

IAEA Safety Standards

for protecting people and the environment

Functions and Processes of the Regulatory Body for Safety

General Safety Guide

No. GSG-13



IAEA

International Atomic Energy Agency



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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**.

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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.

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**FUNCTIONS AND PROCESSES
OF THE REGULATORY BODY
FOR SAFETY**



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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-13

FUNCTIONS AND PROCESSES OF THE REGULATORY BODY FOR SAFETY

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.

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 measures¹ 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.

¹ See also publications issued in the IAEA Nuclear Security Series.

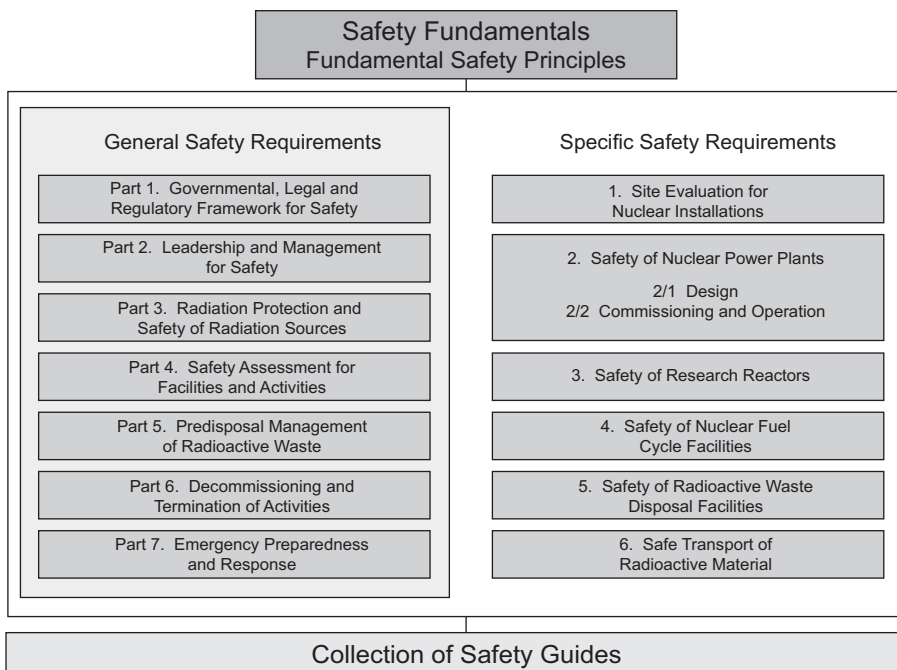


FIG. 1. The long term structure of the IAEA Safety Standards Series.

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

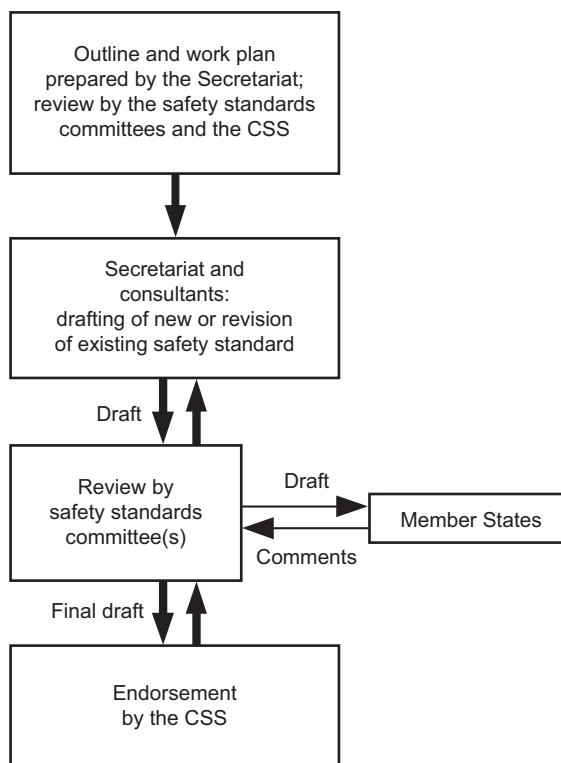


FIG. 2. The process for developing a new safety standard or revising an existing standard.

