

# IAEA Safety Standards

for protecting people and the environment

## Radiation Protection of the Public and the Environment

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## General Safety Guide

### No. GSG-8



**IAEA**

International Atomic Energy Agency

# IAEA SAFETY STANDARDS AND RELATED PUBLICATIONS

## IAEA SAFETY STANDARDS

Under the terms of Article III of its Statute, the IAEA is authorized to establish or adopt standards of safety for protection of health and minimization of danger to life and property, and to provide for the application of these standards.

The publications by means of which the IAEA establishes standards are issued in the **IAEA Safety Standards Series**. This series covers nuclear safety, radiation safety, transport safety and waste safety. The publication categories in the series are **Safety Fundamentals**, **Safety Requirements** and **Safety Guides**.

Information on the IAEA's safety standards programme is available on the IAEA Internet site

<http://www-ns.iaea.org/standards/>

The site provides the texts in English of published and draft safety standards. The texts of safety standards issued in Arabic, Chinese, French, Russian and Spanish, the IAEA Safety Glossary and a status report for safety standards under development are also available. For further information, please contact the IAEA at: Vienna International Centre, PO Box 100, 1400 Vienna, Austria.

All users of IAEA safety standards are invited to inform the IAEA of experience in their use (e.g. as a basis for national regulations, for safety reviews and for training courses) for the purpose of ensuring that they continue to meet users' needs. Information may be provided via the IAEA Internet site or by post, as above, or by email to [Official.Mail@iaea.org](mailto:Official.Mail@iaea.org).

## RELATED PUBLICATIONS

The IAEA provides for the application of the standards and, under the terms of Articles III and VIII.C of its Statute, makes available and fosters the exchange of information relating to peaceful nuclear activities and serves as an intermediary among its Member States for this purpose.

Reports on safety in nuclear activities are issued as **Safety Reports**, which provide practical examples and detailed methods that can be used in support of the safety standards.

Other safety related IAEA publications are issued as **Emergency Preparedness and Response** publications, **Radiological Assessment Reports**, the International Nuclear Safety Group's **INSAG Reports**, **Technical Reports** and **TECDOCs**. The IAEA also issues reports on radiological accidents, training manuals and practical manuals, and other special safety related publications.

Security related publications are issued in the **IAEA Nuclear Security Series**.

The **IAEA Nuclear Energy Series** comprises informational publications to encourage and assist research on, and the development and practical application of, nuclear energy for peaceful purposes. It includes reports and guides on the status of and advances in technology, and on experience, good practices and practical examples in the areas of nuclear power, the nuclear fuel cycle, radioactive waste management and decommissioning.

RADIATION PROTECTION  
OF THE PUBLIC AND  
THE ENVIRONMENT

The Agency's Statute was approved on 23 October 1956 by the Conference on the Statute of the IAEA held at United Nations Headquarters, New York; it entered into force on 29 July 1957. The Headquarters of the Agency are situated in Vienna. Its principal objective is "to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity throughout the world".

IAEA SAFETY STANDARDS SERIES No. GSG-8

# RADIATION PROTECTION OF THE PUBLIC AND THE ENVIRONMENT

GENERAL SAFETY GUIDE

JOINTLY SPONSORED BY THE  
INTERNATIONAL ATOMIC ENERGY AGENCY  
AND UNITED NATIONS ENVIRONMENT PROGRAMME

INTERNATIONAL ATOMIC ENERGY AGENCY  
VIENNA, 2018

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## **FOREWORD**

**by Yukiya Amano**  
**Director General**

The IAEA's Statute authorizes the Agency to "establish or adopt... standards of safety for protection of health and minimization of danger to life and property" — standards that the IAEA must use in its own operations, and which States can apply by means of their regulatory provisions for nuclear and radiation safety. The IAEA does this in consultation with the competent organs of the United Nations and with the specialized agencies concerned. A comprehensive set of high quality standards under regular review is a key element of a stable and sustainable global safety regime, as is the IAEA's assistance in their application.

The IAEA commenced its safety standards programme in 1958. The emphasis placed on quality, fitness for purpose and continuous improvement has led to the widespread use of the IAEA standards throughout the world. The Safety Standards Series now includes unified Fundamental Safety Principles, which represent an international consensus on what must constitute a high level of protection and safety. With the strong support of the Commission on Safety Standards, the IAEA is working to promote the global acceptance and use of its standards.

Standards are only effective if they are properly applied in practice. The IAEA's safety services encompass design, siting and engineering safety, operational safety, radiation safety, safe transport of radioactive material and safe management of radioactive waste, as well as governmental organization, regulatory matters and safety culture in organizations. These safety services assist Member States in the application of the standards and enable valuable experience and insights to be shared.

Regulating safety is a national responsibility, and many States have decided to adopt the IAEA's standards for use in their national regulations. For parties to the various international safety conventions, IAEA standards provide a consistent, reliable means of ensuring the effective fulfilment of obligations under the conventions. The standards are also applied by regulatory bodies and operators around the world to enhance safety in nuclear power generation and in nuclear applications in medicine, industry, agriculture and research.

Safety is not an end in itself but a prerequisite for the purpose of the protection of people in all States and of the environment — now and in the future. The risks associated with ionizing radiation must be assessed and controlled without unduly limiting the contribution of nuclear energy to equitable and sustainable development. Governments, regulatory bodies and operators everywhere must ensure that nuclear material and radiation sources are used beneficially, safely and ethically. The IAEA safety standards are designed to facilitate this, and I encourage all Member States to make use of them.





## PREFACE

Requirements for the protection of people from harmful consequences of exposure to ionizing radiation, for the safety of radiation sources and for protection of the environment are established in the IAEA Safety Requirements for Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards (IAEA Safety Standards Series No. GSR Part 3). GSR Part 3 is jointly sponsored by the European Commission, the Food and Agriculture Organization of the United Nations, the IAEA, the International Labour Organization, the OECD Nuclear Energy Agency, the Pan American Health Organization, the United Nations Environment Programme and the World Health Organization.

Three related Safety Guides were prepared to provide generic guidance on meeting the requirements of GSR Part 3 for protection of the public and protection of the environment, as follows:

- IAEA Safety Standards Series No. GSG-8, Radiation Protection of the Public and the Environment, which provides guidance on the framework for protection of the public and the environment;
- IAEA Safety Standards Series No. GSG-9, Regulatory Control of Radioactive Discharges to the Environment, which provides guidance on application of the principles of radiation protection and the safety objectives associated with the control of discharges and on the process for authorization of discharges;
- IAEA Safety Standards Series No. GSG-10, Prospective Radiological Environmental Impact Assessment for Facilities and Activities, which describes a framework and methodologies for prospective radiological environmental impact assessment.

These three Safety Guides are jointly sponsored by the IAEA and UN Environment, the leading global environmental authority, which sets the global environmental agenda, promotes the coherent implementation of the environmental dimension of sustainable development within the United Nations system, and serves as an authoritative advocate for the global environment. The recommendations provided in these three Safety Guides, together with the requirements of GSR Part 3, provide a basis for including environmental considerations in the assessment and management of radioactive releases. In this context, UN Environment encourages the application of these recommendations in all its Member States, and their use as a foundation for the development of national regulations on protection of the environment from harmful effects of ionizing radiation.



# THE IAEA SAFETY STANDARDS

## BACKGROUND

Radioactivity is a natural phenomenon and natural sources of radiation are features of the environment. Radiation and radioactive substances have many beneficial applications, ranging from power generation to uses in medicine, industry and agriculture. The radiation risks to workers and the public and to the environment that may arise from these applications have to be assessed and, if necessary, controlled.

Activities such as the medical uses of radiation, the operation of nuclear installations, the production, transport and use of radioactive material, and the management of radioactive waste must therefore be subject to standards of safety.

Regulating safety is a national responsibility. However, radiation risks may transcend national borders, and international cooperation serves to promote and enhance safety globally by exchanging experience and by improving capabilities to control hazards, to prevent accidents, to respond to emergencies and to mitigate any harmful consequences.

States have an obligation of diligence and duty of care, and are expected to fulfil their national and international undertakings and obligations.

International safety standards provide support for States in meeting their obligations under general principles of international law, such as those relating to environmental protection. International safety standards also promote and assure confidence in safety and facilitate international commerce and trade.

A global nuclear safety regime is in place and is being continuously improved. IAEA safety standards, which support the implementation of binding international instruments and national safety infrastructures, are a cornerstone of this global regime. The IAEA safety standards constitute a useful tool for contracting parties to assess their performance under these international conventions.

## THE IAEA SAFETY STANDARDS

The status of the IAEA safety standards derives from the IAEA's Statute, which authorizes the IAEA to establish or adopt, in consultation and, where appropriate, in collaboration with the competent organs of the United Nations and with the specialized agencies concerned, standards of safety for protection of health and minimization of danger to life and property, and to provide for their application.

With a view to ensuring the protection of people and the environment from harmful effects of ionizing radiation, the IAEA safety standards establish fundamental safety principles, requirements and measures to control the radiation exposure of people and the release of radioactive material to the environment, to restrict the likelihood of events that might lead to a loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source or any other source of radiation, and to mitigate the consequences of such events if they were to occur. The standards apply to facilities and activities that give rise to radiation risks, including nuclear installations, the use of radiation and radioactive sources, the transport of radioactive material and the management of radioactive waste.

Safety measures and security measures<sup>1</sup> have in common the aim of protecting human life and health and the environment. Safety measures and security measures must be designed and implemented in an integrated manner so that security measures do not compromise safety and safety measures do not compromise security.

The IAEA safety standards reflect an international consensus on what constitutes a high level of safety for protecting people and the environment from harmful effects of ionizing radiation. They are issued in the IAEA Safety Standards Series, which has three categories (see Fig. 1).

### **Safety Fundamentals**

Safety Fundamentals present the fundamental safety objective and principles of protection and safety, and provide the basis for the safety requirements.

### **Safety Requirements**

An integrated and consistent set of Safety Requirements establishes the requirements that must be met to ensure the protection of people and the environment, both now and in the future. The requirements are governed by the objective and principles of the Safety Fundamentals. If the requirements are not met, measures must be taken to reach or restore the required level of safety. The format and style of the requirements facilitate their use for the establishment, in a harmonized manner, of a national regulatory framework. Requirements, including numbered ‘overarching’ requirements, are expressed as ‘shall’ statements. Many requirements are not addressed to a specific party, the implication being that the appropriate parties are responsible for fulfilling them.

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<sup>1</sup> See also publications issued in the IAEA Nuclear Security Series.

