in Articles 50, 51(a), 51(b), 52, 53(1) and 53(2), are fulfilled by or under the oversight of or with the documented advice of a medical physicist, whose degree of involvement is determined by the complexity of the radiological procedures and the associated radiation risks;
- (h) Any delegation of responsibilities by a principal party is documented.

#### **Article 48: Justification of Medical Exposure**

1. Medical exposures shall be justified by weighing the diagnostic or therapeutic benefits that they are expected to yield against the radiation detriment that they might cause, with account taken of the benefits and the risks of available alternative techniques that do not involve medical exposure.

*Note:*

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

2. The justification of medical exposure for an individual patient shall be carried out by means of consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate, with account taken, in particular for patients who are pregnant or breast-feeding or paediatric, of:

- (a) The appropriateness of the request;
- (b) The urgency of the radiological procedure;

- (c) The characteristics of the medical exposure;
- (d) The characteristics of the individual patient;
- (e) Relevant information from the patient's previous radiological procedures.

3. Relevant national or international referral guidelines shall be taken into account for the justification of the medical exposure of an individual patient in a radiological procedure.

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

*Note:*

*Mass screening of population groups involving medical exposure is deemed to be not justified unless the expected advantages for the individuals examined or for the population as a whole are sufficient to compensate for the economic and social costs, including the radiation detriment.*

5. Any radiological procedure on an asymptomatic individual that is intended to be performed for the early detection of disease, but not as part of an approved health screening programme, shall require specific justification for that individual by the radiological medical practitioner and the referring medical practitioner, in accordance with the guidelines of relevant professional bodies or 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.

6. The exposure of volunteers as part of a programme of biomedical research is deemed to be not justified unless:

- (a) It is in accordance with the provisions of the World Medical Association Declaration of Helsinki, *Ethical Principles for Medical Research Involving Human Subjects* and follows the guidelines for its application prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the WHO, *International Ethical Guidelines for Biomedical Research Involving Human Subjects*; and
- (b) It is subject to approval by an ethics committee (or other institutional body that has been assigned functions similar to those of an ethics committee by the relevant authority), subject to any dose constraints that may be specified (as required in Article 54(2)), and subject to applicable national regulations and local regulations (*specify*).

*Note:*

*Guidance on justification of medical exposure is being developed in the draft Safety Guide DS399: Radiation Safety in Medical Uses of Ionizing Radiation.*

#### **Article 49: Optimization of Protection for Medical Exposures**

1. Licensees and radiological medical practitioners shall ensure that protection and safety is optimized for each medical exposure.

#### **Design considerations**

2. In addition to ensuring that the responsibilities stated in Article 68 (1) are discharged, as applicable, licensees, in cooperation with suppliers, shall ensure that medical radiological equipment, and software that could influence the delivery of medical exposure are used only

if they conform to the applicable standards of the International Electrotechnical Commission (IEC) and the International Organization for Standardization (ISO) or to national standards adopted by the regulatory body.

### **Operational considerations**

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

- (a) Appropriate medical radiological equipment and software and, for nuclear medicine, appropriate radiopharmaceuticals;
- (b) Appropriate techniques and parameters to deliver a medical exposure of the patient that is the minimum necessary to fulfil the clinical purpose of the radiological procedure, with account taken of relevant norms of acceptable image quality established by relevant professional bodies and of relevant diagnostic reference levels established in accordance with Article 52.

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 is kept as low as reasonably achievable consistent with delivery of the prescribed dose to the planning target volume within the 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 that for each patient the appropriate radiopharmaceutical with the appropriate activity is selected and administered so that the radioactivity is primarily localized in the organ(s) of interest, while the radioactivity in the rest of the body is kept as low as reasonably achievable.

6. Licensees shall ensure that the 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) Relatively high doses to the patient;
- (e) 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 useful radiation beam or could otherwise receive a significant dose;
- (f) Exposure of a breast-fed infant as a result of a female patient having undergone a radiological procedure with radiopharmaceuticals.

*Note:*

*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 50: Calibration**

In accordance with Articles 47(4f) and 47(4g), 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 means verification by a different, independent medical physicist using different dosimetry equipment. However, other options, such as verification by a second medical physicist or only verification using a second set of equipment, or even using a form of verification by postal thermoluminescence dosimetry could be acceptable. In checking for compliance, the regulatory body needs to be aware of the limitations on local resources.*

## **Article 51: Dosimetry of Patients**

Licensees shall ensure that dosimetry of patients 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 52: Diagnostic Reference Levels**

Licensees shall ensure that:

- (a) Local assessments, on the basis of the measurements required in Article 51, are made at approved intervals for those radiological procedures for which diagnostic reference levels have been established by *{the government, through consultation between the health authority, professional bodies and the regulatory body}*;
- (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.

*Note:*

*The government is to ensure that as a result of consultation between the health authority, relevant professional bodies and the regulatory body, a set of diagnostic reference levels is established for medical exposures incurred in medical imaging, including image guided interventional procedures. In setting such diagnostic reference levels, account shall be taken of the need for adequate image quality. Such diagnostic reference levels shall be based, as far as possible, on wide scale surveys or on published values that are appropriate for the local circumstances.*

### **Article 53: Quality Assurance for Medical Exposure**

1. Licensees 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 complex nuclear medicine facilities, radiopharmacists and radiochemists, and in conjunction with other health professionals as appropriate.
2. Licensees shall ensure that programmes of quality assurance for medical exposures include, as appropriate to the medical radiation facility:
  - (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;
    - (ii) Periodically thereafter;
    - (iii) After any major maintenance procedure that could affect protection and safety of patients;
    - (iv) After any installation of new software or modification of existing software that could affect protection and safety of patients;
  - (b) Implementation of corrective actions if measured values of the physical parameters mentioned in (a) are outside established tolerance limits;
  - (c) Verification of the appropriate physical and clinical factors used in radiological procedures;
  - (d) Maintaining records of relevant procedures and results;
  - (e) Periodic checks of the calibration and conditions of operation of dosimetry equipment and monitoring equipment.
3. Licensees shall ensure that regular and independent audits are made of the programme of quality assurance for medical exposures, and that their frequency is in accordance with the complexity of the radiological procedures being performed and the associated risks.

### **Article 54: Dose Constraints**

1. Licensees shall ensure that relevant dose constraints are used in the optimization of protection and safety in any radiological procedure in which an individual acts as a carer or comforter.
2. Licensees shall ensure that dose constraints specified or approved by the ethics committee, or by another institutional body that has been assigned functions similar to those

of an ethics committee by the relevant authority, on a case by case basis as part of a proposal for biomedical research (Article 48(6)) are used in the optimization of protection and safety for persons subject to exposure as part of a programme of biomedical research.

*Note:*

*The government is to ensure that as a result of consultation between the health authority, relevant professional bodies and the regulatory body, dose constraints are established for (i) exposures of carers and comforters and (ii) exposures due to diagnostic investigations of volunteers participating in a programme of biomedical research. The selection of constraints for carers and comforters is a complex process in which a number of factors have to be taken into account, such as the age of the individual and for a woman the possibility of her being pregnant.*

#### **Article 55: Pregnant or breast-feeding female patients**

1. Licensees shall ensure that there are arrangements in place for appropriate radiation protection in cases where a female patient is or might be pregnant or is breast-feeding.
2. Licensees shall ensure that signs in appropriate languages are placed in public places, waiting rooms for patients, cubicles and other appropriate places, and that other means of communication are also used as appropriate, to request female patients who are to undergo a radiological procedure to notify the radiological medical practitioner, medical radiation technologist or other personnel in the event that:
  - (a) She is or might be pregnant;
  - (b) She is breast-feeding and the scheduled radiological procedure includes the administration of a radiopharmaceutical.
3. Licensees shall ensure that there are procedures in place for ascertaining the pregnancy status of a female patient of reproductive capacity before the performance of any radiological procedure that could result in a significant dose to the embryo or fetus, so that this information can be considered in the justification for the radiological procedure (Article 48(1)) and in the optimization of protection and safety (Article 49(6)).
4. Licensees shall ensure that there are arrangements in place for establishing that a female patient is not currently breast-feeding before the performance of any radiological procedure involving the administration of a radiopharmaceutical that could result in a significant dose to a breast-fed infant, so that this information can be considered in the justification for the radiological procedure (Article 48(1)) and in the optimization of protection and safety (Article 49(6)).

#### **Article 56: Release of Patients after Radionuclide Therapy**

1. Licensees shall ensure that there are arrangements in place to ensure appropriate radiation protection for members of the public and for family members before a patient is released following radionuclide therapy.
2. The radiological medical practitioner shall ensure that no patient who has undergone a therapeutic radiological procedure with sealed sources or unsealed sources is discharged from a medical radiation facility until it has been established by either a medical physicist or the facility's radiation protection officer that:

- (a) The activity of radionuclides in the patient is such that doses that could be received by members of the public and family members would be in compliance with the requirements set by *{the government, through consultation between the health authority, professional bodies and the regulatory body}*;
- (b) The patient or the legal guardian of the patient is provided with:
  - (i) Written instructions for keeping doses to persons in contact with or in the vicinity of the patient as low as reasonably achievable and for avoiding the spread of contamination;
  - (ii) Information on the radiation risks.

*Note:*

*The government is 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 57: Unintended and Accidental Medical Exposures**

Licensees, in accordance with the relevant requirements of Articles 18(11), 18(12), 27, 67(2) and 99, shall ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical exposures arising from flaws in design and operational failures of medical radiological equipment, from failures of and errors in software, or as a result of human error.

### **Article 58: Investigation of Unintended and Accidental Medical Exposures**

1. Licensees shall promptly investigate any of the following unintended or accidental medical exposure:
  - (a) Any medical treatment delivered to the wrong individual or to the wrong tissue or organ of the patient, or using the wrong radiopharmaceutical, or with an activity, a dose or dose fractionation differing substantially from (over or under) the values prescribed by the radiological medical practitioner, or that could lead to unduly severe secondary effects;
  - (b) Any diagnostic radiological procedure or image guided interventional procedure in which the wrong individual or the wrong tissue or organ of the patient is subject to exposure;
  - (c) Any exposure for diagnostic purposes that is substantially greater than was intended;
  - (d) Any exposure arising from an image guided interventional procedure that is substantially greater than was intended;
  - (e) Any inadvertent exposure of the embryo or fetus in the course of performing a radiological procedure;
  - (f) Any 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 that is substantially different from what was intended.
2. Licensees shall, with regard to any unintended or accidental medical exposures investigated as required above:
  - (a) Calculate or estimate the doses received and the dose distribution within the patient;
  - (b) Indicate the corrective actions required to prevent recurrence of such an unintended or accidental exposure;
  - (c) Implement all the corrective actions that are under their own responsibility;

- (d) Produce and keep, as soon as possible after the investigation or as otherwise required by the regulatory body, a written record that states the cause of the unintended or accidental medical exposure and includes the information specified in (a) to (c) above, as relevant, and any other information as required by the regulatory body; and for significant unintended or accidental medical exposures or as otherwise required by the regulatory body, submit this written record, as soon as possible, to the regulatory body, and to the relevant health authority if appropriate;
- (e) Ensure that the appropriate radiological medical practitioner informs the referring medical practitioner and the patient or the patient's legal authorized representative of the unintended or accidental medical exposure.