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. Regulation is essential for ensuring the safety of all facilities and activities that give rise to radiation risks for people and the environment. The establishment of a legally based, independent, fully resourced and technically competent regulatory body is a fundamental element set out in Principle 2 of IAEA Safety Standards Series No. SF-1, Fundamental Safety Principles [1]. This principle is reinforced and further elaborated in IAEA Safety Standards Series Nos GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety [2], and GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [3].

1.2. This Safety Guide provides guidance on the technical aspects of a regulatory body's core functions as defined in GSR Part 1 (Rev. 1) [2] and the associated processes for ensuring the regulatory control of facilities and activities¹. This guidance is particularly important for regulatory bodies having responsibilities covering a range of facilities and activities that give rise to radiation risks, or when interfaces are present between various regulatory authorities, which require effective coordination and cooperation. This guidance promotes a consistent approach to the regulation of radiation risks.

1.3. Corresponding supporting functions, supported by processes within the framework of an integrated management system, are necessary to ensure that the core functions can be performed efficiently and effectively. The regulatory body should manage its organizational structure and staffing in accordance with a graded approach, so that the degree of regulatory control is appropriate. These aspects are covered in the companion Safety Guide, IAEA Safety Standards Series No. GSG-12, Organization, Management and Staffing of the Regulatory Body for Safety [4]. It is strongly recommended that this Safety Guide and GSG-12 [4] be read in conjunction with one another.

¹ Facilities and activities is a general term encompassing nuclear facilities, all uses of all sources of ionizing radiation, all radioactive waste management activities, transport of radioactive material and any other activity or circumstances in which people may be exposed to radiation risks arising from naturally occurring or artificial sources. See footnote 3 of GSR Part 1 (Rev. 1) [2] for a more complete definition.

1.4. The recommendations provided in this Safety Guide and GSG-12 [4] are intended mainly to be used by regulatory bodies, but can be also useful for governments that are developing a regulatory framework for radiation and nuclear safety. This Safety Guide will also assist authorized parties and others dealing with radiation sources in understanding regulatory procedures, processes and expectations.

1.5. This Safety Guide supersedes IAEA Safety Standards Series Nos GS-G-1.2, Review and Assessment of Nuclear Facilities by the Regulatory Body² issued in 2002; GS-G-1.3, Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body³ issued in 2002; GS-G-1.4, Documentation for Use in Regulating Nuclear Facilities⁴ issued in 2002; and GS-G-1.5, Regulatory Control of Radiation Sources⁵ issued in 2004. This Safety Guide also supersedes the parts of IAEA Safety Standards Series No. SSG-12, Licensing Process for Nuclear Installations [5] relating to the functions and processes of the regulatory body and the parts of IAEA Safety Standards Series No. WS-G-5.1, Release of Sites from Regulatory Control on Termination of Practices [6] relating to the regulatory body.

OBJECTIVE

1.6. The objective of this Safety Guide is to provide recommendations on meeting the requirements of GSR Part 1 (Rev. 1) [2] on the regulatory body's core functions and the associated processes to implement those functions. The core functions addressed in this Safety Guide are those described in GSR Part 1 (Rev. 1) [2] and in IAEA Safety Standards Series No. GSR Part 7,

² INTERNATIONAL ATOMIC ENERGY AGENCY, Review and Assessment of Nuclear Facilities by the Regulatory Body, IAEA Safety Standards Series No. GS-G-1.2, IAEA, Vienna (2002).

³ INTERNATIONAL ATOMIC ENERGY AGENCY, Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body, IAEA Safety Standards Series No. GS-G-1.3, IAEA, Vienna (2002).

⁴ INTERNATIONAL ATOMIC ENERGY AGENCY, Documentation for Use in Regulating Nuclear Facilities, IAEA Safety Standards Series No. GS-G-1.4, IAEA, Vienna (2002).

⁵ FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OFFICE, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, Regulatory Control of Radiation Sources, IAEA Safety Standards Series No. GS-G-1.5, IAEA, Vienna (2004).