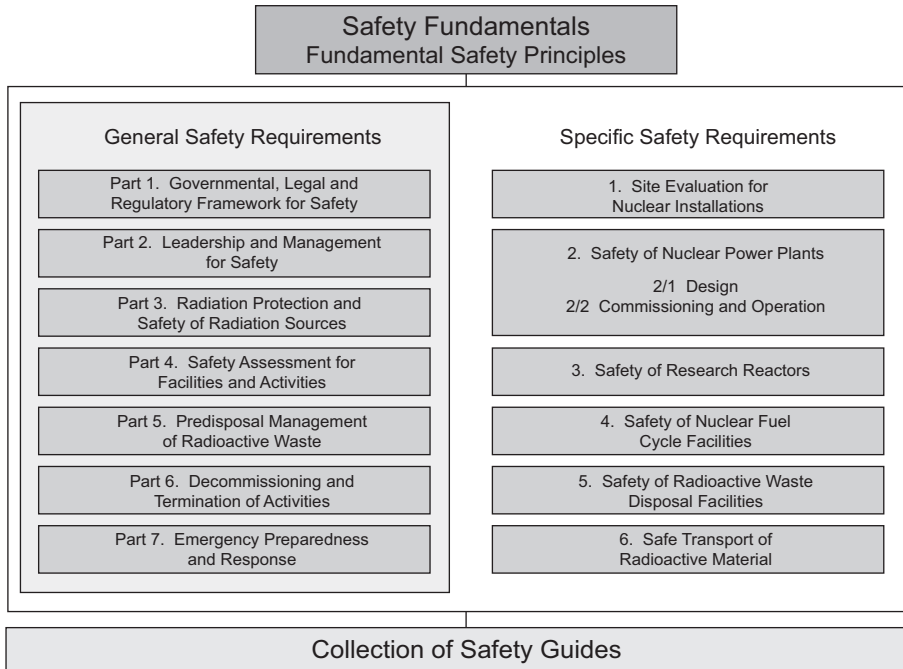


FIG. 1. The long term structure of the IAEA Safety Standards Series.

## Safety Guides

Safety Guides provide recommendations and guidance on how to comply with the safety requirements, indicating an international consensus that it is necessary to take the measures recommended (or equivalent alternative measures). The Safety Guides present international good practices, and increasingly they reflect best practices, to help users striving to achieve high levels of safety. The recommendations provided in Safety Guides are expressed as ‘should’ statements.

## APPLICATION OF THE IAEA SAFETY STANDARDS

The principal users of safety standards in IAEA Member States are regulatory bodies and other relevant national authorities. The IAEA safety standards are also used by co-sponsoring organizations and by many organizations that design, construct and operate nuclear facilities, as well as organizations involved in the use of radiation and radioactive sources.

The IAEA safety standards are applicable, as relevant, throughout the entire lifetime of all facilities and activities — existing and new — utilized for peaceful purposes and to protective actions to reduce existing radiation risks. They can be used by States as a reference for their national regulations in respect of facilities and activities.

The IAEA's Statute makes the safety standards binding on the IAEA in relation to its own operations and also on States in relation to IAEA assisted operations.

The IAEA safety standards also form the basis for the IAEA's safety review services, and they are used by the IAEA in support of competence building, including the development of educational curricula and training courses.

International conventions contain requirements similar to those in the IAEA safety standards and make them binding on contracting parties. The IAEA safety standards, supplemented by international conventions, industry standards and detailed national requirements, establish a consistent basis for protecting people and the environment. There will also be some special aspects of safety that need to be assessed at the national level. For example, many of the IAEA safety standards, in particular those addressing aspects of safety in planning or design, are intended to apply primarily to new facilities and activities. The requirements established in the IAEA safety standards might not be fully met at some existing facilities that were built to earlier standards. The way in which IAEA safety standards are to be applied to such facilities is a decision for individual States.

The scientific considerations underlying the IAEA safety standards provide an objective basis for decisions concerning safety; however, decision makers must also make informed judgements and must determine how best to balance the benefits of an action or an activity against the associated radiation risks and any other detrimental impacts to which it gives rise.

## DEVELOPMENT PROCESS FOR THE IAEA SAFETY STANDARDS

The preparation and review of the safety standards involves the IAEA Secretariat and five safety standards committees, for emergency preparedness and response (EPreSC) (as of 2016), nuclear safety (NUSSC), radiation safety (RASSC), the safety of radioactive waste (WASSC) and the safe transport of radioactive material (TRANSSC), and a Commission on Safety Standards (CSS) which oversees the IAEA safety standards programme (see Fig. 2).

All IAEA Member States may nominate experts for the safety standards committees and may provide comments on draft standards. The membership of

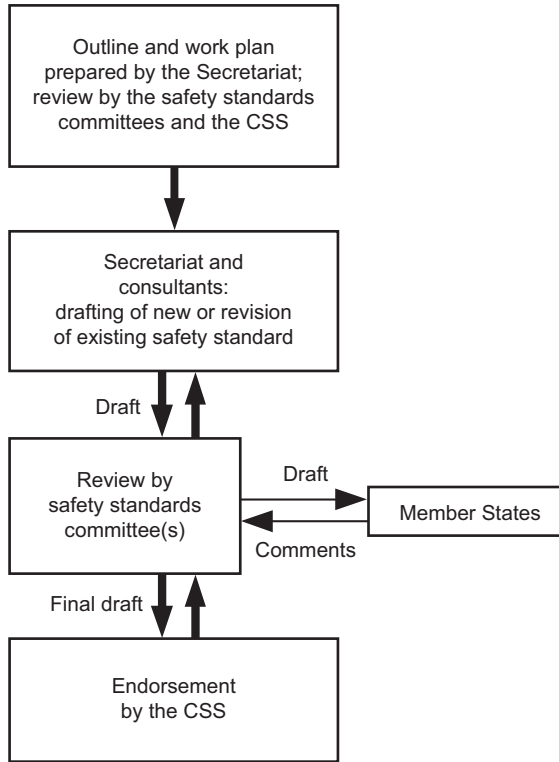


FIG. 2. The process for developing a new safety standard or revising an existing standard.

the Commission on Safety Standards is appointed by the Director General and includes senior governmental officials having responsibility for establishing national standards.

A management system has been established for the processes of planning, developing, reviewing, revising and establishing the IAEA safety standards. It articulates the mandate of the IAEA, the vision for the future application of the safety standards, policies and strategies, and corresponding functions and responsibilities.

## INTERACTION WITH OTHER INTERNATIONAL ORGANIZATIONS

The findings of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the recommendations of international

expert bodies, notably the International Commission on Radiological Protection (ICRP), are taken into account in developing the IAEA safety standards. Some safety standards are developed in cooperation with other bodies in the United Nations system or other specialized agencies, including the Food and Agriculture Organization of the United Nations, the United Nations Environment Programme, the International Labour Organization, the OECD Nuclear Energy Agency, the Pan American Health Organization and the World Health Organization.

## INTERPRETATION OF THE TEXT

Safety related terms are to be understood as defined in the IAEA Safety Glossary (see <http://www-ns.iaea.org/standards/safety-glossary.htm>). Otherwise, words are used with the spellings and meanings assigned to them in the latest edition of The Concise Oxford Dictionary. For Safety Guides, the English version of the text is the authoritative version.

The background and context of each standard in the IAEA Safety Standards Series and its objective, scope and structure are explained in Section 1, Introduction, of each publication.

Material for which there is no appropriate place in the body text (e.g. material that is subsidiary to or separate from the body text, is included in support of statements in the body text, or describes methods of calculation, procedures or limits and conditions) may be presented in appendices or annexes.

An appendix, if included, is considered to form an integral part of the safety standard. Material in an appendix has the same status as the body text, and the IAEA assumes authorship of it. Annexes and footnotes to the main text, if included, are used to provide practical examples or additional information or explanation. Annexes and footnotes are not integral parts of the main text. Annex material published by the IAEA is not necessarily issued under its authorship; material under other authorship may be presented in annexes to the safety standards. Extraneous material presented in annexes is excerpted and adapted as necessary to be generally useful.



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# 1. INTRODUCTION

## BACKGROUND

1.1. The fundamental safety objective established in IAEA Safety Standards Series No. SF-1, Fundamental Safety Principles [1], is “to protect people and the environment from harmful effects of ionizing radiation.” It applies to all circumstances that give rise to radiation risks. The fundamental safety objective is associated with ten safety principles [1]. Virtually all of these safety principles touch on the protection of members of the public and the environment. Principle 7 in particular states that: “People and the environment, present and future, must be protected against radiation risks.”

1.2. General requirements designed to protect members of the public and the environment from harmful effects of ionizing radiation are established in IAEA Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [2]. The requirements for the governmental, legal and regulatory framework to be used are established in IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety [3]. The requirements for emergency preparedness and response are established in IAEA Safety Standards Series No. GSR Part 7, Preparedness and Response for a Nuclear or Radiological Emergency [4].

1.3. Radiation protection has been largely focused on the protection of humans and, for this purpose, three basic categories of exposure have been considered, namely occupational exposure, medical exposure and public exposure. The relevant radiation protection requirements are defined according to the exposure situation, namely planned exposure situations, emergency exposure situations and existing exposure situations.

1.4. Public exposure is defined as exposure incurred by members of the public due to sources in planned exposure situations, emergency exposure situations and existing exposure situations, excluding any occupational exposure or medical exposure [2]. GSR Part 3 [2] defines a member of the public as “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.” GSR Part 3 [2] defines a representative person as “an individual receiving a dose that is representative of the doses to the more highly exposed individuals in the population.”

1.5. In recent years, consideration has also been given to the protection of the environment. As noted by the International Commission on Radiological Protection (ICRP) [5–7], some national regulatory frameworks have already addressed the need to be able to demonstrate that the environment is protected against harmful effects of ionizing radiation, irrespective of any human connection with the environment. The methods and criteria for radiological assessments are being developed and will continue to evolve.

1.6. This Safety Guide provides generic guidance on the application of the requirements of GSR Part 3 [2] and GSR Part 7 [4] in relation to the protection of members of the public in planned exposure situations, existing exposure situations and emergency exposure situations and protection of the environment that is applicable for all facilities and activities.

## OBJECTIVE

1.7. The objective of this Safety Guide is to provide generic guidance on the application of the requirements for the protection of members of the public against radiation exposure and protection of the environment established in GSR Part 3 [2] and GSR Part 7 [4]. It is intended for use by:

- (a) Governments;
- (b) Regulatory bodies;
- (c) Registrants and licensees, or the person or organization responsible for facilities and activities for which notification only is required in planned exposure situations;
- (d) Those persons or organizations designated to deal with emergency exposure situations or existing exposure situations.

## SCOPE

1.8. This Safety Guide covers the generic application of the requirements given in GSR Part 3 [2] that relate to the protection of the environment and protection of members of the public in planned exposure situations and existing exposure situations and in GSR Part 3 [2] and GSR Part 7 [4] in emergency exposure situations.

1.9. This Safety Guide does not deal with the application of the requirements in GSR Part 3 [2] to specific types of facility or activity or in specific exposure situations. In this context, separate Safety Guides exist or are under development, such as:

- For planned exposure situations:
  - IAEA Safety Standards Series No. GSG-5, Justification of Practices, Including Non-Medical Human Imaging [8];
  - IAEA Safety Standards Series No. GSG-10, Prospective Radiological Environmental Impact Assessment for Facilities and Activities [9];
  - IAEA Safety Standards Series No. GSG-9, Regulatory Control of Radioactive Discharges to the Environment [10];
  - IAEA Safety Standards Series No. SSG-36, Radiation Safety for Consumer Products [11];
- For emergency exposure situations:
  - IAEA Safety Standards Series No. GSG-2, Criteria for Use in Preparedness and Response for a Nuclear or Radiological Emergency [12];
  - IAEA Safety Standards Series No. GS-G-2.1, Arrangements for Preparedness for a Nuclear or Radiological Emergency [13];
- For existing exposure situations:
  - IAEA Safety Standards Series No. WS-G-3.1, Remediation Process for Areas Affected by Past Activities and Accidents [14];
  - IAEA Safety Standards Series No. SSG-32, Protection of the Public against Exposure Indoors due to Radon and Other Natural Sources of Radiation [15].