#### **Article 59: Radiological Reviews**

Licensees shall ensure that radiological reviews are performed periodically by the radiological medical practitioners at the medical radiation facility, in cooperation with the medical radiation technologists and the medical physicists. 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 60: Records Related to Medical Exposures**

1. Licensees shall maintain for a period as specified by the regulatory body and shall make available, as required, the following personnel records:

- (a) Records of any delegation of responsibilities by principal parties (as required in Article 47(4h));
- (b) Records of training of personnel in radiation protection.

2. Licensees shall maintain for a period as specified by the regulatory body and shall make available, as required, the following records of calibration, dosimetry and quality assurance:

- (a) Records of the results of the calibrations and periodic checks of the relevant physical and clinical parameters selected during treatment of patients;
- (b) Records of dosimetry of patients, as required in Article 51;
- (c) Records of local assessments and reviews made with regard to diagnostic reference levels, as required in Article 52;
- (d) Records associated with the quality assurance programme, as required in Article 53(2d).

3. Licensees shall maintain for a period as specified by the regulatory body and shall make available, as required, the following records for medical exposure:

- (a) For diagnostic radiology, information necessary for retrospective assessment of doses, including the number of exposures and the duration of fluoroscopic radiological procedures;
- (b) For image guided interventional procedures, information necessary for retrospective assessment of doses, including the duration of the fluoroscopic component and the number of images acquired;
- (c) For nuclear medicine, the types of radiopharmaceutical administered and their activity;
- (d) For external beam radiation therapy or brachytherapy, a description of the planning target volume, the absorbed dose to the centre of the planning target volume, and the maximum and minimum absorbed doses delivered to the planning target volume, or

equivalent alternative information on absorbed doses to the planning target volume, and the absorbed doses to relevant tissues or organs as determined by the radiological medical practitioner; and in addition, for external beam radiation therapy, the dose fractionation and the overall treatment time;

- (e) Exposure records for volunteers subject to medical exposure as part of a programme of biomedical research;
- (f) Reports on investigations of unintended and accidental medical exposures (as required in Article 58(2d)).

## **PART 8: PUBLIC EXPOSURE**

### **Article 61: General Responsibilities**

1. Licensees 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. Licensees 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 any conditions that could affect exposure of members 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;
- (b) Good practice in the operation of similar sources or the conduct of similar practices;
- (c) Possible buildup and 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. Licensees, for sources under their responsibility, shall 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;
- (b) Measures for ensuring:
  - (i) Optimization of protection and safety;
  - (ii) Limitation of exposure of members of the public from such sources, in order that the total exposure is not higher than the dose limits for members of the public as specified in Annex II;
- (c) Measures for ensuring the safety of such sources;
- (d) Provision 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) Emergency plans, emergency procedures and emergency response arrangements, in accordance with the nature and magnitude of the radiation risks associated with the sources;
- (h) Adequate records of monitoring programmes.

#### **Article 62: Control of Visitors**

Licensees, in cooperation with employers where appropriate, shall:

- (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 that 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 a supervised area so as to provide protection and safety for visitors and other individuals who could be affected by their actions;
- (d) Ensure that 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.

#### **Article 63: Sources of External Irradiation**

Licensees shall ensure that if a source can give rise to external exposure of members of the public:

- (a) The floor plans and arrangements of equipment for all new 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 controls, are provided as appropriate for restricting public exposure, in particular at open sites such as for some applications of industrial radiography.

#### **Article 64: Contamination in Areas Accessible to Members of the Public**

Licensees shall ensure 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 that are accessible to members of the public;
- (b) Measures for protection and safety are implemented for restricting public exposure due to contamination in areas within a facility that are accessible to members of the public.

#### **Article 65: Monitoring of Public Exposure**

Licensees shall, as appropriate:

- (a) Establish and implement monitoring programmes to ensure that public exposure due to sources under their responsibility is adequately assessed and that the assessment is sufficient to verify and demonstrate compliance with the authorization. These programmes shall include monitoring of the following, as appropriate: external exposure from such sources; discharges; radioactivity in the environment, other parameters for the assessment of public exposure;
- (b) Maintain appropriate records of the results of the monitoring programmes and estimated doses to members of the public;

- (c) Report or make available the results of the monitoring programme to the regulatory body at approved intervals, including, as applicable, the levels and composition of discharges, dose rates at the site boundary and in premises open to members of the public, results of environmental monitoring and retrospective assessments made of doses to the representative person;
- (d) Report promptly to the regulatory body any levels exceeding the operational limits and conditions relating to public exposure, including authorized limits on discharges, in accordance with reporting criteria established by the regulatory body;
- (e) Report promptly to the regulatory body any significant increase in dose rate or concentrations of radionuclides in the environment that could be attributed to the authorized practice, in accordance with reporting criteria established by the regulatory body;
- (f) Establish and maintain a capability to carry out monitoring in an emergency, in the event of unexpected increases in radiation levels or concentrations of radionuclides in the environment due to accidents or other unusual events attributed to the authorized source or facility;
- (g) Verify the adequacy of the assumptions made for the assessment of public exposure and radiological environmental impacts;
- (h) Publish or make available on request, as appropriate, results from source monitoring and environmental monitoring programmes and assessments made of doses from public exposure.

*Note:*

*Article 65(a) is most frequently applicable to processing/manufacturing operations that handle bulk quantities of radionuclides and release residues in effluents to the environment.*

### **Article 66: Consumer Products**

1. Providers of consumer products shall ensure that such products are not made available to the public unless the justification of their use by members of the public has been approved by the government or regulatory body, and either their use has been exempted on the basis of the criteria specified in Article 16 or their provision to the public has been authorized.
2. Providers of consumer products, who import consumer products, as exempt products, for subsequent sale and distribution shall include in the application to the regulatory body for authorization to distribute, a copy of the exporter's or other legal persons' authorization (i.e. licence) issued by the regulatory body in the country of manufacture or origin which authorizes distribution to members of the public in that country.
3. Providers of consumer products, who import consumer products for sale and distribution as exempt products shall ensure that:
  - (a) Where practicable, a legible label is firmly affixed to a visible surface of each consumer product that:
    - (i) States that the product contains radioactive substances and identifying the radionuclides and their activities;
    - (ii) States that the provision of the product to the public has been authorized by the regulatory body;
    - (iii) Provides information about required or recommended options for recycling or disposal;
  - (b) The information specified in (a) above is printed legibly on the retail packaging of the consumer product.

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

- (a) Correct installation, use and maintenance of the product;
- (b) Servicing and repair;
- (c) The radionuclides and their activities;
- (d) Dose rates in normal operation and during servicing and repair;
- (e) Required or recommended options for recycling or disposal.

5. Providers of consumer products shall provide the product retailers with appropriate information on safety and instructions on transport and storage.

*Notes:*

- 1) *See GS-G-1.5 [9] for more detailed information about the regulation of consumer products.*
- 2) *The provider of consumer products is required to obtain an authorization from the regulatory body to provide the products to the public.*
- 3) *The regulatory body is to require, as part of the application for authorization:*
  - a) *The provider of consumer products to provide documents to demonstrate compliance with the requirements in Article 61;*
  - b) *To verify the assessments and selection of parameters presented in the application for authorization (the generic safety assessment prepared by the manufacturer and the documentation listed in paragraph 4.15 of GS-G-1.5 [9]);*
  - c) *Determine if the end use of the product can be exempted;*
- 4) *An authorization for the provision to the public of the consumer product, where appropriate, subject to specific conditions of authorization. The authorization should be granted for a certain period of time and that the manufacturer should seek re-approval after that time or when any significant change to the product is proposed.*

## **PART 9: RADIATION GENERATORS AND RADIOACTIVE SOURCES**

### **Article 67: General Responsibilities**

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

- (a) Take account of international and national standards;
- (b) Be supported by managerial and organizational features, with the purpose of ensuring protection and safety throughout the lifetime of the facility;
- (c) Include adequate safety margins in the design and construction of the facility, and in operations involving the facility, so as to ensure reliable performance in normal operation, and take account of the necessary quality, redundancy and capability for inspection, with emphasis on preventing accidents, mitigating the consequences of those accidents that do occur and restricting any possible future exposures;
- (d) Take account of relevant developments concerning technical criteria, as well as the results of any relevant research on protection and safety and feedback of information on lessons learned from experience.

2. Where applicable, licensees 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.

### **Article 68: Design of Radiation Generators and Radioactive Sources**

1. Licensees who are manufacturers or other suppliers of radiation generators and radioactive sources shall ensure that the following responsibilities are discharged, as applicable:

- (a) Supplying a well-designed, well manufactured and well-constructed radiation generator or radioactive source and device in which the radiation generator or radioactive source is used that:
  - (i) Provides for protection and safety in accordance with the requirements of these Standards;
  - (ii) Meets engineering, performance and functional specifications. *{Such equipment to conform to applicable technical standards (such as IEC and ISO – equivalent standards may be specified by the regulatory body). Standards applied in the country of origin of equipment must have the acceptance of the competent authorities}*;
  - (iii) Meets quality standards commensurate with the significance for protection and safety of systems and components, including software;
  - (iv) Provides clear displays, gauges and instructions on operating consoles in *(a language understandable to the users) (state the language here)*.
- (b) Ensuring that radiation generators and radioactive sources are tested to demonstrate compliance with the relevant specifications;
- (c) Making information available, *(state the language here)*, on the proper installation and use of the radiation generator or radioactive source and its associated radiation risks, including performance specifications, instructions for operating and maintenance, and instructions for protection and safety *{in compliance with the relevant IEC and ISO standards with regard to accompanying documents}*;
- (d) Ensuring that the protection provided by shielding and by other protective devices is optimized.

2. Licensees shall ensure that sealed sources are categorized in accordance with the categorization scheme set out in ..... *{Schedule II of GSR Part 3 [3]}*, and in accordance with the requirements of the regulatory body.

3. The manufacturer of a radioactive source or a device containing a radioactive source shall ensure that, where practicable, the source itself and its container are marked with applicable symbols.

4. Licensees, in cooperation with manufacturers, shall ensure that, where practicable, sealed sources are identifiable and traceable.

5. Licensees shall ensure that when radioactive sources are not in use they are stored in an appropriate manner for protection and safety.

6. Licensees shall ensure that arrangements are made promptly for the safe management of and control over radiation generators and radioactive sources, including appropriate financial provision, once it has been decided to take them out of use.

#### **Article 69: Supply and Procurement of Radioactive Sources**

1. Licensees who supply or distribute radioactive sources shall ensure that those persons to whom the sources are being supplied are authorized to receive the sources.

2. Before purchasing, or otherwise acquiring, radioactive sources, licensees shall:

- (a) Make arrangements are made for the safe management of the source(s) including financial provisions where appropriate once they have become disused;
- (b) Submit to the regulatory body details of those arrangements, including copies of any contractual arrangements.

*Note:*

*Returning sources to the original supplier is often the best option from the safety perspective, and this could be included in the contract when initially purchasing a source.*

3. Licensees supplying radioactive sources or devices incorporating radioactive sources shall provide the recipient with all relevant technical information to permit their safe management.

### **PART 10: IMPORT AND EXPORT OF CATEGORY 1 AND 2 RADIOACTIVE SOURCES**

#### **Article 70: Export of Category 1 or 2 Radioactive Sources**

1. Licensees intending to export Category 1 or 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 and 2 radioactive sources is provided in reference [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 radionuclides and radioactivity;
- (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 ..... {reference [5]}, if applicable.