Preparedness and Response for a Nuclear or Radiological Emergency [7] and comprise:

- (a) The development and/or provision of regulations and guides;
- (b) Notification and authorization, including registration and licensing;
- (c) Regulatory review and assessment;
- (d) Regulatory inspection;
- (e) Enforcement;
- (f) Emergency preparedness and response;
- (g) Communication and consultation with interested parties.

1.7. The core functions interact with one another; for example, regulations and guides set out the regulatory requirements to be used in review and assessment, in the authorization process, in carrying out inspections, and when determining enforcement actions. Similarly, the findings of review and assessment guide the approach to inspection, and inspection provides areas for review and assessment. Both review and assessment, and inspection may influence the development of regulations and guides. This Safety Guide addresses these interactions between the core functions.

1.8. There are several supporting functions that are necessary to ensure that the core functions can be performed efficiently and effectively. These include:

- (a) Administrative support, including human resources, finance, management of relevant documents and records, equipment purchasing and control;
- (b) Legal assistance;
- (c) Research and development processes;
- (d) Arrangements for contracting external expert support, where needed;
- (e) Establishment of advisory committees;
- (f) Organization of international links and cooperation.

These supporting functions and the associated processes are described in GSG-12 [4].

SCOPE

1.9. This Safety Guide covers the core functions of the regulatory body, and the processes by which they are discharged, for all the stages of the lifetime of a facility or activity, from initial site evaluation and design through to release from regulatory control. While this Safety Guide is based on the regulation of

authorized facilities and activities, many of the functions and processes also apply for any pre-authorization stages. However, in line with a graded approach, not all the regulatory controls and recommendations described will be applicable to all facilities and activities; even where regulatory controls are applicable, they will differ and vary in depth and scope in accordance with the facility and activity, as well as the lifetime stage.

1.10. In this Safety Guide, the terms ‘authorization’ (which is considered to be synonymous with ‘licence’ or ‘permit’) and ‘notification’ are used. Authorization may take different forms, such as licensing, certification, granting of a permit, registration, agreement, consent or granting of another similar regulatory instrument, depending on the legal and regulatory framework of the particular State. The term ‘authorized party’ is used in this Safety Guide to indicate the person or organization responsible for an authorized facility or an authorized activity that gives rise to radiation risks who has been granted written permission (i.e. authorized) by a regulatory body or other governmental body to conduct specified activities; the authorized party may be a licensee, a registrant, an operator or an operating organization. The term ‘safety’ is used in this Safety Guide to mean the protection of people and the environment against radiation risks, and the safety of facilities and activities that give rise to radiation risks. Safety as used here includes the safety of nuclear installations, radiation safety, the safety of radioactive waste management and safety in the transport of radioactive material; it does not include non-radiation-related aspects of safety.

1.11. In this Safety Guide, the expression ‘lifetime of facilities and activities’ is used to cover both the full lifetime of a facility and the duration of an activity. Site evaluation, design, construction, commissioning, operation and decommissioning or closure are the stages in the lifetime of a facility, and of the associated authorization process; while these stages apply for all facilities, they might not apply for all activities. For complex facilities or activities, each stage of the authorization process may include one or more steps (also referred to as ‘hold points’) at which additional information is required by the regulatory body. Further definitions are provided in the IAEA Safety Glossary [8].

1.12. The scope of this Safety Guide is limited to the regulation of safety and does not extend to nuclear security. However, recommendations are provided in this Safety Guide on the interfaces between safety and nuclear security. The regulation of safety and nuclear security should be carried out in such a way that safety measures and nuclear security measures are designed and implemented in an integrated manner so that nuclear security measures do not compromise safety and safety measures do not compromise nuclear security. The essential elements

of an effective nuclear security regime are established in the Nuclear Security Fundamentals [9]. Guidance on addressing nuclear security aspects is provided in IAEA Nuclear Security Series No. 13, Nuclear Security Recommendations on Physical Protection of Nuclear Material and Nuclear Facilities (INFCIRC/225/Revision 5) [10], IAEA Nuclear Security Series No. 14, Nuclear Security Recommendations on Radioactive Material and Associated Facilities [11] and IAEA Nuclear Security Series No. 23-G, Security of Nuclear Information [12].