1.10. Occupational exposure and medical exposure are not considered in this Safety Guide; the relevant recommendations are provided in IAEA Safety Standards Series No. GSG-7, Occupational Radiation Protection [16] and in IAEA Safety Standards Series No. SSG-46, Radiation Protection and Safety in Medical Uses of Ionizing Radiation [17].

## STRUCTURE

1.11. Section 2 provides an overview of the basic framework for radiation protection of members of the public and protection of the environment in planned exposure situations, emergency exposure situations and existing exposure situations. It covers the principles of justification, optimization of protection and dose limits, where appropriate. Section 3 deals with the practical application of the

radiation protection framework for protection of the public in planned exposure situations, emergency exposure situations and existing exposure situations. Section 4 provides guidance on meeting the requirements of GSR Part 3 [2] for protection of the environment. The Appendix summarizes the framework for dose constraints and reference levels as applicable for each exposure situation, in accordance with GSR Part 3 [2].

## **2. FRAMEWORK FOR THE PROTECTION OF THE PUBLIC AND PROTECTION OF THE ENVIRONMENT**

### INTRODUCTION

2.1. Paragraph 2.15 of GSR Part 3 [2] requires the scope of applicability of the legal and regulatory framework to be specified. The regulatory framework established in GSR Part 3 [2] applies to all situations involving radiation exposure that is amenable to control. Exposures that are deemed to be unamenable to control are excluded from the regulatory framework. Examples of exposures that are unamenable to control are  $^{40}\text{K}$  in the body and cosmic radiation at the surface of the Earth.

2.2. GSR Part 3 [2] establishes requirements for each of the three exposure situations: planned exposure situations, emergency exposure situations and existing exposure situations. In addition, in the context of emergency exposure situations, GSR Part 7 [4] establishes requirements for an adequate level of preparedness and response for a nuclear or radiological emergency.

### EXPOSURE SITUATIONS

#### **Planned exposure situations**

2.3. A planned exposure situation is a situation of exposure that arises from the planned operation of a source or from a planned activity that results in an exposure due to a source. Since provision for protection and safety can be made before embarking on the activity concerned, the associated exposures and their likelihood of occurrence can be restricted from the outset. The primary means

of controlling exposure in planned exposure situations is by good design of facilities, equipment and operating procedures, by training and by fostering safety culture [2, 18].

2.4. In planned exposure situations, exposure at some level can be expected to occur. If exposure is not expected to occur with certainty, but could result from an anticipated operational occurrence or accident or owing to an event or a sequence of events that may potentially occur but is not certain to occur, this is referred to as ‘potential exposure’. The magnitude and extent of potential exposure can usually be predicted. Both exposures expected to occur and potential exposures can and should be taken into account at the planning or design stage.

2.5. A term closely related to planned exposure situation is the term practice, which is defined as any human activity that introduces additional sources of radiation or additional exposure pathways, or that modifies the network of exposure pathways from existing sources, so as to increase the exposure or the likelihood of exposure of people or the number of people exposed [19]. Both terms are used in GSR Part 3 [2], although the term ‘planned exposure situation’ emphasizes the planned or intentional nature of the facility or activity that may give rise to radiation exposure.

### **Emergency exposure situations**

2.6. 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 [2]. Preventive measures and mitigatory actions have to be considered before an emergency exposure situation arises. However, once an emergency exposure situation actually arises, exposures can be reduced only by implementing protective actions.

### **Existing exposure situations**

2.7. An existing exposure situation is a situation of exposure that already exists when a decision on the need for control needs to be taken [2]. Existing exposure situations include situations of exposure to natural background radiation. They also include situations of exposure due to residual radioactive material that derives from past practices that were never subject to regulatory control or that were subject to regulatory control but not in accordance with the requirements of current standards, situations of exposure due to residual radioactive material deriving from a nuclear or radiological emergency after an emergency has been

declared to be ended, and situations of exposure due to commodities incorporating radionuclides from such material.

## RADIATION PROTECTION PRINCIPLES

2.8. The three basic principles that underpin radiation protection, which concern justification, optimization of protection and safety, and application of dose limits, are expressed in Safety Principles 4, 5, 6 and 10 of SF-1 [1]. The principles of justification and optimization of protection and safety relate to sources of ionizing radiation and apply to all exposure situations. The principle of application of dose limits relates to individuals and applies to public exposure in planned exposure situations only. Requirement 1 of GSR Part 3 [2] requires that those responsible for protection and safety ensure that these principles of radiation protection are applied for all exposure situations.

### **Justification**

2.9. Paragraph 2.8 of GSR Part 3 [2] states that “For planned exposure situations, each party with responsibilities for protection and safety shall ensure, when relevant requirements apply to that party, that no practice is undertaken unless it is justified.”

2.10. Paragraph 2.9 of GSR Part 3 [2] states that:

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

2.11. For planned exposure situations, justification is the process of determining whether a practice is, overall, beneficial, i.e. whether the expected benefits to individuals and to society from introducing or continuing the practice outweigh the harm (including radiation detriment) resulting from the practice [19]. The benefits apply to individuals and society as a whole, and include benefits to the environment. Radiation detriment may only be a small part of the total harm. Justification thus goes far beyond the scope of radiation protection, and also involves the consideration of economic, societal and environmental factors [5].



2.12. For emergency exposure situations, when considering the justification of proposed protective actions and the overall protection strategy, para. 4.29 of GSR Part 7 [4] states that:

“Each protective action, in the context of the protection strategy, and the protection strategy itself shall be demonstrated to be justified (i.e. to do more good than harm), with account taken not only of those detriments that are associated with radiation exposure but also of those detriments associated with impacts of the actions taken on public health, the economy, society and the environment.”

2.13. Decisions regarding justification should be taken at a sufficiently high governmental level to enable all of the considerations that may be related to the benefits and detriments to be integrated. Thus, while the regulatory body or other national authority concerned with radiation protection should be responsible for evaluating the assessment of the radiation detriment, it may not be in a position to make the justification decision. Any justification decision should therefore always involve a consideration of the radiation doses either to be incurred or to be averted or reduced according to the circumstances. In planned exposure situations, radiation risks from potential exposures are also required to be considered in the justification decision.

### **Optimization of protection and safety**

2.14. Paragraph 2.10 of GSR Part 3 [2] states that “For all exposure situations, each party with responsibilities for protection and safety shall ensure, when relevant requirements apply to that party, that protection and safety is optimized.”

2.15. In this context ‘protection and safety is optimized’ means that optimization of protection and safety has been applied and the result of that process has been implemented.

2.16. Optimization of protection and safety is defined as the process for 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 (ALARA), economic and social factors being taken into account [19]. This means that the level of protection would be the best possible under the prevailing circumstances, and will thus not necessarily be the option with the lowest risk or dose. Protection of the environment should also be considered in the process of optimization of protection and safety.

2.17. Protection and safety should be optimized through an on-going cyclical approach that involves:

- (a) Evaluation of the exposure situation to identify the need for action;
- (b) Identification of possible protective actions to keep the exposure as low as reasonably achievable;
- (c) Selection of the best protective actions under the prevailing circumstances;
- (d) Implementation of the selected protective actions;
- (e) Regular review of the exposure situation to evaluate whether the prevailing circumstances necessitate any changes to the selected protective actions.

2.18. For planned exposure situations, Requirement 11 of GSR Part 3 [2] states that **“The government or the regulatory body shall establish and enforce requirements for the optimization of protection and safety, and registrants and licensees shall ensure that protection and safety is optimized.”** Paragraph 3.23 of GSR Part 3 [2] requires registrants and licensees to ensure that protection and safety is optimized.

2.19. For emergency exposure situations, Requirement 44 of GSR Part 3 [2] and Requirement 5 of GSR Part 7 [4] require the government to ensure that protection strategies are developed, justified and optimized at the stage for taking protective actions and other response actions effectively. Paragraph 4.31 of GSR Part 7 [4] states further that the government is also required to ensure that the protection strategy is implemented safely and effectively in an emergency response through the implementation of emergency arrangements.

2.20. For existing exposure situations, Requirement 48 of GSR Part 3 [2] requires the government and the regulatory body or other relevant authority to ensure that protection and safety is optimized.

2.21. In all three exposure situations, the processes of justification and optimization should, when possible, include consultation with interested parties, such as community groups, local residents and members of the public.

#### *Boundary conditions for optimization*

2.22. Optimization of protection is a prospective, iterative process that examines the available options for protection. Depending upon the circumstances, the process can include the use of a variety of quantitative and qualitative techniques. Optimization should be conducted within a set of boundary conditions on the range of available protection options. These boundary conditions should include

individual source related values of dose or risk that may be regarded as values that should not be exceeded for planning purposes. They are referred to as dose constraints or risk constraints in the case of planned exposure situations and as reference levels in the case of emergency exposure situations or existing exposure situations.

2.23. A constraint is 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 condition in defining the range of options in optimization.

2.24. A dose constraint is a level of dose above which it is unlikely that protection is optimized. It represents a basic level of protection and will always be lower than the pertinent dose limit. However, treating a dose constraint as a target value is not sufficient, and it is expected that optimization of protection will establish an acceptable level of dose below the dose constraint.

2.25. Risk constraints correspond to dose constraints but apply to potential exposure. A 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 such a dose. The risk constraint should equate to a similar health risk to that implied by the corresponding dose constraints for the same source [5, 20]. However, there can be large uncertainties in estimations of the probabilities and the resulting dose, which should be taken into account at the time of defining and using the risk constraints for decision making or decision aiding.

2.26. Reference level is defined as, for an emergency exposure situation or an existing exposure situation, the level of dose, risk or activity concentration above which it is not appropriate to plan to allow exposures to occur and below which optimization of protection and safety would continue to be implemented [19]. The value chosen for a reference level will depend upon the prevailing circumstances for the exposure under consideration. In practice, reference levels for some situations are likely to be established on the basis of one or more exposure scenarios. As such, the chosen reference levels are dependent on the assumptions used in their determination, and may not be universally applicable.

2.27. In an emergency exposure situation or in an existing exposure situation, actual exposures could be above or below the reference level. The reference level

should then be used as a benchmark for judging the extent to which protective actions are necessary and to assist in prioritizing their application. Optimization of protection and safety is to be applied even if the initial estimates of the doses received are below the defined reference levels, if justified and optimized actions are available to reduce exposures. Further recommendations on the application of the concept of the reference level in an emergency exposure situation for dosimetric purposes, in addition to the use of generic criteria, are given in Section 3.

2.28. In an emergency exposure situation or in an existing exposure situation, the implementation of optimized protection strategies should result in levels of dose, risk or activity concentration below the reference level and as low as reasonably achievable, as long as these protection strategies are justified, with account taken of national factors.

2.29. The requirements of GSR Part 3 [2] for optimization of protection and safety, including the use of dose constraints and reference levels, for each of the three exposure situations, are presented in Section 3 of this Safety Guide. A table summarizing the values for the dose constraints and for reference levels as applicable for each exposure situation as required in GSR Part 3 [2] is presented in the Appendix.

### **Dose limits**

2.30. Paragraph 2.11 of GSR Part 3 [2] states that:

“For planned exposure situations other than for medical exposure, each party with responsibilities for protection and safety shall ensure that, when relevant requirements apply to that party, specified dose limits are not exceeded”.