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 transport requirements of the IAEA Regulations for the Safe Transport of Radioactive Material [27]; and
  - (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 radioactivity;
    - (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 should 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 should provide a copy of the notification to the exporting State.*

#### **Article 71: Import of Category 1 or 2 Radioactive Sources**

1. Licensees intending to import Category 1 or 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 reference [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 radionuclides and radioactivity;
- (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, including copies of any contractual agreements;
- (h) Justification or explanation of any need to use the ‘exceptional circumstances’ provisions in ..... {reference [5]}, 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 applicable transport requirements of the IAEA Regulations for the Safe Transport of Radioactive Material [27].

## **PART 11: RESPONSIBILITIES ASSOCIATED WITH THE PREDISPOSAL MANAGEMENT OF RADIOACTIVE WASTE**

### **Article 72: General Licensee Responsibilities**

1. The licensee shall be responsible for the safety of predisposal waste management facilities or activities. 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 radioactive waste management 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) Establishment and maintenance of a mechanism to provide and ensure adequate financial resources to discharge its responsibilities;
- (h) Derivation of operational limits, conditions and controls, including waste acceptance criteria, to assist with ensuring that the predisposal radioactive waste management facility is operated in accordance with the safety case;
- (i) Ensure that generation of radioactive waste is kept to the minimum practicable and that radioactive waste is managed by appropriate classification, segregation, treatment, conditioning, storage and disposal;
- (j) Ensure that there are no unavoidable delays in processing waste and transferring to the next step as soon as practicable;
- (k) Use relevant international experience to ensure operations are as safe as practicable.

*Notes:*

- 1) *The licensee may delegate any work associated with the aforementioned responsibilities to other organizations but shall retain overall responsibility and control.*
- 2) *The licensee may use cost-benefit arguments to justify its proposed program, as long as safety limits are respected.*

2. Licensees shall be responsible for the safe management of the radioactive waste generated by the practices or sources for which they are authorized and shall take all necessary measures to ensure that:

- (a) Generation of the activity and volume of radioactive waste are kept to the minimum practicable by suitable design, operation and decommissioning of its facilities;
- (b) Radioactive waste is managed by appropriate classification, segregation, treatment, conditioning, storage and disposal, and maintaining records of such activities;
- (c) Disposal of radioactive waste is not unnecessarily delayed;
- (d) Reporting is made to the regulatory body of required information at intervals as may be specified in the license, including those related to the changes of ownership of waste.

### **Article 73: Licence Applications**

1. No person or organization shall generate, keep or manage radioactive waste except in accordance with a licence issued by the regulatory body under the terms of Article 17 of these Regulations.

2. An application for licence shall address all elements of management of radioactive waste for which a licence is being sought. Typical elements are:

- (a) Waste generation ;
- (b) Predisposal;
- (c) Pretreatment;
- (d) Characterization;
- (e) Treatment ;
- (f) Conditioning;
- (g) Storage;
- (h) Control of discharges;
- (i) Clearance;
- (j) Packaging strategies;
- (k) Transport;
- (l) Design and manufacture of containers;
- (m) Handling of waste packages;
- (n) Site evaluation, design, construction, operation, closure and the post-closure stage of a waste management facility.

3. An application for a licence shall include a safety case and supporting safety and environmental assessments. 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.

4. The safety case shall be prepared by the applicant (operating organization) early in the development of a facility as a basis for the process of regulatory decision making and approval. The safety case has to be progressively developed and refined as the project proceeds. Such an approach ensures the quality of the technical programme and the associated decision making. It is the operating organization's responsibility to compile the safety assessment as part of the safety case in accordance with the requirements of the regulatory body.

5. 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 the 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 regulatory requirements will be met.

6. 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 address operational safety and all safety aspects of the facility and activities.

7. The safety case shall include considerations for reducing hazards posed to workers, members of the public and the environment during normal operation and in possible accident conditions.

8. 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 the 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 information that is traceable.

9. Licensees shall carry out periodic safety reviews and shall implement any safety upgrades required by the regulatory body following this review. The results of the periodic safety review shall be reflected in the updated version of the safety case for the facility.

10. The safety assessment and the management systems within which it is conducted have to be periodically reviewed at predefined intervals in accordance with regulatory requirements. In addition to such predefined periodic reviews, the safety assessment has to be reviewed and updated:

- (a) When there is any significant change that may affect the safety of the facility or activity;
- (b) When there are significant developments in knowledge and understanding (such as developments arising from research or operational experience feedback);
- (c) When there is an emerging safety issue owing to a regulatory concern or an incident;
- (d) When there have been significant improvements in assessment techniques such as computer codes or input data used in the safety analysis.

*Notes:*

- 1) *The requirements governing the authorization process for radioactive waste management should be established in a regulation or law.*
- 2) *Clear guidance should be provided on regulatory requirements for all relevant aspects of radioactive waste management. The guidance should outline all elements to be addressed in applications and indicate the level of detail required.*
- 3) *When establishing and applying regulatory requirements, the level of hazard should dictate the level of information and oversight required (i.e. a graded regulatory approach should be used). For example, authorization in the form of registration may be sufficient for many small storage operations. In more complex situations, more extensive information and review will be required.*
- 4) *For complex operations, consideration should be given to adopting a staged approval. For example, a safety case and supporting safety assessments may be prepared and updated by the licensee, as necessary, at each step, for example, during the siting, design, construction, commissioning, operation, modification and decommissioning of the radioactive waste predisposal management facility.*
- 5) *Wherever practical, waste management practices should be covered by the authorization for the operation or facility which gives rise to the waste. For example, management of radioactive waste at a nuclear medicine operation could be included in the authorization to conduct nuclear medicine activities.*
- 6) *The regulatory body may choose to use the services of external organizations or experts to review specific aspects of requests for authorization. However, the regulatory body should have sufficient expertise and authority to take all final decisions in the authorization process.*
- 7) *Prior to issuing any authorization the regulatory body should be sure that the adequate financial mechanism is in place to cover the full costs of the safe management of the radioactive waste according to the National Policy and Strategy.*
- 8) *An application for a license should include assessments which :*
  - a) *analyze and demonstrate the radiological and non-radiological safety under normal operation and also to assess the potential effects of incidents and accidents, according to national regulations. Such assessments should make use of appropriate*

- modeling methods and data from available experience. The assessments should demonstrate, where necessary, long term safety;*
- b) cover all stages and aspects of the radioactive waste management process, in relation to the workers, the public and the environment. These assessments should be based on the design of the facility and the process description.*
- 9) Requirements for safety assessment are set out in GSR Part 4 [26]. General recommendations on the development of a safety assessment for radioactive waste management practices are provided in WS-G-1.1 [28], WS-G 2.7 [15], WS-G-6.1 [29], WS-G-2.5 [16] and WS-G-5.2 [30].

#### **Article 74: Management system for management of radioactive waste**

1. The licensee shall establish and implement a management system. The management system shall be commensurate with the hazard of the waste management activities and shall be approved by the regulatory body. The management system shall contain at least the following elements:

- (a) Policies and procedures that identify safety as being of the highest priority.
- (b) Clear lines of authority for decisions on safety and compliance with procedures and processes.
- (c) Organizational arrangements and lines of communications that result in an appropriate flow of information on safety at and between the various levels in the entire organization of the licensee.
- (d) Clear specification of safety responsibilities for each individual.
- (e) Responsibilities for compliance with program requirements.
- (f) Clear requirement that problems affecting safety must be promptly identified and corrected in a manner to commensurate with their importance.
- (g) Provision that each individual is suitably trained and qualified.
- (h) A quality assurance program that provides information on the performance of the radioactive waste management program and equipment and establishes a review regime of the program. This program shall ensure that all necessary records are maintained and are readily retrievable when required.
- (i) Provisions to ensure that the confidentiality of information that is received in confidence from another party is protected, and only provided to a third party with the consent of the first party.

2. The management system shall provide

- (a) Adequate assurance that the established requirements for safety and environmental protection are being met.
- (b) Assurance that the components of the safety systems are quality sufficient for their tasks.

3. The licensee shall promote and maintain a strong safety culture.

*Notes:*

- 1) *The regulatory body should make sure that the operator establishes a robust management system. Requirements and guidance for the management system can be found in GS-R-3[31], GS-G-3.3 [32] and GS-G-3.4[33].*
- 2) *The effectiveness of the management system for radioactive waste should be verified on regular basis through independent auditing by experts in management systems.*

## **Article 75: Appointment of Radioactive Waste Management Officer**

Licensees shall appoint, if necessary and when required by the regulatory body, a technically competent person with the appropriate independence and authority to be a Radioactive Waste Management Officer in order to assist licensees in the safe and efficient on-site management of radioactive waste.

*Notes:*

*In discharging his or her duties, the Radioactive Waste Management Officer will need to:*

- 1) Make and maintain contact with all relevant persons involved with radioactive waste to provide an authoritative point of advice and guidance;*
- 2) Liaise as needed with the Radiation Protection Officer and with other radioactive waste management organizations;*
- 3) Establish and maintain a detailed record-keeping system for all stages of radioactive waste management, including the inventory of radioactive waste;*
- 4) Ensure proper radioactive waste conditioning;*
- 5) Ensure that on-site transfer of radioactive waste is carried out in accordance with written safety procedures;*
- 6) Ensure that waste packages for off-site transportation are prepared to be in compliance with transport regulations;*
- 7) Obtain approval from the regulatory body for the transport of radioactive waste;*
- 8) Ensure appropriate shielding, labelling, physical security and integrity of waste packages;*
- 9) Ensure that any discharge of effluents is made below the limits authorized by the regulatory body;*
- 10) Ensure that solid waste disposed of at a municipal landfill is in accordance with clearance levels established by the regulatory body;*
- 11) Report on accidents and inappropriate waste management practices to the licensees' management;*
- 12) Maintain an up-to-date knowledge of the characteristics of discharge and disposal options.*

## **Article 76: Radioactive Waste Records and Reports**

1. 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 shall allow for traceability of radioactive waste from the point of its collection through to its long term storage and its disposal.

2. All records related to radioactive waste inventory (including disused 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.

3. When waste is being transferred, associated records shall be provided to the licensee of the subsequent step.

4. The licensee shall provide reports on its radioactive waste management activities to the regulatory body, as specified by the regulatory body.

Notes:

- 1) *In this regard the regulatory body should define the timing, scope and content of:*
  - a) *Periodic reports to be submitted by the licensee;*
  - b) *Reports describing any non-compliance with safety requirements or unplanned situations.*
- 2) *A waste characterization record should contain at least the following information pertaining to the waste:*
  - a) *The source or origin;*
  - b) *The physical and chemical form;*
  - c) *The amount (volume and/or mass);*
  - d) *The radiological characteristics (the activity concentration, the total activity, the radionuclides present and their relative proportions);*
  - e) *The classification in accordance with the national waste classification system;*
  - f) *Any chemical, pathogenic or other hazards associated with the waste and the concentrations of hazardous material;*
  - g) *Any special handling necessary owing to criticality concerns, the need for the removal of decay heat or significantly elevated radiation fields.*
- 3) *The licensee of a facility generating radioactive waste, in order to ensure the proper control under waste management activities, should maintain records for:*
  - a) *Generated radioactive waste (date of generation, waste characteristics, etc.);*
  - b) *Stored radioactive waste (including identification, origin, location, physical and chemical characteristics);*
  - c) *Material from which regulatory control has been removed or that has been discharged to the environment (including data related to the process);*
  - d) *Spent and/or disused radiation sources returned to suppliers;*
  - e) *Radioactive waste and disused sources transferred to management waste facility or another user;*
  - f) *Non-compliances and action taken in response.*
- 4) *These records should be used to report to the regulatory body.*
- 5) *In case of processing and storage facilities for radioactive waste the records concerning waste management activities should include:*
  - a) *The data of waste and disused sources collected or received from generating facilities;*
  - b) *The data needed for a national inventory of waste;*
  - c) *The data needed for waste characterization;*
  - d) *The records from the control processes for treatment, packaging and conditioning;*
  - e) *The documents on the procurement of containers required to provide confinement for a certain period (e.g. in a repository);*
  - f) *The specifications for waste packages and audit records for individual containers and packages;*
  - g) *Trends in operating performance;*
  - h) *Non-compliances with the specifications for waste packages and the actions taken to rectify them;*
  - i) *Discharges.*

**Article 77: Interdependencies in the predisposal management of radioactive waste**

1. Licensees shall take into account, as appropriate, interdependencies among all steps in the predisposal management of radioactive waste, as well as the impact of the anticipated disposal option.