STRUCTURE

1.13. Section 2 of this Safety Guide provides recommendations on the application of a graded approach to the regulation of nuclear and radiation safety. Section 3 provides recommendations for each of the core regulatory functions and processes. Four Appendices provide more detailed guidance on authorization for the provision of consumer products, authorization conditions for the various steps of the authorization process, topics to be covered by review and assessment, and inspection areas for nuclear facilities, respectively.

2. GRADED APPROACH TO FUNCTIONS AND PROCESSES OF THE REGULATORY BODY

2.1. Paragraph 3.24 of SF-1 [1] states that:

“The resources devoted to safety by the licensee, and the scope and stringency of regulations and their application, have to be commensurate with the magnitude of the radiation risks and their amenability to control.”

2.2. Requirement 1 of GSR Part 1 (Rev. 1) [2] states that:

“The government shall establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities.”

2.3. Paragraph 2.4 of GSR Part 1 (Rev. 1) [2] states that:

“The national policy and strategy for safety shall be implemented in accordance with a graded approach, depending on national circumstances, to ensure that the radiation risks associated with facilities and activities, including activities involving the use of radiation sources, receive appropriate attention by the government or by the regulatory body.”

2.4. Furthermore, para. 4.3 of GSR Part 1 (Rev. 1) [2] states that:

“The performance of regulatory functions shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach.”

2.5. Specific reference is made to the application of a graded approach in relation to the core functions of the regulatory body, as follows:

- (a) Regulations and guides “shall provide adequate coverage commensurate with the radiation risks associated with the facilities and activities, in accordance with a graded approach” (GSR Part 1 (Rev. 1) [2], para. 4.62).
- (b) For notification and authorization “[t]he extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach” (GSR Part 1 (Rev. 1) [2], para. 4.33).
- (c) **“Review and assessment of a facility or an activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach”** (GSR Part 1 (Rev. 1) [2], Requirement 26).
- (d) **“Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach”** (GSR Part 1 (Rev. 1) [2], Requirement 29).
- (e) For enforcement, “[t]he response of the regulatory body to non-compliances with regulatory requirements or with any conditions specified in the authorization shall be commensurate with the significance for safety of the non-compliance, in accordance with a graded approach” (GSR Part 1 (Rev. 1) [2], para. 4.54).
- (f) For communication and consultation with interested parties, “[p]ublic information activities shall reflect the radiation risks associated with facilities and activities, in accordance with a graded approach” (GSR Part 1 (Rev. 1) [2], para. 4.69).

2.6. Furthermore, para. 3.36 of SF-1 [1] states that:

“The scope and extent of arrangements for emergency preparedness and response have to reflect...[t]he likelihood and the possible consequences of a nuclear or radiation emergency.”

This is further addressed in GSR Part 7 [7], particularly in Requirement 4.

2.7. Thus, all the regulatory core functions (see Section 3) are required to be subject to a graded approach so that, while the descriptions of these functions are generic, the degree of application will differ in accordance with the facility or activity. For example, the degree of review and assessment applied to a nuclear power plant would clearly not be the same as for a medical X ray unit.

2.8. The main factor to take into consideration in the application of a graded approach is that the application of the regulatory functions should be consistent with the magnitude of the possible radiation risks⁶ arising from the facility or activity. The approach should take into account any exposures to radiation, and discharges or releases of radioactive substances in normal operation, anticipated operational occurrences and accident conditions, as well as the possibility of events with a very low probability of occurrence, without neglecting very low probability events with potentially high consequences. An approach to screening of events based on their probability is included in IAEA Safety Standards Series No. NS-G-3.1, External Human Induced Events in Site Evaluation for Nuclear Power Plants [13].