2.31. Dose limits apply for exposure of workers and for public exposure in planned exposure situations only. Dose limits for members of the public are presented in Section 3. Dose limits do not apply for medical exposures. The annual effective dose to members of the public, for comparison with the dose limit for effective dose, is the sum of the effective dose from external exposure in one year and the committed effective dose from intakes within the same year.

2.32. Doses to members of the public are usually not assessed by individual monitoring, as for occupational exposure, but are generally estimated using

the predictions of models that simulate the transport of radionuclides in the environment combined with data on habits of members of the public for relevant exposure scenarios and dose coefficients.

## RESPONSIBILITIES

### **Responsibilities of the government**

2.33. The responsibilities of the government with regard to protection and safety for all three exposure situations are established in general terms in paras 2.13–2.28 of GSR Part 3 [2]. These include:

- (a) Establishing an effective legal and regulatory framework for protection and safety in all exposure situations;
- (b) Establishing legislation that meets specified requirements;
- (c) Establishing an independent regulatory body with the necessary legal authority, competence and resources;
- (d) Establishing requirements for education and training in protection and safety;
- (e) Ensuring arrangements are in place for the provision of technical services and education and training services.

2.34. The responsibilities of the government or the regulatory body with regard to protection of the public in planned exposure situations are set out in Requirement 29 and in paras 3.118–3.121 and 3.124 of GSR Part 3 [2]. These responsibilities include:

- (a) Establishing the responsibilities of registrants, licensees and suppliers and of providers of consumer products in relation to the application of requirements for public exposure in planned exposure situations;
- (b) Establishing and enforcing requirements for the optimization of protection and safety, including establishing or approving constraints on dose and constraints on risk to be used in the optimization of protection and safety for members of the public;
- (c) Establishing dose limits for public exposure in planned exposure situations.

2.35. The responsibilities of the government for protection of the public in emergency exposure situations are set out in Requirements 43 and 44 of

GSR Part 3 [2] in general terms, and in greater detail in GSR Part 7 [4]. Some of the responsibilities of the government include:

- (a) Establishing an integrated and coordinated emergency management system;
- (b) Developing justified and optimized protection strategies at the preparedness stage;
- (c) Ensuring safe and effective implementation of emergency arrangements in accordance with the protection strategy.

In addition to assigning responsibilities to the government in general terms, GSR Part 3 [2] and GSR Part 7 [4] assign specific responsibilities in emergency preparedness and response to response organizations.

2.36. The responsibilities of the government for protection of the public in existing exposure situations are set out in Requirements 47, 48, 49 and 50 of GSR Part 3 [2]. The government is required to ensure that existing exposure situations that have been identified are evaluated to determine which public exposures are of concern from the point of view of radiation protection, and to ensure that remedial actions and protective actions are justified and that protection and safety is optimized. The government is required to ensure that provision for the management of existing exposure situations is included in the legal and regulatory framework for protection and safety. The government, in the legal and regulatory framework, is required to assign responsibilities for the establishment and implementation of protection strategies to the regulatory body and to other relevant authorities, and, as appropriate, to registrants, licensees and other parties involved in the implementation of remedial actions and protective actions.

### **Responsibilities of the regulatory body**

2.37. The responsibilities of the regulatory body with regard to protection and safety that are applicable to all three exposure situations are set out in Requirements 16–36 of GSR Part 1 (Rev. 1) [3] and in Requirement 3 and paras 2.29–2.38 of GSR Part 3 [2]. These responsibilities include:

- (a) Establishing requirements for applying the principles of radiation protection;
- (b) Establishing a regulatory system that meets specified requirements;
- (c) Ensuring the application of the requirements for education and training in protection and safety;

- (d) Specifying acceptance requirements and performance requirements for protection and safety;
- (e) Making provision for the establishment and maintenance of records.

2.38. The responsibilities of the regulatory body specific to protection of the public in planned exposure situations are set out in Requirements 29 and 32, and in paras 3.118–3.124, 3.135, 3.136, and 3.139 of GSR Part 3 [2]. The regulatory body is responsible for enforcing compliance with the dose limits for public exposure; for authorization of practices; for establishing or approving authorized limits for discharges; for ensuring that programmes for source monitoring and environmental monitoring are in place, and that the results from the monitoring are recorded and are made available; and for authorizing the provision to the public of consumer products.

2.39. The responsibilities of the regulatory body in relation to emergency preparedness and response are set out in paras 4.11–4.15 of GSR Part 7 [4]. These responsibilities include:

- (a) Ensuring that arrangements for preparedness and response to a nuclear or radiological emergency are dealt with through the regulatory process;
- (b) Establishing or adopting regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based;
- (c) Requiring that arrangements for preparedness and response for a nuclear or radiological emergency be in place for the on-site area for any regulated facility or activity that could necessitate emergency response actions;
- (d) Establishing reference levels;
- (e) Ensuring that the on-site emergency arrangements are adequate;
- (f) Ensuring that the operating organization is given sufficient authority to promptly take necessary protective actions on the site in response to a nuclear or radiological emergency.

2.40. The responsibilities of the regulatory body or other relevant authority specific to protection of the public in existing exposure situations are set out in paras 5.4 and 5.5 and in Requirements 48 and 51 of GSR Part 3 [2]. These responsibilities include:

- (a) Establishing and implementing a protection strategy for an existing exposure situation commensurate with the associated radiation risks;
- (b) Ensuring that remedial actions or protective actions are expected to yield sufficient benefits to outweigh the detriments associated with taking them;

- (c) Ensuring that the form, scale and duration of remedial actions or protective actions are optimized;
- (d) Establishing reference levels for exposure due to radionuclides in commodities;
- (e) Establishing reference levels and reviewing them periodically.

2.41. It is the responsibility of the regulatory body in relation to protection of the environment to specify requirements for the prospective assessment of radiological environmental impacts, as set out in para. 3.9(e) of GSR Part 3 [2].

### **Responsibilities of registrants and licensees, and operating organizations**

2.42. Requirement 4 of GSR Part 3 [2] states that **“The person or organization responsible for facilities and activities that give rise to radiation risks shall have the prime responsibility for protection and safety.”**

2.43. Requirement 9 of GSR Part 3 [2] states that **“Registrants and licensees shall be responsible for protection and safety in planned exposure situations.”**

2.44. Registrants and licensees are required to ensure that protection and safety is optimized and that relevant constraints are used in the optimization of protection and safety for any source within a practice (paras 3.23 and 3.25 of GSR Part 3 [2]).

2.45. Registrants and licensees are required to ensure that exposures of individuals due to practices for which registrants and 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 Schedule III of GSR Part 3 [2].

2.46. Registrants and licensees are required to ensure that programmes for source monitoring and environmental monitoring are in place and that the results from the monitoring are recorded and are made available [2].

2.47. In GSR Part 7 [4], the term ‘operating organization’ is used in this context. The responsibilities of the operating organization in relation to emergency preparedness and response are set out in GSR Part 7 [4], particularly in paras 4.16 and 4.17.



2.48. Further recommendations on the responsibilities of the government, the regulatory body and other national authorities, and of the registrant or licensee or operating organization are provided in Section 3 and in Section 4.

## GRADED APPROACH

2.49. GSR Part 3 [2] establishes requirements for a graded approach to be taken to the control of exposures. In particular, para. 2.12 of GSR Part 3 [2] states: “The application of the requirements for the system of protection and safety shall be commensurate with the radiation risks associated with the exposure situation.”

2.50. It is the general responsibility of the government to ensure that the overall application of the principles of radiation protection are in line with this graded approach (see para. 2.18 of GSR Part 3 [2]). The regulatory body is responsible for adopting the graded approach in the application of the regulatory requirements (see para. 2.31 of GSR Part 3 [2]).

2.51. Requirement 6 of GSR Part 3 [2] refers to the graded approach in the context of planned exposure situations, as follows:

**“The application of the requirements of [GSR Part 3 [2]] in planned exposure situations shall be commensurate with the characteristics of the practice or the source within a practice, and with the likelihood and magnitude of exposures.”**

An important feature of the graded approach in planned exposure situations is the provision for exemption and clearance, and for notification, authorization by registration and authorization by licensing. These concepts are discussed further in Section 3.

2.52. Requirement 4 of GSR Part 7 [4] states that **“The government shall ensure that a hazard assessment is performed to provide a basis for a graded approach in preparedness and response for a nuclear or radiological emergency.”**

2.53. Paragraph 5.7 of GSR Part 3 [2] states that:

“The government and the regulatory body or other relevant authority shall ensure that the protection strategy for the management of existing exposure

situations ... is commensurate with the radiation risks associated with the existing exposure situation”.

2.54. The application of a graded approach in each exposure situation is discussed further in Section 3.

### 3. RADIATION PROTECTION OF THE PUBLIC

#### PLANNED EXPOSURE SITUATIONS

##### **Introduction**

3.1. Paragraphs 3.1–3.4 of GSR Part 3 [2] set out the practices and sources within practices that are included in the scope of planned exposure situations. Practices include:

- (a) The production, supply, provision and transport of radioactive material and of devices that contain radioactive material;
- (b) The production and supply of devices that generate radiation;
- (c) The generation of nuclear power, including any activities within the nuclear fuel cycle that involve or that could involve exposure to radiation or exposure due to radioactive material;
- (d) The use of radiation or radioactive material for medical, industrial, veterinary, agricultural, legal or security purposes;
- (e) The use of radiation or radioactive material for education, training or research;
- (f) The mining and processing of raw materials that involve exposure due to radioactive material;
- (g) Any other practice as specified by the regulatory body.

3.2. Sources within practices include:

- (a) Facilities that contain radioactive material and facilities that contain radiation generators, such as nuclear installations, medical radiation facilities, facilities for the management of radioactive waste and mineral extraction and processing facilities;
- (b) Individual sources of radiation, including the sources within the types of facility mentioned in para. 3.2(a).

3.3. In GSR Part 3 [2], exposure due to natural sources is generally considered to be an existing exposure situation. However, para. 3.4 of GSR Part 3 [2] states that the relevant requirements for planned exposure situations apply, inter alia, to:

- (a) Exposure due to material in any practice where the activity concentration in the material of any radionuclide in the uranium decay chain, the actinium decay chain or the thorium decay chain is greater than 1 Bq/g or the activity concentration of  $^{40}\text{K}$  is greater than 10 Bq/g (exposure situations due to radionuclides of natural origin in food, feed, drinking water, agricultural fertilizer and soil amendments, construction material and existing residues should be treated as existing exposure situations);
- (b) Public exposure due to discharges or due to the management of radioactive waste arising from a practice involving material as specified in para. 3.3(a).

3.4. Public exposures in planned exposure situations arise from:

- (a) Liquid and airborne discharges from facilities and activities (see GSG-9 [10]);
- (b) Direct radiation from sources within practices, e.g. X ray equipment in a medical facility, a patient released from hospital after radionuclide therapy, industrial radiography, the transport of radioactive material, the management of solid radioactive waste;
- (c) Consumer products (see SSG-36 [11]).

3.5. Paragraph 3.78 of GSR Part 3 [2] states that:

“Employers, registrants and licensees 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.”

Therefore the dose limits and dose constraints for exposure of members of the public apply for such workers.

3.6. For sources that are included in the regulatory system, appropriate tools for application of the requirements for radiation protection and safety, based on a graded approach, are exemption and clearance, notification, and authorization; authorization may take the form of either registration or licensing.