2. It is necessary that those persons responsible for a particular step in the predisposal management of radioactive waste, or for an operation in which waste is generated, adequately recognize these interactions and relationships so that the safety and the effectiveness of the predisposal management of radioactive waste may be considered in an integrated manner. This includes taking into account the identification of waste streams, the characterization of waste, and the implications of transporting and disposing of waste.

3. In considering possible options for the processing of waste, care has to be taken to avoid conflicting demands that might compromise safety. It is not consistent with an integrated approach to optimize one step in the predisposal management of radioactive waste in such a way that it imposes significant constraints on the subsequent steps or forecloses viable options.

### **Article 78: Emergency Preparedness**

1. Licensees shall ensure that their emergency plans include arrangements for their radioactive waste management activities and inventory. The effectiveness of the plans shall be verified to the satisfaction of the regulatory body.

2. Licensees shall ensure that the emergency plans define on-site responsibilities and take account of off-site responsibilities of other intervening organizations appropriate for implementation of the emergency plan. Such emergency plans shall, as appropriate:

- (a) Characterize the content, features and extent of a potential emergency taking into account the results of any accident analysis and any lessons learned from operating experience and from accidents that have occurred with sources of a similar type;
- (b) Identify the various operating and other conditions of radioactive waste inventory which could lead to the need for intervention;
- (c) Describe the methods and instruments for assessing the accident and its consequences on and off the site;
- (d) Provide for protective actions and mitigation actions, and assignment of responsibilities for initiating and discharging such actions;
- (e) Provide for rapid and continuous assessment of the accident as it proceeds and determining the need for protective actions;
- (f) Allocate responsibilities for notifying the relevant authorities and for initiating intervention;
- (g) Provide procedures, including communication arrangements for contacting any relevant intervening organization (e.g. civil defence) and for obtaining assistance from fire-fighting, medical, police and other relevant organizations;
- (h) Provide for training personnel involved in implementing emergency plans and be rehearsed at suitable intervals;
- (i) Provide for periodic review and updating of the plan.

*Note:*

*Requirements for emergency preparedness and response are set out in GS-R-2 [34]. Guidance applying the requirements is provided in GS-G-2.1 [35] and GSG-2 [36].*

### **Article 79: Physical Protection and Security**

The licensee shall adopt appropriate measures to ensure the physical protection and security at waste management facilities to prevent the unauthorized access of individuals and the unauthorized removal of radioactive materials.

## **Article 80: Nuclear safeguards**

The licensee shall consider nuclear safeguards requirements in the design and the operation of waste management facilities to which nuclear safeguards apply. These requirements shall be implemented in such a way as not to compromise the safety of the facility.

## **PART 12: STEPS IN THE PREDISPOSAL MANAGEMENT OF RADIOACTIVE WASTE**

### **Article 81: Control of Radioactive Waste Generation**

1. 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) 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;
- (b) Applying to the extent possible the reuse and recycling of materials;
- (c) 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;
- (d) Minimizing the activity and volume of waste by using the minimum quantity of radioactive material needed;
- (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;
- (h) Maintaining consistency with the radioactive management policy and strategy.

#### *Notes:*

- 1) *The licensee, in order to keep the generation of radioactive waste to the minimum and in addition to the above mentioned requirements, should adopt provisions such as:*
  - a) *Careful control of the collecting, segregating, packaging and handling of radioactive materials;*
  - b) *Adopting good segregation practices, including clearance of materials, at point of waste generation;*
  - c) *Efficient operation of collecting and processing systems for gaseous and liquid radioactive waste;*
  - d) *Taking precautions to avoid the contamination of materials, equipment and building surfaces in order to reduce the need of decontamination;*
  - e) *Restrictions on taking packaging and other unnecessary material into the controlled area;*
  - f) *Planning and performing periodical surface monitoring and maintenance work with due care and with particular emphasis on precautions to avoid the spread of contamination;*
  - g) *Creating and maintaining proper record system that would allow the periodical assessment of the effectiveness of measures adopted to minimize radioactive wastes*

- generation. The system should include the definition of measurable indicators to assess the effectiveness of the applied system.*
- 2) *The regulatory body should require the licensee to submit, as part of the authorization process, specific comprehensive information on the provision adopted to ensure the waste minimization.*
  - 3) *The regulatory body should define clearance levels and the requirements for its implementation as well as the criteria for the authorization of discharges and their impact evaluation to the environment and selected individuals.*
  - 4) *The IAEA safety publications RS-G-1.7 [23] and SRS-44 [38] provide specific guidance on the establishment and application of clearance levels.*

## **Article 82: Radioactive Waste Characterization and Classification**

1. The licensee shall characterize radioactive waste in terms of its physical, mechanical, chemical, radiological and biological properties. The characterization serves to provide information relevant to process control and assurance that the waste or waste package will meet the acceptance criteria for processing, storage, transport and disposal of the waste. The relevant characteristics of the waste shall be recorded to facilitate its further management.
2. The licensee shall classify radioactive waste under its responsibility in accordance with the national radioactive waste classification scheme.

### *Notes:*

- 1) *The regulatory body should promote the establishment of a national waste classification scheme. This should be done in consultation with the government, the waste generators and the management facilities and in conformity with the national policy and strategy for radioactive waste management. Such scheme should be based on long-term safety considerations, in particular the safety aspect of the disposal of radioactive waste. The scheme should be applicable to all types of radioactive waste in the country.*
- 2) *Classification systems for radioactive waste may be considered from different points of view, such as safety related aspects, process engineering demand or regulatory issues. A classification of radioactive waste may be useful at any stage between generation of the raw waste and its conditioning, storage, transportation and disposal. To satisfy all the needs that a classification system will serve, it should meet a number of objectives, including the following that cover the full range of types of radioactive waste:*
  - a) *To address all stages of radioactive waste management;*
  - b) *To relate classes of radioactive waste to the associated potential hazard;*
  - c) *To be flexible to serve specific needs;*
  - d) *To modify as little as possible already accepted terminology;*
  - e) *To be simple and easy to understand;*
  - f) *To be as universally applicable as possible.*
- 3) *Typical characteristics used for classification of radioactive waste are:*
  - a) *Non-radioactive and radioactive materials;*
  - b) *Half-life of radionuclides present: short lived radionuclides (for example, half-lives not exceeding 100 d) suitable for decay storage or long lived radionuclides (for example, half-lives exceeding 30 y);*
  - c) *Activity and radionuclide content;*
  - d) *Physical and chemical form:*
    - (i) *Liquid: aqueous; organic;*
    - (ii) *Non-homogeneous (e.g. containing sludge or suspended solids);*
    - (iii) *Solid: combustible/non-combustible; compactable/non-compactable; metallic or non-metallic.*

- e) *Fixed or non-fixed surface contamination;*
  - f) *Spent sealed sources;*
  - g) *Non-radiological hazards characteristics (e.g. chemical and biological toxicity).*
- 4) *The IAEA safety guide GSG-1 [37] sets out a general scheme for classifying radioactive waste.*

### **Article 83: Acceptance Criteria for Radioactive Waste**

1. The interdependence among the steps in the management of radioactive waste shall be considered for achieving continuity in operations and consistency of the entire waste management process.
2. The licensee of a particular waste predisposal management step or disposal facility shall define its own waste acceptance criteria bearing in mind the criteria established for other steps within the waste management process. Each criterion established by the licensee of a facility shall be submitted to the regulatory body for review, assessment and approval as part of the safety case.
3. The waste acceptance criteria defined for each step of the waste management process shall specify the characteristics of waste packages and unpackaged waste, under normal and abnormal conditions, to be processed, stored or disposed of in that step.
4. The licensee shall ensure that an appropriate control system is established to provide confidence that the waste under its responsibility meets the applicable waste acceptance criteria.
5. The licensee shall ensure that radioactive waste to be transferred to other installations or waste management steps meets the waste acceptance criteria established by the licensee of the subsequent step.
6. The licensees' procedures for the reception of waste shall contain provisions for safely managing waste that fails to meet the acceptance criteria; for example, by taking remedial actions or by returning the waste.

#### *Notes:*

- 1) *The waste acceptance criteria should consider the required radiological, mechanical, physical, chemical and biological properties of the waste and of any package.*
- 2) *Some elements of the waste acceptance criteria are:*
  - a) *The stability of the waste form with respect to mechanical, chemical, structural, radiological and biological characteristics;*
  - b) *The maximum content of liquids;*
  - c) *Limitations on activity (for example, activity per package);*
  - d) *Potential for criticality;*
  - e) *The extent to which the waste should be non-pyrophoric, non-explosive or non-reactive;*
  - f) *Possibility of generation of toxic gases;*
- 3) *GSR Part 5 [6] sets out the requirements for acceptance criteria for radioactive waste. WS-G-2.5 [16] and WS-G-6.1 [29] provide specific guidance on the development and use of waste acceptance criteria.*
- 4) *The regulatory body should verify the overall consistency of all waste acceptance criteria developed in support of the implementation of the national waste management strategy, in order to ensure adequate waste management process continuity and safety.*

## **Article 84: Processing of radioactive waste from collection up to treatment**

1. 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, shall be processed as radioactive waste.
2. Licensees shall ensure that waste is collected, characterized and segregated, at the point of origin in accordance with:
  - (a) Established criteria;
  - (b) A defined waste management strategy;
  - (c) The waste acceptance criteria defined for the next step in the waste management process.
3. Licensees shall ensure that waste is rendered into a safe and passive form for storage or disposal as soon as possible. The processing of waste may yield effluent that is suitable for authorized discharge, or material that is suitable for authorized use or clearance from regulatory control.
4. Licensees shall ensure that waste is processed in such a way that the safety of the operations is appropriately ensured during normal operations, that measures are taken to prevent the occurrence of incidents or accidents, and that provisions are made to mitigate the consequences if accidents occur.
5. Licensees shall ensure that the processing of radioactive waste is consistent with the type of waste, the possible need for its storage, the anticipated disposal option, and the limits, conditions and controls established in the safety case and in the assessment of environmental impacts.
6. Licensees shall ensure that radioactive waste is processed in such a way that the resulting waste form can be safely stored and retrieved from the storage facility until its ultimate disposal.
7. Licensees shall establish provisions for identifying, assessing and dealing with waste and/or waste packages that do not meet process specifications and requirements for its and/or their safe handling, transport, storage and/or disposal.
8. Consideration has to be given to the consequences of dealing with any secondary waste (both radioactive and non-radioactive) that is created during processing.