2.9. Other relevant factors, such as the maturity or complexity of the facility or activity and the knowledge and expertise of the authorized party, should also be taken into account in a graded approach to regulatory activities. The consideration of maturity relates to the use of established practices and procedures, established designs, data on operational performance of similar facilities or activities, uncertainties in the performance of the facility or activity, and the continuing and future availability of experienced manufacturers and constructors. Complexity relates to the extent and difficulty of the effort required to construct and operate a facility or to implement an activity, the number of related processes for which control is necessary, the extent to which radioactive material has to

⁶ The term ‘possible radiation risks’ relates to the maximum possible radiological consequences that could occur when radioactive material is released from the facility or the activity, with no credit being taken for the safety systems or protective measures in place to prevent this.

be handled, the half-lives of the radionuclides involved, the reliability and complexity of systems and components, and their accessibility for maintenance, inspection, testing and repair. These factors need special consideration during decommissioning or remediation activities, which will involve new procedures and processes not applied in other stages of the lifetime (e.g. institutional controls, including continuing environmental monitoring programmes and controls of the radiological status of the facility).

2.10. The application of the graded approach should be reassessed as a better understanding is obtained of the radiation risks arising from the facility or activity. For example, the extent and frequency of inspections (see GSR Part 1 (Rev. 1) [2], para. 4.52) in the plan for periodic inspections may be adapted in accordance with the trend of findings from previous inspections. In Section 3, more detailed consideration is given to the application of a graded approach in each of the core functions of the regulatory body.

3. CORE REGULATORY FUNCTIONS AND PROCESSES

3.1. The core functions of a regulatory body are described in the following subsections. The first subsection contains guidance on establishing and maintaining regulations that set out the safety requirements for operating a facility or conducting an activity and guides that set out the procedures and processes that should be carried out by the regulatory body and authorized parties. These include the process for notification or authorization of a facility or activity, which is expanded on in the next subsection.

3.2. The subsequent subsections cover the responsibilities of the regulatory body from the initial application to operate a facility or conduct an activity, and thereafter throughout the entire lifetime of the facility or duration of the activity. The regulatory body carries out review and assessment of information relevant to safety, much of which will be submitted by the authorized party as part of the notification or authorization process, to ensure that all regulatory requirements are being addressed. The regulatory body also carries out inspections of the facility or activity to ensure compliance with the safety requirements. Where non-compliance or violations exist, enforcement is used to identify and document their nature and require corrective actions to be taken by authorized parties. The regulatory body in most States also has a role in emergency preparedness and

response, although this will differ in accordance with national practices. Finally, communication and consultation with interested parties are important throughout the lifetime of the facility or duration of the activity to both inform and obtain the views of the public and other interested parties.

REGULATIONS AND GUIDES

3.3. The provision of regulations and guides is subject to Requirements 32–34 of GSR Part 1 (Rev. 1) [2]. The system of regulations and guides should be in accordance with the legal system of the State, and the nature and extent of the facilities and activities to be regulated. The regulations and guides should specify the requirements and associated criteria for ensuring the protection of people and the environment.

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

3.5. When regulations are not established directly by the regulatory body, mechanisms established within the legal and governmental framework should ensure that such regulations are developed and issued in a timely manner. The regulatory body should advise the government on the need for regulations on matters affecting safety to be established or adopted.

3.6. The regulatory body should specify the purposes of the various documents in the legal framework that are necessary to perform its functions. The documents may be categorized, for example, as legislation and regulations (mandatory by law), supporting guides (not mandatory by law) to be used either by the authorized parties or by the regulatory body (internal guidance) and other relevant documents.

3.7. A suitable system of guides will help the regulatory body to maintain consistency in the implementation of the regulatory requirements. However, the regulatory body should refrain from prescribing specific solutions in its guides. The advisory status of a guide carries the implication that alternative approaches would be acceptable provided that the authorized party can demonstrate that the required level of safety will be achieved.

3.8. Internationally recognized standards and recommendations as well as technical standards developed by organizations working in various technological fields may be referenced by the regulatory body in its regulations and guides or in the authorization conditions, or may be proposed by the authorized party in the authorization process.