## Exemption and clearance

3.7. Exemption is defined as the determination by a regulatory body that a source or practice need not be subject to some or all aspects of regulatory control on the basis that the exposure and the potential exposure due to the source or practice are too small to warrant the application of those aspects or that this is the optimum option for protection irrespective of the actual level of the doses or risks [2]. Only justified practices may be exempted.

3.8. The general criteria for exemption, specified in para I.1 of Schedule I of GSR Part 3 [2], are that:

- (a) “Radiation risks arising from the practice or from a source within the practice are sufficiently low as not to warrant regulatory control, with no appreciable likelihood of situations arising that could lead to a failure to meet the general criterion for exemption; or
- (b) Regulatory control of the practice or the source would yield no net benefit, in that no reasonable measures for regulatory control would achieve a worthwhile return in terms of reduction of individual doses or of health risks.”

3.9. Under these criteria, a practice or a source within a practice may be exempted without further consideration from some or all of the requirements of GSR Part 3 [2] provided that the effective dose expected to be incurred by any individual (para. I.2 of GSR Part 3 [2]) owing to the exempt practice or the exempt source within the practice:

- Is of the order of 10  $\mu$ Sv or less in a year under all reasonably foreseeable circumstances;
- Does not exceed 1 mSv in a year for low probability scenarios<sup>1</sup>.

3.10. Clearance is defined as the removal of regulatory control by the regulatory body from radioactive material or radioactive objects within notified or authorized practices. The general criteria for clearance parallel those for exemption, are also specified in para. I.10 of Schedule I of GSR Part 3 [2] and are that:

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<sup>1</sup> The individual dose criterion for low probability scenarios is based on the assumption that the probability of occurrence of such a scenario does not exceed  $10^{-2}$  per year [21].

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

3.11. Under these criteria, material may be cleared without further consideration under the terms of para. 3.10(a) provided that in reasonably foreseeable circumstances the effective dose expected to be incurred by any individual owing to the cleared material is of the order of 10  $\mu$ Sv or less in a year. To take into account low probability scenarios, a different criterion can be used, namely that the effective dose expected to be incurred by any individual for such low probability scenarios does not exceed 1 mSv in a year.

3.12. Based on the criteria for exemption and clearance, table I.1 of GSR Part 3 [2] presents activity concentrations and activities of radionuclides for moderate amounts of material that may be exempted without further consideration from some or all of the requirements of GSR Part 3 [2]. Table I.2 of GSR Part 3 [2] presents activity concentrations of radionuclides of artificial origin for bulk amounts of solid material that may be exempted without further consideration and solid material that can be cleared without further consideration.

3.13. Paragraph I.3(c) of GSR Part 3 [2] provides for the exemption of radiation generators of a type approved by the regulatory body, and para. I.6 of GSR Part 3 [2] provides for the exemption of equipment containing radioactive material if it is of a type approved by the regulatory body and the material is not otherwise exempted on the basis of its activity (table I.1 of GSR Part 3 [2]).

3.14. The provision in para. I.6 of GSR Part 3 [2] for the exemption of equipment containing sealed radioactive sources can be applied to consumer products. While a limit applies to the dose rate outside the equipment, no limit is specified in terms of the activity of the sealed source. Thus, for example, smoke detectors containing ionization chambers with higher levels of activity than those specified for exemption can still be exempted without further consideration provided that the conditions stipulated by the regulatory body in respect of dose rate and other criteria are met and they are of a type approved by the regulatory body [11].

3.15. Schedule I of GSR Part 3 [2] also provides for the exemption and clearance of material containing radionuclides of natural origin. Table I.3 of GSR Part 3 [2] establishes activity concentration levels for material containing natural radionuclides that may be cleared without further consideration. Based on a dose criterion of the order of 1 mSv, commensurate with typical doses due to natural background levels of radiation, para. I.4 of GSR Part 3 [2] provides for the exemption of bulk amounts of material on a case-by-case basis and para. I.12(c) of GSR Part 3 [2] provides for the clearance of residues for recycling into construction materials or for which disposal is liable to cause the contamination of drinking water supplies.

3.16. Further guidance on exemption and clearance may be found in IAEA Safety Standards Series No. RS-G-1.7, Application of the Concepts of Exclusion, Exemption and Clearance [22].

### **Notification and authorization**

3.17. Within a graded approach for protection of the public and the environment, notification to the regulatory body alone:

“is sufficient provided that the exposures expected to be associated with the practice or action are unlikely to exceed a small fraction, as specified by the regulatory body, of the relevant limits, and that the likelihood and magnitude of potential exposures and any other potential detrimental consequences are negligible” (para. 3.7 of GSR Part 3 [2]).

3.18. The exposure and risk associated with activities subject to notification is, by definition, so small as not to warrant many or sometimes any additional control measures to ensure the protection of the public and protection of the environment. Decisions regarding the use of notification alone should be based on a generic assessment of safety. The doses expected from notified activities should be sufficiently low that there is no need for further consideration regarding public exposures or for investigations or assessments with respect to environmental protection. Notification is not required for exempted sources or practices.

3.19. Paragraph 3.8 of GSR Part 3 [2] states that:

“Any person or organization intending to carry out any of the actions specified in para. 3.5 [of GSR Part 3 [2]<sup>2</sup>] shall, unless notification alone is sufficient, apply to the regulatory body for authorization, which shall take the form of either registration or licensing.”

3.20. The acceptance that a certain kind of practice is suitable for registration is determined by the regulatory body, which also determines the accompanying conditions (e.g. provision of working procedures, training of personnel, design of the equipment). The exposures, and potential exposures, of the public, and the radiological environmental impact from a source that is registered should be inherently small, so that separate investigations or assessments by the registrant for demonstrating safety are not needed.

3.21. Licensing is the most complete and sophisticated form of authorization. In principle, a licence should be required for higher risk or more complex practices, including those for which radiation protection and safety depend significantly or largely on human performance.

3.22. The applicant for an authorization is required by GSR Part 3 [2] to provide the regulatory body with relevant information necessary to support the application, which includes:

- (a) An assessment of the nature, likelihood and magnitude of the exposures due to the source in normal operation and a description of all necessary measures for protection and safety;
- (b) A safety assessment, as required by the regulatory body;
- (c) An appropriate prospective assessment made for radiological environmental impacts, commensurate with the radiation risks associated with the facility or activity, as required by the regulatory body.

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<sup>2</sup> Paragraph 3.5 of GSR Part 3 [2] states that:

“No person or organization shall adopt, introduce, conduct, discontinue or cease a practice, or shall, as applicable, mine, extract, process, design, manufacture, construct, assemble, install, acquire, import, export, supply, provide, distribute, loan, hire, receive, site, locate, commission, possess, use, operate, maintain, repair, transfer, decommission, disassemble, transport, store or dispose of a source within a practice other than in accordance with the requirements of [GSR Part 3 [2]].”

GSG-10 [9] provides guidance on how to evaluate exposures and on the use of criteria for the assessment of radiological environmental impact for planned exposure situations.

3.23. A graded approach should be used within licensing that takes into account the expected likelihood and magnitude of exposures in normal operation and of potential exposures, the complexity of the practice, and the protection and control measures needed. The graded approach should be reflected in the content and extent of the safety assessment and the assessment for radiological environmental impact. The regulatory body should evaluate the results of the assessments to determine possible additional conditions on which a licence can be granted.

3.24. A source within a practice could also cause public exposure outside the territory or other area under the jurisdiction or control of the State in which the source is located. In accordance with para. 3.124 of GSR Part 3 [2], in such situations, the government or the regulatory body:

- “(a) Shall ensure that the assessment for radiological impacts includes those impacts outside the territory or other area under the jurisdiction or control of the State;
- (b) Shall, to the extent possible, establish requirements for the control of discharges;
- (c) Shall arrange with the affected State the means for the exchange of information and consultations, as appropriate.”

### **Justification**

3.25. Requirement 10 of GSR Part 3 [2] requires the government or the regulatory body to ensure that only justified practices are authorized. Justification is implemented as a structured process to determine whether the benefits from a practice outweigh the harm (including radiation detriment) to individuals, society and the environment from the practice. This process should be repeated if necessary when there is new information or experience.

3.26. Paragraph 3.17 of GSR Part 3 [2] defines a number of practices that are deemed to be not justified. These are as follows:

- “(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, 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 consumer products such as toys and personal jewellery or adornments, which result in an increase in activity, by the deliberate addition of radioactive substances or by activation;
  - (c) Human imaging using radiation that is performed as a form of art or for publicity purposes.”

3.27. One consideration in justification is the possibility of alternative methods that do not involve the use of radiation or radioactive material. All alternative methods will have their own costs and benefits. Thus, the mere existence of an alternative method should not be used as a reason for deciding that the type of practice involving the use of radiation is not justified. Nevertheless, if such comparisons with ‘non-radioactive’ alternatives or ‘non-radiation-emitting’ alternatives are necessary, they should be undertaken with appropriate caution. The methods should be judged on the basis of their effectiveness in accomplishing the intended objective.

3.28. Decisions regarding the justification of a particular type of practice should take account of exposures in all the relevant categories of exposure (occupational exposure, public exposure) and, as appropriate, the assessment of the radiological environmental impact. The decision should include consideration of exposures expected to occur and the possibility of accidents (potential exposures) in operations, decommissioning and waste management. Justification should not be separately applied to one component part of a practice, such as the management of radioactive waste at a nuclear power plant.

3.29. In some States, many of the facilities and activities that produce radiation exposures may not have been subject to a formal justification process. A formal procedure of justification would normally only take place when new techniques are to be authorized for the first time. Nevertheless, the justification for any particular type of practice is required to be subject to review.

3.30. Guidance on the elements that should be considered and the process that should be followed in determining whether the introduction of a particular type of practice is justified is provided in GSG-5 [8].

## **Optimization of protection and safety**

3.31. Requirement 11 of GSR Part 3 [2] states that **“The government or the regulatory body shall establish and enforce requirements for the optimization of protection and safety, and registrants and licensees shall ensure that protection and safety is optimized.”**

3.32. Optimization of protection and safety for a planned exposure situation will include both formal reviews as part of the application and authorization process at the design and construction stage, and reviews during operation.

3.33. Optimization of protection and safety can be applied to the component parts of a particular practice and can be limited to consideration of the doses to particular groups of people. However, the boundary conditions for any analysis for the purposes of optimization should be carefully chosen since there may be consequences for other component parts of the practice or other groups of people. For instance, the costs and benefits of different effluent treatment options at a nuclear power plant should be considered in the optimization of protection of the public and protection of the environment against exposures due to radioactive discharges to the environment. Some of these options may have significant implications for the way solid wastes are stored at the facility, or for the occupational exposure of workers, which also have to be considered in the optimization process.

3.34. Optimization decisions involve many different factors, and thus may benefit from consideration in a matrix type of approach [23], where the different elements of the matrix, including protection of the public and of the environment, are considerations contributing to the overall decision.

### *Dose constraints and risk constraints*

3.35. Dose constraints should be expressed in terms of effective dose. The dose calculated for comparison with the dose constraint is the sum of the effective dose from external exposure in one year and the committed effective dose from intakes within the same year.

3.36. The dose constraint for a particular source is intended to ensure that the sum of the doses from planned operations for all sources that may contribute to the exposure of the representative person remains within the dose limit. In this respect, possible future practices should be considered at the design stage or planning stage in establishing the dose constraint.