### *Notes:*

- 1) *Segregation of radioactive waste should be performed according to a categorization scheme to allow for safe and adequate accomplishment of further predisposal steps.*
- 2) *Waste containers should be properly identified and labelled so that the required information will be available at all stages of the waste management. The information should be sufficient to ensure the effectiveness and safety of the next step in the management process. It should include:*
  - a) *Identification number;*
  - b) *Radionuclides;*
  - c) *Activity (if measured or estimated)/date of measurement;*
  - d) *Origin (room, laboratory, individual, etc. if applicable);*
  - e) *A radiation trefoil;*
  - f) *Potential/actual hazards (chemical, infectious, etc.);*

- g) *Surface dose rate/date of measurement;*
  - h) *Quantity (weight or volume).*
- 3) *During the waste collection phase the licensee should ensure that:*
    - a) *Containers for solid wastes should be lined with a durable plastic bag that can be sealed (tied with plastic adhesive tape, heat-sealed with a radio-frequency welder);*
    - b) *Sharps should be collected separately and stored in rigid, puncture-resistant containers (preferably metal) that have been clearly labelled 'sharps';*
    - c) *Damp solid waste and liquid waste should be collected in suitable containers according to the chemical and radiological characteristics, volume of the waste, handling and storage requirements. Normally double packaging is used;*
    - d) *Disused sealed sources should be kept in their shielding;*
    - e) *Containers should be checked for radioactive contamination and loose contamination should be removed before reuse.*
  - 4) *Where necessary to adjust the characteristics of the collected radioactive waste, it should be done based upon appropriate consideration of the characteristics of the waste, of the requirements imposed by subsequent steps and through formally approved operating instructions.*
  - 5) *The treatment of waste may be necessary for safety, technical or financial reasons. Whenever necessary, carry out any waste treatment process, the licensee shall ensure that:*
    - a) *The waste is processed only after its precise characterization.*
    - b) *The methods for waste treatment are selected on the basis of the waste characteristics and taking into account the generation of secondary radioactive waste.*
  - 6) *The pretreatment processes of radioactive waste may include physical or chemical adjustment to make the waste less hazardous or more amenable to further processing.*
  - 7) *The treatment processes of radioactive waste may include:*
    - a) *The reduction in volume of the waste (by incineration of combustible waste, compaction of solid waste and segmentation or disassembly of bulky waste components or equipment);*
    - b) *The removal of radionuclides (by evaporation or ion exchange for liquid waste streams and filtration of gaseous waste streams);*
    - c) *Change of form or composition (by chemical processes such as precipitation, flocculation and acid digestion as well as chemical and thermal oxidation).*
  - 8) *The regulatory body should establish requirements and criteria pertaining to the safety of all processes and operations encompassed in the predisposal management of radioactive waste.*

### **Article 85: Conditioning<sup>5</sup>**

1. In selecting a conditioning process, the licensee shall consider the following aspects:
  - (a) Whether safety would be improved from the use of a matrix material;
  - (b) Compatibility of the radioactive waste with the selected materials and processes;
  - (c) The minimization of the generation of secondary radioactive waste.

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<sup>5</sup> Those operations that produce a waste package suitable for handling, transport, storage and/or disposal. Conditioning may include the conversion of the waste to a solid waste form, enclosure of the waste in containers and, if necessary, provision of an overpack. (IAEA Safety Glossary, 2007 Edition) [39]

2. Licensees shall ensure that the waste packages are designed and produced so that radionuclides are confined under both normal conditions and accident conditions that may occur during handling, storage, and disposal.

3. Licensees shall ensure that each package of conditioned waste is provided with a durable label bearing the identification number and relevant information and that a proper record of each package is kept under the management system.

*Notes:*

- 1) *The regulatory body should be aware that other regulatory organizations e.g. those responsible for transport, may be involved in the transfer of radioactive waste to a subsequent management step. Timely liaison with these organizations should be considered in order to avoid unnecessary delays and duplication of process.*
- 2) *The conditioning processes should include provision to ensure the maximum homogeneity and stability of the waste form; minimum free space in the container; low leachability, and maximum container durability.*
- 3) *Guidance concerning the specifications of waste packages is provided in WS-G-6.1 [29].*
- 4) *Since the waste packages may be used for a long time, quality control of the conditioning process and produced wastes packages is a key aspect to be considered by the licensee. The quality control should include, but is not limited to:*
  - a) *The definition of quality standards applying to waste packages;*
  - b) *An unambiguous definition of quality indicators for the conditioning processes as well as for the final packages. The quality indicators should demonstrate that the packages meet specified requirements and acceptance criteria;*
  - c) *The development of a testing program to verify the performance of the packages;*
  - d) *Appropriate record keeping;*
  - e) *Making available technical support for radiological and non-radiological measurements and procedures.*
- 5) *Each conditioned waste package should be provided with a durable label bearing the identification number, and a proper record of each waste package should be kept under the management system. All records should be securely stored, easily accessible and retrievable over an extended period. Information should include as a minimum for each individual package:*
  - a) *Origin of the waste;*
  - b) *Identification number of the package;*
  - c) *Type and design details of the package and unloading documentation;*
  - d) *Weight of the package;*
  - e) *External size and/or volume of the package;*
  - f) *Maximum dose rate at contact and 1 m (transport index) and date of measurement;*
  - g) *Results of surface contamination measurement;*
  - h) *Radionuclide content and activity content;*
  - i) *Content of fissile material (such as 239 Pu–Be sources);*
  - j) *Physical nature;*
  - k) *Presence of potential biological, chemical and other hazards.*

#### **Article 86: Storage of Radioactive Waste**

1. Prior to generating radioactive waste that may require subsequent management, licensees shall ensure the availability of an appropriate storage facility within their own organization, or in another authorized facility.

2. Licensees shall follow the national policy and strategy for radioactive waste when they define the arrangements for the storage of radioactive waste.
3. Licensees shall have arrangements in place to verify that the radioactive waste, collected or received in the storage facility under its responsibility, meets the acceptance criteria approved by the regulatory body in the safety case for this facility.
4. In case the waste or sources to be stored do not meet the acceptance criteria, the licensee shall establish provisions which compensate for the non-compliance or refuse the transfer.
5. The licensee shall adopt provisions to ensure that radioactive waste and disused sealed sources will be stored in such containers, packages and facilities that meet the requirements approved by the regulatory body in the safety case.
6. Radioactive waste shall be stored in a manner that ensures proper segregation, and protection of the workers, the public and the environment, and enables its subsequent inspection, monitoring, retrieval and preservation in a condition suitable for movement, handling, transport or disposal. Full traceability of the waste packages by means of record keeping and adequate labelling should be maintained during the different stages of storage.
7. In defining criteria for acceptance of waste packages in a storage facility, the licensee shall take account of the known or likely requirements for subsequent disposal of the radioactive waste.
8. The licensee shall ensure that the integrity of waste packages in storage is maintained until it is retrieved for further treatment, conditioning or disposal.
9. The licensee shall ensure that the waste package container provides integrity throughout the storage period and permits:
  - (a) Retrieval at the end of the storage period;
  - (b) Enclosure in an overpack, if necessary;
  - (c) Transport to and handling at a disposal facility;
  - (d) Compliance with relevant waste acceptance criteria
10. If according to the national policy and strategy for radioactive waste that radioactive waste is to be stored in a centralized storage facility, licensees shall adopt provisions to ensure the prompt transfer of radioactive waste and disused sources to that facility.
11. The adequacy of the storage capacity has to be periodically reviewed, with account taken of the predicted waste arisings, both from normal operation and from possible incidents, of the expected lifetime of the storage facility and of the availability of disposal options.

*Notes:*

- 1) *Storage is by definition an interim measure, but it can last for several decades. The intention in storing waste is that the waste can be retrieved for clearance, processing and/or disposal at a later time, or, in the case of effluent, for authorized discharge*
- 2) *Typical provisions are:*
  - a) *The radioactive waste containing only radionuclides of very short half-life with activity concentrations above the clearance levels can be stored in the facility of the*

- generating institution, until the activity has fallen below the levels for clearance, allowing for the cleared waste to be managed as conventional waste;*
- b) The radioactive waste containing radionuclides with half-life greater than 100 days and the declared disused radioactive sources should be stored in a centralized storage facility.*
  - 3) For more specific and performance type requirements use the WS-G-6.1 [29].*
  - 4) The licensee should also consider, in addition to the above requirements that the waste should be stored in a way that ensures:*
    - a) Separation of treated and conditioned radioactive waste from unconditioned waste, non-radioactive materials and maintenance equipment;*
    - b) That consideration is given to the assignment of a separate storage area, when biomedical radioactive waste is produced in large volumes.*

### **Article 87: Management of Disused Radioactive Sources**

1. Licensees shall review their radioactive source inventory at least annually to identify any sources that have become disused. Disused sources shall be included on the inventory of radioactive material. The licensee has the responsibility to meet any regulatory requirements for reporting disused sources.
2. Before declaring disused radioactive source as a radioactive waste the licensee shall first attempt to return the source to its supplier.
3. Once the radioactive sources have become disused, the licensee shall ensure the maintenance of continuity of control. Licensees shall periodically review the status of control of such sources.
4. Unless the authorization allows otherwise, the licensee shall make arrangements for the prompt transfer of any disused radioactive sources to a centralized or otherwise authorized radioactive waste management facility.

#### *Notes:*

- 1) The regulatory body should pay attention to situation involving disused sealed sources, which cannot be returned to the supplier or manufacturer. Such sources may require subsequent management such as conditioning for which the licensee is neither qualified nor licensed. While not strictly a responsibility of the regulatory body, it could be helpful if the regulatory body gives consideration to the assignment and authorization of an appropriate organization, which is better equipped to safely conduct the necessary management operations.*
- 2) In instances where the licensee does not have either the facilities or the expertise for the conditioning of spent and disused sealed sources or adequate storage facilities, arrangements shall be made to transfer the sources to another licensed organization with proper and adequate facilities.*
- 3) The following aspects should be considered, to promote the safe management of disused sealed sources:*
  - a) Return to the manufacturer or supplier;*
  - b) Further authorized use by some other authorized organization, when the source complies with the requirements for its safe use;*
  - c) Temporary storage in its original shielding (for example for radionuclides with half-lives of less than 100 days);*
  - d) Conditioning (for example overpacking);*

- e) *Transfer to a licensed, interim or long-term storage facility;*
- f) *Safe Disposal in accordance with national regulation.*
- 4) *The following aspects should be considered in respect of the management of disused sealed sources:*
  - a) *Disused sealed sources with high potential hazard should be segregated and stored separately. For sources (such as radium sources) with a potential for leaking, particular radiological precautions should also be taken during the handling and storage;*
  - b) *Special attention should be paid to monitoring the surface and the air for contamination. These sources should be stored in a dedicated area with appropriate ventilation and equipment;*
  - c) *Disused sealed sources should be conditioned if that will improve safety, unless the half-life of the radionuclides they contain is short enough to permit their removal from regulatory control. Conditioning methods that may be used should be approved by the regulatory body;*
  - d) *Procedures should be established to ensure that disused sealed sources are not subjected to compaction, shredding or incineration;*
  - e) *Special attention should be given to measures aimed to ensure that control of disused sources is maintained in order to prevent that the sources get lost.*

#### **Article 88: 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 shall ensure compliance with national regulations (see Article 69).