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

Objectives of regulations and guides

3.10. An important objective of the regulations and guides is to ensure the stability and consistency of regulatory control and to prevent subjectivity in decision making by individual staff members of the regulatory body. The regulatory body is required to be able to justify its decisions if they are challenged [2]. The provision of regulations and guides also enables the regulatory body to inform authorized parties and applicants of the objectives, principles and associated criteria for safety on which its requirements, judgements and decisions, in connection with its reviews and assessments, inspections and enforcement actions, are based.

3.11. As part of its integrated management system, the regulatory body should establish a process for the development of regulations and guides. This process should ensure that the regulations and guides:

- (a) Provide the framework for regulatory requirements and conditions to be incorporated into individual authorizations or applications for authorization;
- (b) Establish principles, requirements and the criteria to be used for assessing compliance;
- (c) Are consistent and comprehensive;
- (d) Are commensurate with the radiation risks associated with the facilities and activities;
- (e) Involve consultations with interested parties;
- (f) Take into account internationally agreed standards and feedback gained from related experience;
- (g) Are made available to interested parties;
- (h) Are reviewed and revised as necessary and are kept up to date.

3.12. Regulations have the force of law and may be issued either by the government, or by the regulatory body on behalf of the government. The principal purpose of establishing a system of regulations is to codify safety requirements of general applicability that require mandatory compliance by all authorized parties. The system of regulations should provide an appropriate balance between regulatory provisions that are sufficiently detailed to achieve and maintain safety, and sufficiently flexible to permit their application to developing technologies and in new circumstances. The degree to which the regulations are performance based or prescriptive, and the level of detail in the associated guidance, will depend on the national approach; however, this should not reduce the authorized party's prime responsibility for safety.

3.13. The regulatory body may develop safety objectives and requirements itself or it may adopt objectives and requirements that have been developed and issued by international organizations or by regulatory bodies in other States. If safety objectives and regulatory requirements are to be adopted, the regulatory body should ensure that it obtains a good understanding of their basis, use and effectiveness in other States by means of appropriate contact with the relevant bodies. Safety objectives and regulatory requirements should be adopted as necessary for specific purposes.

3.14. The safety objectives and regulatory requirements should specify the performance criteria for structures, systems and components, and management and operational procedures and processes, to be achieved in operating the facility or conducting the activity. The regulatory body should refrain from prescribing specific designs, management systems or operational procedures.

3.15. The safety objectives and regulatory requirements should include the following, as appropriate:

- (a) Emphasis on prevention of, rather than mitigation of, accidents;
- (b) Application of the concept of defence in depth;
- (c) Meeting the single failure criterion for safety systems;
- (d) Requirements for redundancy, diversity and separation;
- (e) Requirements for adequate safety demonstration of any passive systems that are used;
- (f) Criteria relating to human factors and the human-machine interface;
- (g) Dose limits and dose constraints (for both occupational exposure and public exposure), and limits on discharges to the environment;
- (h) Criteria for assessing radiation risks to workers and the public;

- (i) Minimization of waste and management of the waste generated, including waste from decommissioning;
- (j) Emergency preparedness.

3.16. The regulations should explicitly state the obligations, roles and responsibilities of the applicant or authorized party. In this respect, the regulatory body should include provisions in the regulations requiring that the applicant or authorized party accomplish some or all of the following, depending on the facility or activity:

- (a) Prepare and submit a comprehensive application to the regulatory body that demonstrates that highest priority is given to safety; this means that the level of safety is as high as reasonably achievable and that safety will be maintained for the entire lifetime of the facility or duration of the activity, until it is released from regulatory control by the regulatory body.
- (b) Have the capability within its own organization (either at the facility or activity or within the organization as a whole) to understand the design basis and safety analyses for the facility or activity, and the limits and conditions under which the facility is to be operated or the activity performed.
- (c) Exercise control over the work of contractors, understand the safety significance of their work (an ‘intelligent customer’ capability⁷) and take responsibility for the implementation of the work.
- (d) Submit a procedure or description of the process for dealing with modifications that may be subject to approval by the regulatory body.
- (e) Have a design capability and a formal and effective external relationship with the original design organization of the facility or equipment, or an acceptable alternative arrangement.
- (f) Assess safety in a systematic manner and on a regular basis.
- (g) Develop a safety assessment and submit it to the regulatory body as part of the application, depending on the magnitude of the possible radiation risks associated with the facility or activity (e.g. if there is a possibility for an exposure to be greater than a level specified by the regulatory body).
- (h) Have an appropriate prospective assessment made of radiological environmental impacts, commensurate with the radiation risks associated with the facility or activity (see GSR Part 3 [3], para. 3.9(e)).