3.37. Dose constraints for public exposure in planned exposure situations are required to be established or approved by the government or the regulatory body (para. 3.120 of GSR Part 3 [2]). The dose constraint can be proposed by the registrant or licensee or operating organization and be subject to review and approval by the regulatory body. In setting dose constraints, the characteristics of the site and of the facility or activity that are relevant for public exposure, good practices in the operation of similar sources, the dose contribution from other relevant authorized practices, the scenarios for exposure and the views of interested parties should all be considered.

3.38. Dose constraints should be established in respect of public exposure due to all sources for which an application for authorization is made, for example, for discharges to the environment during normal operation from facilities or activities or for optimizing the shielding in the design of facilities or activities (e.g. a room used for X ray imaging in a hospital or in an industrial radiography facility).

3.39. The value for the dose constraint for public exposure in a planned exposure situation should be below the dose limit for the effective dose of 1 mSv in a year. The dose limit applies to the total dose received by an individual from all sources in planned exposure situations. On the other hand, the value for the dose constraint should be higher than the exemption level established by the regulatory body, e.g. a dose of the order of 10  $\mu$ Sv in a year. Therefore, in practical terms, dose constraints should be selected within the range of 0.1 mSv to <1 mSv in a year.

3.40. The value for the dose constraint should be selected in accordance with the characteristics of the exposure. In establishing the value, the regulatory body should consider the typical number and type of radiation sources in use in the State or region. Some States may establish a generic value for the dose constraint for all sources. However, there may be circumstances that could allow for a specific value for the dose constraint for a particular source to be set by the regulatory body (see para. 3.41).

3.41. In establishing the generic value or specific value for the dose constraint, the regional contribution to the exposure of the public from existing or planned practices and other existing or planned practices in the vicinity of the source should be considered. For example, for nuclear installations, other installations on the same site should be assumed to contribute to the exposure of the representative person. In the case of facilities or activities in an urban environment (e.g. hospitals or industrial applications), more than one source could be assumed to contribute

to the exposure of the representative person. On the other hand, for facilities or activities located in remote areas, e.g. a uranium mine in an extremely remote area, the contribution from other local sources is not likely to be significant, and thus should not be included in the assessment.

3.42. Dose constraints should not be used as dose limits. More specifically, exceeding a dose constraint should not represent a regulatory infraction, as would be the case if a dose limit is exceeded. Given that the dose constraint represents a level of dose for planning measures for protection and safety, if the dose constraint is approached or exceeded in the course of operations, this should result in investigation of the situation, and development of modifications or follow-up actions that may be necessary.

3.43. 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 such a dose. Risk constraints correspond to dose constraints but apply to potential exposure [2].

3.44. Potential exposure of the public includes events resulting in an unplanned release of radioactive material to the environment (e.g. a major accident at a nuclear facility or the malicious use of radioactive material); events resulting in the loss of control of a radiation source; and events in which potential exposures could occur far into the future and doses would be delivered over long time periods (e.g. disposal facilities for radioactive waste after their closure) [5].

3.45. Paragraph 266 of ICRP Publication 103 [5] states that:

“The evaluation of potential exposures, for the purpose of planning or judging protection measures, is usually based on: a) the construction of scenarios which are intended to represent the sequence of events leading to the exposures; b) the assessment of the probabilities of each of these sequences; c) the assessment of the resulting dose; d) the evaluation of the detriment associated with that dose; e) comparison of the results with some criterion of acceptability [e.g. risk constraint]; and f) optimisation of protection which may require several iterations of the previous steps.”

3.46. Risk constraints for public exposure are required to be set by the government or the regulatory body [2]. In setting risk constraints, the characteristics of the source and of the practice, good practice in the operation of similar sources and the views of interested parties are required to be considered [2]. The government

or regulatory body should also take into account the prevailing legal, economic and social conditions in establishing risk constraints.

3.47. The ICRP recommends that risk constraints for potential exposures should equate to a similar level of health risk to that implied by the corresponding dose constraints used for normal operation of the same source [5, 20]. However, there can be large uncertainties in estimating the probability of an unintended event causing exposure. It is often sufficient to use a generic value for a risk constraint.

3.48. GSG-10 [9] presents a general framework for assessing radiological impacts to the public and for the protection of the environment, which describes the estimation of risk and the use of risk constraints for planned exposure situations.

### **Dose limits**

3.49. Requirement 12 of GSR Part 3 [2] states that: **“The government or the regulatory body shall establish dose limits for ... public exposure, and registrants and licensees shall apply these limits.”**

3.50. The dose limits for the public in planned exposure situations are set out in Schedule III of GSR Part 3 [2]. The dose limits for public exposure are:

- “(a) An effective dose of 1 mSv in a year;
- (b) In special circumstances<sup>68</sup>, a higher value of effective dose in a single year could apply, provided that the average effective dose over five consecutive years does not exceed 1 mSv per year;
- (c) An equivalent dose to the lens of the eye of 15 mSv in a year;
- (d) An equivalent dose to the skin of 50 mSv in a year.

“<sup>68</sup> For example, in authorized, justified and planned operational conditions that lead to transitory increases in exposures.”

3.51. Although averaging of effective dose over a five year period is permitted in GSR Part 3 [2], this flexibility is generally not needed in the control of public exposure in planned exposure situations. Furthermore, it is not a straightforward matter to apply such averaging, since the dose limits for public exposure are more hypothetical in nature than they are in the case of occupational exposure, where doses to specific individuals are directly assessed. Thus, a regulatory body should allow flexibility only upon application by a licensee, so that the specific circumstances can be properly addressed. If averaging is used, this should not

be done retrospectively of the date of implementation of the requirements of GSR Part 3 [2].

3.52. Dose limits are restrictions related to an individual and apply to the total dose received by an individual from all relevant sources in planned exposure situations. The calculation of the dose for purposes of comparison with the dose limit should not include the dose due to the natural background levels of radiation. Paragraph 3.27 of GSR Part 3 [2] states that:

“The government or the regulatory body shall determine what additional restrictions, if any, are required to be complied with by registrants and licensees to ensure that the dose limits ... are not exceeded owing to possible combinations of doses from exposures due to different authorized practices.”

3.53. The effective dose received by members of the public depends upon a number of factors, such as the behaviour of radionuclides in the environment and their transfer to people, the duration and rate of exposure and other relevant factors. These factors cause a wide variation in the effective dose among the exposed population. For the purpose of verifying compliance with the annual dose limit for public exposure, the dose to members of the public should be estimated for the representative person. All members of the public are considered to be adequately protected if the estimated effective dose to the representative person complies with the dose limit. The ICRP indicates that the dose to the representative person “is the equivalent of, and replaces, the mean dose in the ‘critical group’” [23].

3.54. According to Requirement 14 of GSR Part 3 [2], “**Registrants and licensees and employers shall conduct monitoring to verify compliance with the requirements for protection and safety.**” Such monitoring should provide sufficient information to determine whether the levels of public exposures comply with the dose limits and to demonstrate that protection and safety is optimized.

## EMERGENCY EXPOSURE SITUATIONS

### Introduction

3.55. The requirements in GSR Part 7 [4] and in Section 4 of GSR Part 3 [2] for emergency exposure situations apply for preparedness and response for a nuclear or radiological emergency. These requirements include those relating to the

transition from an emergency exposure situation to an existing exposure situation (Requirement 46 of GSR Part 3 [2] and para. 5.99 of GSR Part 7 [4]).

3.56. Requirement 4 of GSR Part 7 [4] requires governments to ensure that a hazard assessment is performed to provide a basis for a graded approach in emergency preparedness and response. In the hazard assessment, facilities and activities, on-site areas, off-site areas and locations are required to be identified where an emergency could warrant taking protective and other response actions, with account taken of the uncertainties in, and limitations of, the information available at the preparedness stage. Paragraph 4.19 of GSR Part 7 [4] introduces five emergency preparedness categories that establish the basis for developing generically justified and optimized arrangements for preparedness for and response to a nuclear or radiological emergency.

3.57. Paragraph 4.27 of GSR Part 7 [4] states that:

“The government shall ensure that, on the basis of the hazards identified and the potential consequences of a nuclear or radiological emergency, protection strategies are developed, justified and optimized at the preparedness stage for taking protective actions and other response actions effectively in a nuclear or radiological emergency to achieve the goals of emergency response.”

3.58. In the protection strategy for an emergency exposure situation, in order to ensure that the goals of emergency response are achieved, different actions should be considered for regaining control over the source and/or preventing exposure. These actions should be considered in terms of all possible pathways of exposure and/or the individuals who may be exposed, with account taken of the time necessary for the effective implementation of these actions. For example, in order to prevent or reduce the release of radioactive material following an accident, mitigatory actions could be taken at the source. However, if it is no longer possible to control the source or to prevent a release, actions will have to be taken in respect of the pathways or in respect of those individuals who may be exposed. In such cases, both urgent protective actions and early protective actions and other response actions are warranted, such as evacuation, sheltering, iodine thyroid blocking, relocation, and restrictions on food, milk, drinking water and other commodities.

3.59. The protection strategy and overall emergency arrangements developed in accordance with GSR Part 7 [4] should provide for the safe and effective implementation of the emergency response, particularly during the urgent phase

and the early phase of a nuclear or radiological emergency, when very little information is available. However, as the emergency evolves, such as during the transition phase, more information on the circumstances surrounding the emergency and its consequences will become available.

3.60. In the light of increased understanding on the emergency situation as it evolves, the effectiveness of actions and the overall strategy taken early in the emergency response are required to be assessed and adjusted on the basis of the prevailing conditions and the available information on the emergency. Further justified and optimized strategies should then be considered and implemented as necessary (para. 4.31 of GSR Part 7 [4]).

### **Goals of emergency response**

3.61. Paragraph 3.2 of GSR Part 7 [4] lists the goals of emergency response as follows:

- (a) “To regain control of the situation and to mitigate consequences;
- (b) To save lives;
- (c) To avoid or to minimize severe deterministic effects;
- (d) To render first aid, to provide critical medical treatment and to manage the treatment of radiation injuries;
- (e) To reduce the risk of stochastic effects;
- (f) To keep the public informed and to maintain public trust;
- (g) To mitigate, to the extent practicable, non-radiological consequences;
- (h) To protect, to the extent practicable, property and the environment;
- (i) To prepare, to the extent practicable, for the resumption of normal social and economic activity.”

These goals should guide the development of a protection strategy and of overall emergency arrangements for preparedness and response for a nuclear or radiological emergency in order to ensure an effective emergency response.

### **Justification**

3.62. Requirement 44 of GSR Part 3 [2] and Requirement 5 of GSR Part 7 [4] state that the protection strategies are required to be justified at the preparedness stage for taking protective actions and other response actions effectively in a nuclear or radiological emergency.



3.63. As stated in para. 4.29 of GSR Part 7 [4], the requirement for justification applies for each protective action, in the context of the protection strategy, and for the protection strategy itself. Protective actions taken in an emergency can be disruptive and have adverse psychological or societal consequences (particularly for those individuals evacuated or relocated) as well as major economic and environmental impacts in the affected areas. In addition, the absence of adequate preparedness can result in the taking of actions that are not warranted in the belief that they provide for the protection and safety of individuals affected, but which cause more harm than good. Therefore, it is required to demonstrate that the protective actions and the overall protection strategy do more good than harm, with account taken not only of those detriments that are associated with radiation exposure of individuals but also of those detriments associated with impacts of the actions taken on public health, the economy, society and the environment.