*Notes:*

- 1) *The applicant for a radioactive waste management license should demonstrate that the option of reuse and recycling of radioactive material has been considered.*
- 2) *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.*
- 3) *The licensee should adopt provisions for possible reuse and recycling of materials as part of the radioactive waste management programme, whenever feasible.*
- 4) *Recycling and reuse often involves transfer of equipment and materials from one organization to another. Such transfer of any radioactive materials should be carried out according to the national radiation safety legislation and regulation. In this case the licensee should ensure 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 IAEA-TECDOC-1130 [40].*

#### **Article 89: Discharge of Radioactive Materials to the Environment**

1. Before initiating the discharge to the environment, licensees in applying for an authorization for discharges:

- (a) Shall determine the characteristics and activity of the material to be discharged, and the possible points and methods of discharge;
  - (b) Shall determine by an appropriate pre-operational study all significant exposure pathways by which discharged radionuclides could give rise to exposure of members of the public;
  - (c) Shall assess doses to the representative person due to the planned discharges;
  - (d) Shall consider the radiological environmental impacts in an integrated manner with features of the system of protection and safety, as required by the regulatory body;
  - (e) Shall submit to the regulatory body the findings of (a) to (d) above as an input to the establishment by the regulatory body of authorized limits on discharges and conditions on their implementation.
2. Licensees shall ensure that radioactive materials from authorized practices are not discharged to the environment unless such discharges are within the limits and conditions on their implementation specified by the regulatory body.
3. During the operational stage the licensee, in addition to above mentioned, shall:
- (a) Keep all radioactive discharges as far below the authorized limits as is reasonably achievable;
  - (b) Monitor and record the discharges of radionuclides with sufficient detail and accuracy to demonstrate compliance with the authorized discharge limits and to permit estimation of the exposure of the representative person;
  - (c) Maintain an appropriate management system for the activities related to effluent or environmental monitoring;
  - (d) Report discharges to the regulatory body at intervals as may be specified in the licence; and, promptly when any discharges will exceed the authorized limits.
4. The licensee shall review operating experience of discharges and, in agreement with the regulatory body, adjust their discharge control measures to ensure optimization of protection and safety.

*Notes:*

- 1) *The regulatory body should specify the value of dose constraints that applies for discharge control for the particular practice. The choice of a value for a dose constraint should reflect the need to ensure that a representative person dose, both now and in the future, is unlikely to exceed the dose limit, with account taken of contributions of dose expected to be delivered by all other sources to which the representative person could be also exposed. WS-G-2.3 [41] provides recommendations and guidance on setting such limitations and on control of radioactive discharge.*
- 2) *The licensee should propose discharge levels based on an assessment of the radiological impacts of such discharges using appropriate modeling. Expected doses to the most highly exposed individuals should be estimated. It may be necessary to conduct a survey of life-style of the members of the public to establish the members of the public, who would be highly exposed as a result of the discharges (representative person).*
- 3) *As part of the discharge control the licensee should establish and document technical procedures to carry out discharge operations, as well as define the involvement of individual responsibility.*
- 4) *Compliance with authorized discharge limitations should be demonstrated through the monitoring of discharges by approved methods of sampling and measurements. The effluent and environmental monitoring programs should be incorporated into the quality management system.*

- 5) *Consideration should be given to including abnormal environmental discharges in site emergency arrangements.*
- 6) *Further guidance on radioactive discharges can be found in WS-G-2.3 [41].*

#### **Article 90: Clearance and its Control**

1. In an application for authorization, the applicant shall declare its intention to clear materials from regulatory framework during the operational phase.
2. In regard to clearance and its control, the licensee shall adopt provisions to ensure that:
  - (a) The clearance of radioactive waste complies with clearance levels approved by the regulatory body;
  - (b) A formal mechanism is in place, including rigorous control measures, to demonstrate compliance with regulatory requirements in respect of clearance;
  - (c) Deliberate dilution of material, other than the dilution that takes place in normal operations shall not be carried out;
  - (d) Any radiation markings will be removed from any material of which regulatory controls no longer apply.
3. Information on material which has been removed from regulatory control shall be recorded, retained within a management system and reported to the regulatory body as required.

#### *Notes:*

- 1) *The regulatory body should establish clearance levels. The primary radiological principles for establishing values of activity concentration for clearance are:*
  - a) *The effective doses to individuals should be of the order of 10  $\mu$ Sv or less in a year;*
  - b) *To take account of the occurrence of low probability events leading to higher radiation exposures, the effective doses due to such low probability events should not exceed 1 mSv in a year.*
- 2) *The regulatory body should provide guidance on the content and scope of the information to be submitted by an applicant seeking authorization to release waste with radionuclide concentrations exceeding clearance levels. General recommendations on this regard are provided in RS-G-1.7 [23].*
- 3) *Control measures for release of radioactive materials may include:*
  - a) *Determination of the activity concentration of the waste;*
  - b) *Segregation of such waste designated for decay;*
  - c) *Sampling of each batch of waste prior to removal from control.*
- 4) *Whenever the activity concentrations exceed the approved clearance levels and the removal from regulatory control appears to be the optimum option for the management of radioactive materials, the licensee should consider seeking regulatory approval.*

## **PART 13: DEVELOPMENT AND OPERATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES**

### **Article 91: Location and Design of Radioactive Waste Management Facilities**

1. Predisposal radioactive waste management facilities shall be located and designed so as to ensure safety for the expected operating lifetime under both normal and possible accident conditions, and for their decommissioning.
2. The need for operational maintenance, testing, examination and inspection has to be addressed from the conceptual design stage onward.

### **Article 92: Construction and Commissioning of Radioactive Waste Management Facilities**

1. Predisposal radioactive waste management facilities shall be constructed in accordance with the design as described in the safety case and approved by the regulatory body. Commissioning of the facility shall be carried out to verify that the equipment, structures, systems and components, and the facility as a whole, perform as planned.
2. In cases when commissioning is carried out in several stages all of them should be subject to the review and approval of the regulatory body.
3. Upon the completion of commissioning, a final commissioning report is usually produced by the licensee. The safety case has to be updated, as necessary, to reflect the as-built status of the facility and the conclusions of the commissioning report.
4. A modification of a facility with significant safety implications that requires a revision of the safety case has to be subject to the same regulatory controls and approvals as are applicable for the new facility.

### **Article 93: Operation of Radioactive Waste Management Facilities**

1. Predisposal radioactive waste management facilities shall be operated in accordance with national regulations and with the conditions imposed by the regulatory body. Operations shall be based on documented procedures.
2. The applicant for a license to operate any facility for predisposal management of radioactive waste shall demonstrate to regulatory body that the conception of the facility is consistent with the agreed national policy and strategy.
3. The licensee shall ensure that the facility for predisposal management of radioactive waste has sufficient capacity to process and store all such waste demanded by technological requirements of the installation or by the national policy and strategy.
4. All operations and activities important to safety have to be subject to documented limits, conditions and controls, and have to be carried out by trained, qualified and competent personnel. Due consideration shall be given to the maintenance of the facility to ensure its safe performance.
5. The applicant for a license to operate large and/or centralized storage facility shall design and construct a facility which:
  - (a) Has sufficient storage capacity to account for uncertainties in the availability of facilities for treatment, conditioning and disposal. The design of a facility shall take into account the possible need to process waste arising from incidents or accidents;

- (b) Is suitable for the expected period of storage, preferably using passive safety features, considering the potential degradation and with due consideration of natural site characteristics that could impact performance as geology, hydrology and climate;
- (c) Allows that waste can be inspected, monitored and preserved in a condition suitable for release or transport, as appropriate;
- (d) Ensures appropriate containment of the waste; for example, on the integrity of the facility's structures and equipment, as well as the integrity of the waste forms and containers over the expected duration of storage. Consideration should be given to interactions between the waste, the containers and their environment (e.g. corrosion processes due to chemical or galvanic reactions);
- (e) Makes provision for retrieval of the waste whenever required.

6. The licensee of the storage facility shall periodically review and assess the adequacy of the storage capacity, with account taken of the predicted waste arising, the expected lifetime of the facility and the availability of disposal options.

*Notes:*

- 1) *The regulatory body should provide guidance to licensees, especially to the licensees of large and/or centralized facilities on requirements relating to the storage of radioactive waste. The justification, conception and design of those facilities should be in line with the agreed national policy and strategy.*
- 2) *Guidance for radioactive waste management facilities is provided in WS-G 2.7 [15], WS-G-6.1 [29] and WS-G-2.5 [16].*
- 3) *The siting and design of any predisposal facility will depend largely upon the properties, the total inventory and potential hazard of the radioactive waste, the radioactive waste management options and the requirements of the regulatory body.*
- 4) *In designing facilities for predisposal management of radioactive waste, including storage facilities, the licensee should take in to account the following factors:*
  - a) *Minimization of waste generation;*
  - b) *In case of the small waste storage facility within large installation the area outside should have a low public occupancy factor and should be a low traffic area;*
  - c) *Separate the radioactive waste processing systems from the other systems, as well as from the premises and facilities, where other potentially hazardous materials are stored (for example radioactive materials should not be store with explosive materials);*
  - d) *Provide auxiliary systems, for example for air sampling, radiation alarms or decontamination;*
  - e) *Compartments, in order to separate different kinds of waste that may be stored (e.g. to facilitate the safe storage of specially hazardous materials, such as volatile, pathogenic and putrescible materials, chemically reactive materials);*
  - f) *Provide radiological control at all stages including control over the receipt of waste and elements affecting personnel protection and protection of the working environment;*
  - g) *Provide adequate containment (e.g. fume cupboards, drip trays, sealed and dipped work benches) and shielding (e.g. lead or concrete blocks);*
  - h) *Provide for demarcation of the working premises according to their classification (e.g. labels, rope or other barriers) for area and personnel, as appropriate;*
  - i) *Provide for radiation control (measurement of dose rates and surface contamination);*
  - j) *Arrange the location and layout of the equipment and systems in a way that provides ease of access for normal operation, maintenance and control;*

- k) *Provide for the safe handling of waste by having appropriate handling equipment and selecting short and uncomplicated routes;*
- l) *Provide adequate drainage and ventilation systems (e.g. by means of air filtration, air pressure differentials and flow considerations);*
- m) *Provide normal and emergency electrical supplies;*
- n) *Provide premises for emergency equipment;*
- o) *Provide fire detection and protection systems;*
- p) *Provide physical protection and security of radioactive waste.*

#### **Article 94: Existing facilities**

1. The safety at existing facilities shall be reviewed to verify compliance with requirements. For those facilities not in compliance with all of the requirements, safety related upgrades shall be made by the licensee in line with national policies and as required by the regulatory body.

*Notes:*

*If any radioactive waste or any radioactive waste management facility is present at the time of entry into force of new regulations, the regulatory body should:*

- a) *Ensure that a detailed inventory of that material is established;*
- b) *Determine what risk such waste or facility represents for individuals, society or the environment;*
- c) *Review the safety level to determine compliance with requirements;*
- d) *Determine what measures, if any, need to be taken to upgrade the existing level of safety;*
- e) *Determine if any facilities need to be shut down;*
- f) *Establish a reasonable time frame for the existing facilities to comply with the new regulations.*

#### **Article 95: Disposal of Radioactive Waste**

1. The applicant for a license for a radioactive waste disposal facility shall prepare a safety case and safety assessment, as necessary, at each step in the design, construction, operation and closure of the disposal facility, with the due attention being paid to the operational and long term safety implications. The characteristics and quantities of the radioactive waste to be disposed of shall be considered in the design.