3.64. Paragraph 4.30 of GSR Part 7 [4] states that “The government shall ensure that interested parties are involved and are consulted, as appropriate, in the development of the protection strategy.” In the context of an emergency, interested parties should be consulted throughout the process of justification of the overall protection strategy and any protective action in the context of the protection strategy.

3.65. During the urgent phase and the early phase of an emergency, there may be no time to consult interested parties or to consider justification of protective actions and the protection strategy; therefore, adequate preparedness needs to account for this. As the emergency response moves towards the transition phase and to remediation activities, there is time to consult interested parties and to address justification. In this phase, more thorough justification of the strategies to enable the termination of the emergency should be implemented. In this context, para. 5.98 of GSR Part 7 [4] states that:

“Both radiological consequences and non-radiological consequences shall be considered in deciding on the termination of an emergency as well as in the justification and optimization of further protection strategies as necessary.”

3.66. GSR Part 7 [4] requires protective actions and other response actions to be discontinued when they are no longer justified. When such decisions are taken, they should be clearly communicated to all interested parties.

## Optimization

3.67. Requirement 44 of GSR Part 3 [2] and Requirement 5 of GSR Part 7 [4] set a requirement for the protection strategies to be optimized at the preparedness stage for taking protective actions and other response actions effectively in a nuclear or radiological emergency.

3.68. As indicated in paras 4.30 and 4.31 of GSR Part 7 [4], in the context of an emergency, consultation of interested parties throughout the process of optimization of the overall protection strategy is required to be done at the preparedness stage and the optimized strategy is required to be implemented in the response.

3.69. During the urgent phase and the early phase of an emergency, there may be no time available to dedicate to the optimization process; therefore, adequate preparedness needs to account for this. The situation changes as the emergency moves towards recovery activities and the transition phase. At this point, time will allow for more thorough optimization of the strategy to be implemented to enable the termination of the emergency. The extent of optimization at this point would be as at the preparedness stage.

3.70. The optimization of protection strategies should ensure that the best protective actions have been taken under the prevailing circumstances, and all that is reasonable and justified has been done to keep exposure as low as reasonably achievable.

### *Reference levels*

3.71. For emergency exposure situations, GSR Part 3 [2] and GSR Part 7 [4] require that a reference level expressed in terms of residual dose be set, typically as an effective dose in the range of 20–100 mSv, acute or annual, that includes dose contributions via all exposure pathways. The residual dose is the dose expected to be incurred after protective actions have been terminated (or after a decision has been taken not to take protective actions) and so is the dose accumulated from the initiation of the event, through a specified period of time. The purpose of a reference level in an emergency exposure situation is to guide the optimization process of protection strategies aimed at reducing the doses to be incurred by individuals and to be a benchmark for a retrospective assessment of the effectiveness of protective actions taken and the protection strategy in an emergency response.

3.72. The reference level is not the only input in the development, justification and optimization of the protection strategies. Paragraph 4.28 of GSR Part 7 [4] indicates the need for using the reference level in this context in conjunction with the goals of emergency response (see para. 3.61) and the specific time frame in which particular goals are to be achieved.

3.73. Although the decision to select a particular value within the proposed band of reference levels remains with national authorities, para. 4.28 of GSR Part 7 [4] explains that such selection will depend on the phase of the emergency, the practicality of reducing or preventing exposures and other factors.

### **Generic criteria and operational criteria**

3.74. In addition to reference levels, national generic criteria are required to be used to indicate the need for taking protective actions and other response actions in an emergency. If the doses projected or received in an emergency exceed the national generic criteria, protective actions and other response actions, either individually or in combination within the protection strategy, are required to be implemented.

3.75. Appendix II of GSR Part 7 [4] provides a comprehensive set of generic criteria to be considered when developing the justified and optimized protection strategy, including national generic criteria. The protective actions and other response actions associated with these generic criteria are considered to prevent severe deterministic effects, to reduce the risk of stochastic effects, to mitigate the impact of non-radiological consequences by providing a basis for the continuation or the resumption of international trade following an emergency and for enabling a transition to an existing exposure situation. The process for deriving national generic criteria while taking account of these generic criteria should be such that the associated protective actions and other response actions undergo thorough justification and optimization.

3.76. Once an emergency has occurred, protective actions and other response actions should be promptly implemented on the basis of pre-established operational criteria (emergency action levels, operational intervention levels and observables) that derive from the national generic criteria providing a basis to take effective actions, particularly before substantial information on the situation is available.

## EXISTING EXPOSURE SITUATIONS

### Introduction

3.77. Paragraph 5.1 of GSR Part 3 [2] sets out situations that shall be regarded as existing exposure situations. These include:

- “(a) Exposure due to contamination of areas<sup>[3]</sup> by residual radioactive material deriving from:
  - (i) Past activities that were never subject to regulatory control or that were subject to regulatory control but not in accordance with the requirements of [GSR Part 3 [2]];
  - (ii) A nuclear or radiological emergency, after an emergency has been declared to be ended...
- (b) Exposure due to commodities, including food, feed, drinking water and construction materials, that incorporate radionuclides deriving from residual radioactive material...
- (c) Exposure due to natural sources, including:
  - (i)  $^{222}\text{Rn}$  and its progeny and  $^{220}\text{Rn}$  and its progeny... in dwellings and in other buildings with high occupancy factors for members of the public;
  - (ii) Radionuclides of natural origin, regardless of activity concentration, in commodities, including food, feed, drinking water, agricultural fertilizer and soil amendments, and construction materials, and residual radioactive material in the environment;
  - (iii) Materials ... in which the activity concentration of no radionuclide in either the uranium decay chain[, the actinium decay chain] or the thorium decay chain exceeds 1 Bq/g and the activity concentration of  $^{40}\text{K}$  does not exceed 10 Bq/g”.

3.78. Contamination of areas can also arise from the operation of facilities and activities that are subject to regulatory control under the requirements for planned exposure situations, as a result of authorized activities such as discharges, the management of radioactive waste and decommissioning. The control of such contamination is through the requirements for planned exposure situations, and not through the requirements for existing exposure situations.

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<sup>3</sup> The term ‘areas’ is used in its broadest sense and can include land and water bodies.

3.79. For existing exposure situations, exposures can be reduced only by either protective action or remedial action on the source, the exposure pathway or the exposed populations. In addition, some potential existing exposure situations warranting such actions may be avoided by design. For example, high levels of radon indoors may be avoided by incorporating appropriate preventive measures for radon into the design of new dwellings. Further guidance on such measures is provided in SSG-32 [15].

3.80. Requirement 47 of GSR Part 3 [2] states that:

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

3.81. The government and the regulatory body should take measures to identify and evaluate existing exposure situations, taking into account the types of existing exposure situations mentioned in para. 3.77, on the basis of indication or evidence of public exposures that are of concern from the point of view of radiation protection.

### **Justification**

3.82. Requirement 48 of GSR Part 3 [2] states that **“The government and the regulatory body or other relevant authority shall ensure that remedial actions and protective actions are justified and that protection and safety is optimized.”**

3.83. The protection strategy for a particular existing exposure situation is required to be established in accordance with the principle of justification. Any decisions to implement a remedial action or protective action to reduce the radiation dose to the public, which will always have some disadvantages, should be justified in the sense that they are to do more good than harm.

3.84. The remedial actions or protective actions may include, depending on the type of existing exposure situation and the level of projected doses:

- (a) Corrective actions in existing buildings and preventive measures in new buildings to reduce radon levels [15];
- (b) Remediation of areas with residual radioactive material [14];

- (c) Restrictions on access to contaminated buildings or to areas with residual radioactive material [14];
- (d) Restrictions on the use of locally produced feed, food or drinking water (see paras 3.99–3.102);
- (e) Restrictions on the use of construction materials [15];
- (f) Restrictions on the use of agricultural fertilizer and soil amendments.

3.85. The justification process should consider, in addition to radiation exposure, other factors such as societal and ethical aspects, available resources, waste management options and equity issues. Where public doses are relatively high, the radiation risk may be the most important factor in decision making. However, where exposures are low, other factors may become more important and the justification process should go beyond the scope of radiation protection. This broader decision making process calls for input from other organizations and from interested parties.

## **Optimization**

3.86. The optimization process for an existing exposure situation is implemented through the protection strategy. The protection strategy should be commensurate with the associated radiation risks and may consist of more than one remedial action or protective action. The remedial actions and protective actions selected depend on their technical feasibility and on cost, societal factors, potential adverse impacts, long term effectiveness and the concerns of the public. A process should be applied to achieve residual doses to the public that are as low as reasonably achievable and that are below the reference level.

3.87. Paragraph 5.8 of GSR Part 3 [2] states that:

“The regulatory body or other relevant authority and other parties responsible for remedial actions or protective actions shall 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 shall be given to those groups for whom the dose exceeds the reference level. All reasonable steps shall be taken to prevent doses from remaining above the reference levels.”

3.88. The success of the implementation of the protection strategy depends on the support and commitment of the parties involved, including the exposed population. This can be achieved by involving interested parties in the decision making process regarding the development and implementation of remedial

actions and protective actions. The levels of public exposure also depend strongly on living habits, which calls for transparent communication to the members of the public on the possible ways they can reduce their exposure. The involvement of the affected communities in the implementation of the protection strategy through self-help actions can also reduce their exposure, and may make an important contribution to the success of the strategy. The regulatory body or other national authority should provide guidance on how self-help actions can be carried out at the local or individual level. The regulatory body or other national authority should periodically evaluate the effectiveness of such self-help actions to provide support that could further improve the situation. Further guidance on self-help actions in the remediation of contaminated areas is currently in preparation.<sup>4</sup>

3.89. The process of optimization should also consider that some remedial actions, such as cleanup work involving the removal of contaminated soil, may lead to exposure of the remediation workers, as well as generating radioactive waste requiring appropriate actions for its processing and disposal. The collection, treatment, storage and disposal of large volumes of such waste may lead to exposure of the public.

3.90. The selection of the optimized remediation option is required to take into account that some remedial actions could have considerable radiological and non-radiological impacts on the environment, which should be considered within the process of optimization, together with technical, societal and economic factors (para. 5.12(d) of GSR Part 3 [2]).

### *Reference levels*

3.91. Paragraph 5.4 of GSR Part 3 [2] states that “The regulatory body or other relevant authority assigned to establish a protection strategy for an existing exposure situation shall ensure that it specifies ... appropriate reference levels.” Paragraph 5.8 of GSR Part 3 [2] states that:

“Reference levels shall typically be expressed as an annual effective dose to the representative person in the range 1–20 mSv or other corresponding quantity, the actual value depending on the feasibility of controlling the situation and on experience in managing similar situations in the past.”

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<sup>4</sup> A revision of WS-G-3.1 [14] is in preparation.

3.92. For existing exposure situations, the reference level is expressed in terms of effective dose to the representative person, or in terms of activity concentration, with account taken of all possible pathways of exposure. The reference level should be used to guide the optimization of protection such that projected doses greater than the reference level are reduced, and further reductions are achieved given the circumstances. GSR Part 3 [2] provides a general framework for establishing reference levels. Table 1 in the Appendix summarizes values of dose constraints and reference levels in terms of effective doses.