2. The licensee shall prepare waste acceptance criteria for the radioactive waste disposal facility.

*Notes:*

*Given the complexity and specificity of this subject the regulatory body should develop and issue specific regulatory requirements covering this topic. The requirements that must be met to ensure safety consistent with the established principles of safety for radioactive waste management are provided in SSR-5 [7]. SSR-5 is to be used as a basis for an application to construct and operate a disposal facility.*

#### **Article 96: Disposal of Radioactive Waste from Mining and Mineral Processing**

1. The applicant (or licensee) shall propose to the regulatory body which option has to be followed for the siting, design, construction, operation, closure and post-closure activity for a disposal of radioactive waste from mining and mineral processing.

Notes:

- 1) *The regulatory body should provide safety requirements and guidance on the safe management of radioactive waste that result from the mining and milling of ores. These requirements should be consistent with GSR Part 3 [3] and SSR-5 [7].*
- 2) *When planning for the disposal of waste from mining and milling operations, the applicant for a license should take into account the fact that this waste:*
  - a) *Represents very large volumes and can hardly ever be relocated;*
  - b) *Contains long-lived radionuclides that may require institutional control of very long, if not indefinite, duration;*
  - c) *Often contains chemicals that may pose significant non-radiological hazards.*
- 3) *When submitting a proposal to the regulatory body for the design of a mining or milling waste disposal facility, the applicant should plan to:*
  - a) *Maximize the use of natural materials for containment;*
  - b) *Maximize the placement of waste material below ground level where possible;*
  - c) *Minimize the impact on the environment during operation and closure;*
  - d) *Minimize the need to retrieve or relocate the waste;*
  - e) *Minimize the need for surveillance and maintenance during operation and for institutional control after closure.*
- 4) *Guidance on the disposal of waste from mining and mineral processing in WS-G-1.2 [17].*

## **PART 14: DECOMMISSIONING OF FACILITIES AND ACTIVITIES**

### **Article 97: Decommissioning of facilities and activities**

1. The licensee shall be responsible for the following during the decommissioning of facilities and activities:
  - (a) Ensure the safety of workers and the public, and the protection of the environment during and after decommissioning activities;
  - (b) Establish a decommissioning strategy and preparing and maintaining a decommissioning plan;
  - (c) Establish a waste management strategy for decommissioning facilities including the identification of an acceptable destination for all wastes arising from decommissioning;
  - (d) Perform safety assessments and environmental impact assessments related to decommissioning;
  - (e) Prepare and implement appropriate safety procedures, including emergency preparedness, and apply good engineering practices;
  - (f) Ensure that properly trained, qualified and competent staff are available for the decommissioning project;
  - (g) Perform appropriate radiological surveys in support of decommissioning;
  - (h) Keep records and submit reports as required by the regulatory body;
  - (i) Establish a management system including organization and administrative controls, staffing and qualification, project management, documentation and recordkeeping, subcontractor's involvement, and safety management;
  - (j) Ensure that end state criteria have been met by performing a final survey;
  - (k) Notify the regulatory body prior to shutdown of the facilities permanently or terminating the activity.

2. A graded approach shall be applied to the planning, conduct and completion of decommissioning.
3. The licensee shall prepare and maintain a decommissioning plan throughout the lifetime of the facility, unless otherwise approved by the regulatory body, in order to show that the decommissioning can be accomplished safely to meet the defined end state. In this regard, the licensee shall:
  - (a) Prepare and submit an initial decommissioning plan in support of the licence application for the construction of the facility or at the time of applying for an authorization to operate the facility;
  - (b) Review and update periodically the initial decommissioning plan during operation, as prescribed by the regulatory body;
  - (c) Prepare without undue delay the initial decommissioning plan for facilities where one has not yet been prepared.
4. The licensee shall retain the necessary resources, expertise and knowledge for decommissioning and shall keep records and documentation relevant to the design, construction, operation and decommissioning process during transition from operation to decommissioning.
5. Prior to the conduct of decommissioning phase, the licensee shall prepare and submit a final decommissioning plan to the regulatory body for approval. In doing so the licensee shall:
  - (a) Not implement the decommissioning plan until the regulatory body has approved it. The licensee shall ensure that the facility is maintained in a safe configuration until approval of the decommissioning plan;
  - (b) Ensure that the decommissioning plan states the methodology and criteria that will used to demonstrate that the proposed end state has been achieved. For most medical, industrial and research facilities, this end state is typically release for unrestricted use;
  - (c) Define how the project will be managed.
6. After shutdown, the responsibility for the facility may be transferred to a different organization which becomes the operating organization of the facility for decommissioning. Knowledge of the operational history of the facility shall be maintained and passed to the new operating organization. For such transfer of responsibility, the new operating organization shall have the necessary resources, expertise and knowledge.
7. The licensee shall ensure adequate financial provisions are available to decommissioning the facility including the management of the resulting waste when needed, even in the event of premature shutdown in accordance with the national regulatory framework. The decommissioning cost for the facility shall be calculated.
8. Financial assurance for decommissioning shall be included as part of the license application, and needs to be in place prior to initiation of construction or operation of the facility.
9. If financial assurance for decommissioning an existing facility has not been obtained, appropriate funding provisions should be put in place as soon as possible. In any event, financial assurance shall be in place prior to approval of license renewal or license extension.
10. Decontamination and dismantling techniques shall be chosen such that the protection of workers, the public and the environment is optimized and the generation of waste is minimized.

11. Prior to using any new or untried methods for decommissioning, it shall be demonstrated that the use of such methods is justified and is addressed within the optimization analysis supporting the decommissioning plan. Such analyses shall be subject to review and approval by the regulatory body.

12. On completion of decommissioning, the licensee shall demonstrate that the end state criteria as defined in the decommissioning plan and any additional regulatory requirements have been met. In this regards the licensee shall consider that:

- (a) They could only be relieved of further responsibility for the facility after approval by the regulatory body;
- (b) The facility shall not be released from regulatory control, nor shall authorization be terminated, until the licensee has demonstrated that the end state in the decommissioning plan has been reached and that any additional regulatory requirements have been met;
- (c) On completion of decommissioning, appropriate records should be retained as specified by the regulatory body. A system shall be established to ensure that all records are maintained in accordance with the records retention requirements of the management system and the regulatory requirements;
- (d) If waste is stored on the site, a revised or new, separate authorization, including requirements for decommissioning, shall be requested by the licensee and issued for the facility.

13. The licensee shall prepare and submit to the regulatory body a final decommissioning report. This report shall document, in particular, the end state of the facility or site.

14. If a facility cannot be released for unrestricted use, appropriate controls shall be maintained to ensure the protection of human health and the environment. In this case, the licensee shall:

- (a) Specify these controls which shall be subject to approval by the regulatory body. Clear responsibility shall be assigned for implementing and maintaining these controls;
- (b) Ensure that in the case of restricted release of the facility or site from the regulatory control, appropriate arrangements for continuous controls are established to guarantee the protection of the workers, the public and the environment.

*Notes:*

- 1) *In this regard, the regulatory body should provide guidance and requirements to the operating organization on:*
  - a) *Safety and environmental criteria for the decommissioning of facilities;*
  - b) *Content and scope of the initial and final decommissioning plans;*
  - c) *Management and completion of decommissioning;*
  - d) *Release from regulatory control.*
- 2) *The regulatory body should evaluate the end state of the site by performing a thorough inspection of the remainder of the facility after decommissioning activities have been completed to ensure that the end point criteria have been met.*
- 3) *Decommissioning will require special attention in those countries with large nuclear programs, where the regulatory body shall develop and issue specific regulation. In the countries where there are limited numbers of applications requiring an extensive decommissioning program (i.e. research reactor, irradiation facility, etc.), the regulatory body could prepare a regulatory guide covering the most important regulatory requirements for its decommissioning.*
- 4) *Requirements on decommissioning are provided in WS-R-5 [24]. WS-G-2.2 [18] provides guidance on planning, conducting and completing decommissioning of medical,*

*industrial and research facilities and provides recommendations to assist in fulfilling the requirements for decommissioning.*

- 5) *For most medical, industrial and research facilities, a relatively simple decommissioning plan with logical and adequate justification will be sufficient. This plan should include:
  - a) *Facility description including the facility and site radiological characterization;*
  - b) *Decommissioning strategy;*
  - c) *Decommissioning management including management system;*
  - d) *Conduct of decommissioning including decontamination and dismantling techniques and technologies, surveillance and maintenance, removal of contaminated material and radiation sources and waste management;*
  - e) *Cost estimate;*
  - f) *Radiation protection;*
  - g) *Final survey design;*
  - h) *Any other information required by the regulatory body.**
- 6) *The decommissioning final report could consist of several reports. Alternatively, as in the case of simple facilities, this final decommissioning report could be a summary of these reports.*
- 7) *In cases when a facility cannot be released for unrestricted use, the regulatory body shall ensure that a programme has been established to apply the remaining regulatory requirements and to monitor compliance with them.*

## **PART 15: REQUIREMENTS FOR TRANSPORT OF RADIOACTIVE MATERIAL**

### **Article 98: Transport Requirements**

Licenseses transporting radioactive sources, radioactive waste or any other radioactive material, either domestically or internationally shall do so in compliance with all applicable transport requirements of the IAEA Regulations for the Safe Transport of Radioactive Material [27].

*Note:*

*This Article will require modification if the country has transport safety regulations in place that can be cited.*

## **PART 16: REQUIREMENTS FOR EMERGENCY PREPAREDNESS AND RESPONSE**

### **Article 99: Responsibilities of Licensees**

1. If an authorized practice or source including radioactive waste within a practice has a potential for an emergency affecting either workers or members of the public, the licensee shall prepare an emergency plan for the protection of people and the environment. As part of this emergency plan, the 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 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.
2. 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, 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 100: Emergency Preparedness and Response**

Each licensee responsible for sources, including radioactive waste, for which prompt intervention may be required, shall ensure that the emergency plan defines at the scene responsibilities and takes account of off-site responsibilities of response organizations appropriate for implementation of the emergency plan. Such emergency plans shall, as appropriate:

- (a) Characterize the content, features and extent of a potential emergency taking into account the results of any hazard assessment and any lessons learned from operating experience and from accidents that have occurred with sources of a similar type;
- (b) Identify the various operating and other conditions of the source which could lead to the need for intervention;
- (c) Describe the methods and instruments for assessing the accident and its consequences on and off the site;
- (d) Provide for protective actions and mitigation actions, and assignment of responsibilities for initiating and discharging such actions;
- (e) Provide for rapid and continuous assessment of the accident as it proceeds and determining the need for protective actions;
- (f) Allocate responsibilities for notifying the relevant authorities and for initiating intervention;
- (g) Provide procedures, including communication arrangements for contacting any relevant response organization (e.g. civil defence) and for obtaining assistance from fire-fighting, medical, police and other relevant organizations;
- (h) Provide for training personnel involved in implementing emergency plans and be rehearsed at suitable intervals based on requirements defined in Article 29(2) in conjunction with designated authorities;
- (i) Provide for periodic review and updating of the plan.

### **Article 101: Implementation of Intervention**

1. The licensee shall ensure that the protective actions or remedial actions aimed at reducing or averting accidental exposures are only undertaken when they are justified, taking into account health, social and economic factors.

2. The form, scale and duration of any justified intervention shall be optimized so as to produce the maximum net benefit under the prevailing social and economic circumstances.

3. Licensees shall promptly notify the regulatory body when an accidental situation requiring intervention has arisen or is expected to arise and shall keep the regulatory body informed of:

- (a) The current situation and its expected evolution;
- (b) The measures taken to terminate the accident and to protect workers and members of the public;
- (c) The exposures that have been incurred and that are expected to be incurred.

### **Article 102: Protection of Emergency Workers in an Emergency Exposure Situation**

1. The response organization and employers responsible for ensuring compliance with the requirements in paragraphs (2) – (8) below shall be specified in the emergency plan

2. In an emergency exposure situation, the relevant requirements for occupational exposure in planned exposure situations (Articles 36-46) shall be applied for emergency workers, in accordance with a graded approach, except as required in para. (3) of this Article.

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

- (a) For the purposes of saving life or preventing serious injury;
- (b) When undertaking actions to avert a large collective dose; or
- (c) 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.

4. In the exceptional circumstances of para. (3) of this Article, response organizations and employers shall make all reasonable efforts to keep doses to emergency workers below the values set out in .....{*Schedule IV, Table IV-2 of GSR Part 3 [3]*}. In addition, emergency workers undertaking actions due to which their doses could approach or exceed the values set out in .....{*Schedule IV, Table IV-2 of GSR Part 3 [3]*} shall do so only when the expected benefits to others would clearly outweigh the risks to the emergency workers.

5. Response organizations and employers shall ensure that emergency workers who undertake actions in which the doses received might exceed 50 mSv do so voluntarily<sup>6</sup>; that they have been clearly and comprehensively informed in advance of the associated health risks, as well as of available measures for protection and safety; and that they are, to the extent possible, trained in the actions that they may be required to take.

6. Workers undertaking work such as repairs to plant and buildings or activities for radioactive waste management or remedial work for the decontamination of the site and surrounding areas, shall be subject to the relevant requirements for occupational exposure specified in these Regulations.

7. Response organizations and employers shall take all reasonable steps to assess and record the doses received in an emergency by emergency workers. Information of the doses received and information concerning the associated health risks shall be communicated to the workers involved.

8. Workers who receive doses in an emergency exposure situation shall not normally be precluded from incurring further occupational exposure. However, qualified medical advice

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<sup>6</sup> The voluntary basis for response actions by emergency workers is usually covered in the emergency response arrangements.

shall be obtained before any further occupational exposure if a worker has received a dose exceeding 200 mSv or at the request of the worker.

*Note:*

*Requirements for emergency preparedness and response are set out in GS-R-2 [34]. Guidance applying the requirements is provided in GS-G-2.1 [35] and GSG-2 [36].*

## **PART 17: EXISTING EXPOSURE SITUATIONS**

*Notes*

*Existing Exposure Situations*

- 1) The government is to ensure that when an existing exposure situation is identified, responsibilities for protection and safety are assigned and appropriate reference levels are established.*
- 2) The scope of these Regulations (Article 3) does not include existing exposure situations. If existing exposure situations are to be included in the Regulations, a separate Article for the scope of the existing exposure situations would need to be developed.*
- 3) The government is to include in the legal and regulatory framework for protection and safety provision for the management of existing exposure situations. The government, in the legal and regulatory framework, as appropriate is to specify the exposure situation that are included in the scope of existing exposure situations; specify the general principles underlying the protection strategies developed to reduce exposure when remedial actions and protective actions have been determined to be justified; and assign responsibilities for the establishment and implementation of protection strategies to the regulatory body and to 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; and is to provide for the involvement of interested parties in decisions regarding the development and implementation of protection strategies, as appropriate.*
- 4) The regulatory body or other relevant authority assigned to establish a protection strategy for an existing exposure situation is to ensure that it defines: (a) The objectives to be achieved by means of the protection strategy; (b) Appropriate reference levels.*
- 5) The regulatory body or other relevant authority is responsible for implementing the protection strategy, including: (a) Arranging 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) Ensuring 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.*
- 6) The government and the regulatory body or other relevant authority is 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.*
- 7) The regulatory body or other relevant authority and other parties responsible for remedial actions or protective actions are to ensure that the form, scale and duration of such actions are optimized. While this optimization process is intended to provide optimized protection for all individuals subject to exposure, priority is to be given to those groups for whom residual dose exceeds the reference level. All reasonable steps*

*are to be taken to prevent doses remaining above the reference levels. Reference levels are typically expressed as an annual effective dose to the representative person in the range 1–20 mSv or other equivalent quantity, the actual value depending on the feasibility of controlling the situation and experience in managing similar situations in the past.*

- 8) *The regulatory body or other relevant authority is to periodically review the reference levels to ensure that they remain appropriate in the light of the prevailing circumstances.*

### **Article 103: Remediation of areas with residual radioactive material**

*Notes:*

- 1) *Where the government has identified areas with residual radioactive material from past activities or from a nuclear or radiological emergency that require remediation, the government is to ensure that provision is made in the framework for protection and safety for:*

- a) *The identification of those persons or organizations responsible for the contamination of areas and those responsible for financing the remediation programme, and the determination of appropriate arrangements for alternative sources of funding if such persons or organizations are no longer present or are unable to meet their liabilities;*
- b) *The designation of persons or organizations responsible for planning, implementing and verifying the results of remedial actions;*
- c) *The establishment of any restrictions on the use of or access to the areas concerned before, during and, if necessary, after remediation;*
- d) *An appropriate system for maintaining, retrieval and amendment of 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 and surveillance programmes after completion of the remedial actions;*

- 2) *The government is to ensure that the strategy for radioactive waste management deals with any radioactive waste arising from the remedial actions and that provision for such a strategy is made in the framework for protection and safety.*

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

- (a) A remedial action plan, supported by a safety assessment, is prepared and is submitted to the regulatory body or other relevant authority for approval;
- (b) The remedial action plan is aimed at the timely and progressive reduction of the radiation risks and eventually, if possible, the removal of restrictions on use of or access to the area;
- (c) Any additional dose received by members of the public as a result of the remedial actions is justified on the basis of the resulting net benefit, including consideration of the consequent reduction of the annual dose;
- (d) In the choice of the optimized remediation option:
  - (i) The radiological impacts on people and the environment are considered together with non-radiological impacts on people and the environment, and technical, societal and economic factors;
  - (ii) The costs of the transport and management of radioactive waste, the radiation exposure of and health risks to the workers managing the waste, and any subsequent public exposure associated with its disposal are all taken into account;

- (e) A mechanism for public information is in place and the interested parties affected by the existing exposure situation are involved in the planning, implementation and verification of the remedial actions, including any monitoring and surveillance following remediation;
  - (f) A monitoring programme is established and implemented;
  - (g) A system for maintaining adequate records relating to the existing exposure situation and actions taken for protection and safety is in place;
  - (h) Procedures are in place for reporting to the regulatory body on any abnormal conditions relevant to protection and safety.
2. The person or organization responsible 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 performance of a safety assessment;
  - (c) Monitor and perform a radiological survey of the area regularly during the remediation work so as to verify levels of contamination, to verify compliance with the requirements for waste management, and to enable any unexpected levels of radiation to be detected and the remedial action plan to be modified accordingly, subject to approval by the regulatory body or other relevant authority;
  - (d) Perform a 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) Prepare and retain a final remediation report and shall submit a copy to the regulatory body or other relevant authority.
3. 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 provisions for monitoring and surveillance, to verify the long term effectiveness of the completed remedial actions for areas in which controls are required after remediation has been completed.

*Notes:*

- 1) *The regulatory body or other relevant authority is to take responsibility in particular 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 of any necessary authorization (licence);*
  - 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 members of the public;*
  - e) *Where necessary, establishment of regulatory requirements for control measures following remediation.*
- 2) *After the remedial actions have been completed, the regulatory body or other relevant authority will:*
  - a) *Review, amend as necessary and formalize the type, extent and duration of any post-remediation control measures already 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) *Where necessary impose specific restrictions 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 of the area, including the use of water resources and use for the production of food or feed, and the consumption of food from the area;*
- d) *Periodically review conditions in the remediated area and, if appropriate, shall amend or remove any restrictions.*
- 3) *For those areas with long lasting residual radioactive material in which the government has decided to allow habitation and the resumption of social and economic activities, the government, in consultation with interested parties, is to ensure that arrangements are in place, as necessary, for the on-going control of exposure with the aim of establishing conditions for sustainable living, including:*
  - a) *Establishment of reference levels for protection and safety consistent with day to day life;*
  - b) *Establishment of an infrastructure to support continuing 'self-help protective actions' in the affected areas, such as by the provision of information and advice and by monitoring.*
- 4) *The conditions prevailing after the completion of remedial actions, if the regulatory body or other relevant authority has imposed no restrictions or controls, shall be considered to constitute the background conditions for any new facilities and activities or for habitation of the land.*

## **PART 18: USE OF INTERNATIONAL SAFETY STANDARDS AND OTHER PUBLICATIONS**

*Notes:*

*In the absence of national prescriptive regulations, the regulatory body may include a provision by which international recommendations can be applied.*

- 1) *Applicants for authorizations may propose to apply recommendations regarding facilities and 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.*
- 2) *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.*
- 3) *The regulatory body on its own initiative or upon request will revise and update the list under References from time to time.*

**ANNEX I: FORM FOR NOTIFICATION OF PRACTICES AND SOURCES**

(Name and address of the regulatory body)

(Use one form for each source to be notified)

1. Name and address of the legal person.
2. Name and address of the organization.
3. Nature of the practice in which the source is used:
4. Identification of each source:

**RADIONUCLIDE**

Activity (Bq):

Chemical form:

Sealed source: YES/NO

If Yes = Manufacturer:

Model:

**RADIATION GENERATING EQUIPMENT**

Manufacturer:

Model:

Operating potential:

Nature of the equipment in which the source is installed:

Model (if appropriate):

Date:

.....

Signature of legal person

*Note: This is only a suggested form. It can be designed in any manner being more appropriate for the local situation.*

## ANNEXII: DOSE LIMITS FOR EXPOSURES INCURRED FROM PRACTICES IN PLANNED EXPOSURE SITUATIONS

### I-1. OCCUPATIONAL EXPOSURE

1. For occupational exposure of workers over the age of 18 years, the dose limits are:
  - (a) An effective dose of 20 mSv per year averaged over five consecutive years<sup>7</sup> (100 mSv in 5 years) and of 50 mSv in any single year; an equivalent dose to the lens of the eye of 150 mSv in a 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 the skin of 500 mSv in a year.
2. For occupational exposure of apprentices of 16 to 18 years of age who are trained for employment involving exposure to radiation and for students of age 16 to 18 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 the skin of 150 mSv in a year.

### I-2. PUBLIC EXPOSURE

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 could apply, provided that the average 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.

### I-3. INTERNAL EXPOSURE

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

*Note:*

*Most radiation sources in the Member States to which this Model Regulations is addressed will not involve significant internal exposure. Therefore, the tables related to this subject are not included in the Model Regulations.*

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<sup>7</sup> The start of the averaging period shall be coincident with the first day of the relevant annual period starting from the date of entry into force of the Regulations, with no retroactive averaging.

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