3.93. Where activity concentrations of radon are of concern for public health, para. 5.20 of GSR Part 3 [2] requires the government to ensure that an action plan for radon is established, which includes the establishment of an appropriate reference level for  $^{222}\text{Rn}$  for dwellings and other buildings with high occupancy factors for members of the public that in general will not exceed an annual average activity concentration due to  $^{222}\text{Rn}$  of  $300 \text{ Bq/m}^3$ .<sup>5</sup> The reference level for exposure indoors due to radon should be selected such that the resulting actions are practicable and manageable. For example, it would be impractical to set a reference level such that corrective actions would be necessary for the majority of existing dwellings. The percentages of dwellings that would require corrective remedial actions under different reference levels should be considered in the choice of an appropriate reference level. SSG-32 [15] provides recommendations and guidance on the establishment of a reference level for radon in dwellings and other buildings with high occupancy factors for members of the public, and on protection of members of the public against exposure indoors due to  $^{222}\text{Rn}$ .

3.94. Requirement 51 of GSR Part 3 [2] states that “**The regulatory body or other relevant authority shall establish reference levels for exposure due to radionuclides in commodities**”, while para. 5.22 of GSR Part 3 [2] states that:

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

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<sup>5</sup> On the assumption of an equilibrium factor for  $^{222}\text{Rn}$  of 0.4 and an annual occupancy factor of 7000 hours, the value of  $300 \text{ Bq/m}^3$  corresponds to an annual effective dose of the order of 10 mSv.



3.95. Tables 1 and 2 of RS-G-1.7 [22] provide values of activity concentration for radionuclides of natural origin and for radionuclides of artificial origin, respectively. Paragraph 5.8 of RS-G-1.7 [22] states that:

“National and international trade in commodities containing radionuclides with activity concentrations below the values of activity concentration provided in Tables 1 and 2 [of RS-G-1.7 [22]] should not be subject to regulatory control for the purposes of radiation protection.”

The commodities referred to above do not include foodstuffs, drinking water, animal feed or any material intended for use in food or animal feed: these are all outside the scope of RS-G-1.7 [22].

3.96. The activity concentration values for radionuclides of artificial origin set out in table 2 of RS-G-1.7 [22] are for bulk quantities of solid material and were derived using the dose criteria for exemption as set out in para. 3.9 of this Safety Guide. The activity concentration values for radionuclides of natural origin set out in table 1 of RS-G-1.7 [22] were selected on the basis of consideration of the upper end of the worldwide distribution of activity concentrations in soil.

3.97. Paragraph 5.1 of RS-G-1.7 [22] states that:

“There are some situations (such as the use of some building materials containing natural radionuclides) for which exposures from materials due to radionuclides of natural origin with activity concentrations below those given in Table 1 [of RS-G-1.7 [22]] would necessitate consideration by the regulatory body for some types of regulatory control.”

3.98. The regulatory body or other national authority should establish a process to determine the compliance of building materials containing radionuclides of natural origin with the reference level. SSG-32 [15] provides an example of such a process for a reference level of 1 mSv per year for external exposure to gamma radiation for the protection of members of the public against exposure indoors due to radionuclides in building materials. Factors to be considered include amenability to control and the possibility of different values being determined for different societal groups.

3.99. The regulatory body or other national authority should establish a process to evaluate the levels of radionuclides in food grown in the State in areas that may be affected by past activities or by a nuclear or radiological emergency, and in food imported into the State that may incorporate radionuclides arising from

residual radioactive material deriving from a nuclear or radiological emergency after it has been declared ended. This process should identify radionuclides that may be of concern, and should include a methodology for developing guideline levels of activity concentration for these radionuclides in food, on the basis of the specific reference level for food that does not exceed a value of about 1 mSv established by the regulatory body. While in most instances a reference level of 1 mSv or less is appropriate, there may be special circumstances where consideration of a higher value for the reference level may be appropriate, owing to local societal and economic circumstances.

3.100. In developing the national guidelines, the regulatory body or other national authority should consider the methodology used, and is required to consider the guideline levels for radionuclides contained in food traded internationally that could contain radioactive substances as a result of a nuclear or radiological emergency, published by the Joint Food and Agriculture Organization/World Health Organization Codex Alimentarius Commission [24] (as established in para. 5.23 of GSR Part 3 [2]). It is noted that the Codex guideline values for activity concentration of radionuclides in food were calculated assuming that 10% of the diet consists of imported food, all of which is contaminated, and assuming an exemption level for interventions of 1 mSv per year.

3.101. The regulatory body or other national authority should establish a process to determine the compliance of drinking water in the State with the guideline levels for drinking water published by the World Health Organization (WHO) [25]. The WHO guideline levels for specific radionuclides are calculated using a generic criterion of 0.1 mSv per year for ingestion.

3.102. The situation may arise where the guideline levels for drinking water are consistently exceeded for one radionuclide or for a combination of radionuclides. The regulatory body or other national authority will then need to make a decision regarding the need to implement protective actions or to place some restriction on the continued use of the water supply for drinking [25]. In such situations, the regulatory body or other national authority should establish a reference level for drinking water that would be applied to those water supplies that contain radionuclides that consistently exceed the guideline levels published by WHO. The regulatory body or other national authority should provide guidance to the public and to water authorities on the need for protective actions or on the need to place restrictions on the use of the water supply for drinking. The regulatory body or other national authority will need to take account of the availability of other

drinking water supplies, and of the costs of protective actions, such as additional water treatment [25].

3.103. Paragraph 5.9 of GSR Part 3 [2] states that “The regulatory body or other relevant authority shall periodically review the reference levels to ensure that they remain appropriate in the light of the prevailing circumstances.”

## **4. PROTECTION OF THE ENVIRONMENT**

4.1. The Rio Declaration on Environment and Development states that “environmental protection shall constitute an integral part of the development process and cannot be considered in isolation from it” [26]. According to the ICRP [5–7, 27], the aims of environmental protection are to prevent or reduce the frequency of deleterious radiation effects on flora and fauna to a level where they would have a negligible impact on the maintenance of biological diversity, the conservation of species and the health and status of natural habitats, communities and ecosystems. The Safety Fundamentals SF-1 [1] recognizes that the present system of radiation protection generally provides appropriate protection of ecosystems in the human environment from harmful effects of radiation exposure. Paragraph 3.28 of SF-1 [1] states that:

“The general intent of the measures taken for the purposes of environmental protection has been to protect ecosystems against radiation exposure that would have adverse consequences for populations of a species (as distinct from individual organisms).”

4.2. Paragraph 1.34 of GSR Part 3 [2] states that:

“Radiological impacts in a particular environment constitute only one type of impact and, in most cases, may not be the dominant impacts of a particular facility or activity. Furthermore, the assessment of impacts on the environment needs to be viewed in an integrated manner with other features of the system of protection and safety to establish the requirements applicable to a particular source. Since there are complex interrelations, the approach to the protection of people and the environment is not limited to the prevention of radiological effects on humans and on other species. When establishing regulations, an integrated perspective has to be adopted

to ensure the sustainability, now and in the future, of agriculture, forestry, fisheries and tourism, and of the use of natural resources.”

In general this is achieved by the appropriate application of the optimization principle [2].

4.3. Some States, on the basis of evidence such as experience or simplified analysis, may consider that specific assessment of effects in the environment is not necessary. In these cases, the regulatory body may decide that the radiological environmental impact assessment does not need to include explicit consideration of exposures of flora and fauna.

4.4. Other States may consider that it is necessary to include in the radiological environmental impact assessments for certain facilities and activities the estimation and control of exposures of flora and fauna.

4.5. Paragraph 3.9(e) of GSR Part 3 [2] states that:

“Any person or organization applying for authorization ... Shall, as required by the regulatory body, have an appropriate prospective assessment made for radiological environmental impacts, commensurate with the radiation risks associated with the facility or activity.”

4.6. Requirement 9 and para. 3.15 of GSR Part 3 [2] state the responsibilities of registrants and licensees in planned exposure situations. Paragraph 3.15(d) of GSR Part 3 [2] states that:

“Registrants and licensees ... Shall, for the sources for which they are authorized and for which the regulatory body requires a prospective assessment to be made for radiological environmental impacts ... conduct such an assessment and keep it up to date”.

4.7. GSG-10 [9] provides a framework for the prospective assessment of radiological environmental impact in planned exposure situations, which includes the assessment and control of the impact of radioactive releases during normal operation and releases from events and accidents that are determined by means of a safety assessment. The use of such a framework should not impose an unnecessary burden on registrants and licensees or on the regulatory body. GSG-10 [9] discusses the aspects to be considered when prospectively assessing the radiological environmental impact for planned exposure situations and provides, in annex I of GSG-10 [9], a methodology to assess the radiological

impact on flora and fauna from normal operation on the basis of the ICRP approach for the protection of the environment [7, 27].

4.8. The requirements of GSR Part 3 [2] for a graded approach for the control of exposures also apply to the assessment of radiological environmental impacts. The efforts to assess radiological environmental impact, including protection of flora and fauna if considered necessary, should be commensurate with the radiation risks associated with the particular facility or activity.

4.9. For the management of environmental aspects in existing exposure situations and emergency exposure situations, impact on the environment should be considered as an element in the process of optimization of protection and safety. It will be of particular importance to give consideration to the impacts on the environment from the protective actions and remedial actions to be taken to reduce the exposure of members of the public, as such impacts may in some cases be irreversible. These impacts should be considered in the justification and optimization processes of the overall protection strategy, as well as of individual protective actions and remedial actions.



## Appendix

### DOSE CONSTRAINTS AND REFERENCE LEVELS

A.1. Table 1 summarizes the dose constraints and reference levels for existing exposure situations, planned exposure situations and emergency exposure situations, and for different categories of exposure, as established in GSR Part 3 [2].

TABLE 1. FRAMEWORK FOR SOURCE RELATED DOSE CONSTRAINTS AND REFERENCE LEVELS

Range in which the value for a dose constraint or reference level is set	Category of exposure and type of exposure situation
20 to 100 mSv <sup>a,b,c</sup>	<ul style="list-style-type: none"><li>• Reference level for public exposure in an emergency exposure situation</li></ul>
1 to 20 mSv per year	<ul style="list-style-type: none"><li>• Dose constraint for occupational exposure in a planned exposure situation</li><li>• Dose constraint for medical exposure of carers and comforters in a planned exposure situation</li><li>• Dose constraint for individuals undergoing non-medical human imaging that is conducted by medical personnel using medical radiological equipment in a planned exposure situation</li><li>• Reference level for workers in an existing exposure situation</li><li>• Reference level for public exposure in specific existing exposure situations, e.g. exposure due to radon in dwellings, areas with residual radioactive material</li></ul>
Not greater than 1 mSv per year	<ul style="list-style-type: none"><li>• Dose constraint for public exposure in planned exposure situations</li><li>• Reference level for public exposure in specific existing exposure situations, e.g. exposure due to radionuclides in commodities such as food, drinking water or construction materials</li></ul>

<sup>a</sup> Acute dose or annual dose.

<sup>b</sup> In exceptional situations, informed volunteer workers may receive doses above this band of values to save lives, to prevent severe deterministic health effects or to prevent the development of catastrophic conditions.

<sup>c</sup> Situations in which the dose threshold for deterministic effects in relevant organs or tissues could be exceeded always require action.





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