⁷ An intelligent customer capability is the capability of the organization to have a clear understanding and knowledge of the product or service being supplied. The intelligent customer concept relates mainly to a capability required of organizations when using contractors or external expert support.

- (i) For an application for authorization, demonstrate that it has and will continue to maintain:
 - (i) Adequate financial resources for construction, operation and maintenance of the facility or activity as well as for the timely decommissioning (or closure) of the facility or termination of the activity and the management of radioactive waste and/or spent radiation sources, including disposal;
 - (ii) Adequate human resources to safely construct, maintain, operate and decommission the facility or activity and deal with any radioactive material and waste and to ensure that regulatory requirements and safety standards are met and will continue to be met.

3.17. A system of regulations is no substitute for good technical and administrative approaches. Unduly detailed formal regulatory requirements can inhibit engineering innovation and good management initiatives, and may even be counterproductive if they have the effect of relieving (or tending to relieve) the authorized party of the responsibility for safety. Only a serious commitment to safety on the part of all those concerned, not limited to the obligation just to meet regulatory requirements, will engender a strong safety culture and bring about lasting resolutions of safety issues.

3.18. Irrespective of the degree to which the government or regulatory body has developed prescriptive regulations, the regulatory body should give consideration to supplementing its regulations with supporting guides of a non-mandatory nature on how to comply with regulations, where appropriate.

3.19. Guides are advisory in nature; they should allow the authorized party flexibility in applying new technologies and developing new procedures to enhance safety. The processes for developing guides should also enable the regulatory body to promote learning and improvement by modifying guides as necessary to include innovative good practices and to revoke impractical or unnecessary provisions.

3.20. The overall purpose of guides is to advise authorized parties on how to comply with laws and regulations, and on how to implement the regulatory requirements, thus improving effectiveness and efficiency and enhancing safety. Guides also provide detailed and specific information on acceptable technical and administrative approaches to satisfying the requirements established in the regulations. Guides should always be consistent with the law and regulations.

3.21. In developing guides, recent operating experience and developments should be taken into account, including technological advances that have been shown by experience or by research results to be capable of providing effective and reliable means of satisfying regulatory requirements.

3.22. The regulatory body should, where appropriate, also support the production of guidance documents by professional bodies wishing to help their members in the discharge of their responsibilities regarding safety; the provision of such support should be such that any undue influence that may compromise regulatory independence is avoided.

3.23. In determining whether a particular topic should be made mandatory and thus be addressed in a regulation rather than a guide, consideration should be given to the regulatory requirements and the extent to which the topic in question can be considered as essential for implementing these requirements.

3.24. Safety requirements that apply to a particular type of facility or activity should be established in the regulations. Other safety requirements, such as those applicable for only a short duration or relating to a particular characteristic of an individual facility or activity, should be specified in mandatory conditions attached to the authorization (see para. 3.112). However, the extent to which detailed provisions are made in authorization conditions will depend upon the legal system and the approach to authorization of the State concerned.

Scope and content of regulations and guides

3.25. Requirement 3 of GSR Part 3 [3] states that: **“The regulatory body shall establish or adopt regulations and guides for protection and safety and shall establish a system to ensure their implementation.”**

The system is required to cover all exposure situations, namely planned exposure situations, emergency exposure situations and existing exposure situations (see para. 2.29 of GSR Part 3 [3]).

3.26. The regulatory body is required to establish a regulatory system for safety that includes (see GSR Part 3 [3], para. 2.30):

- (a) Notification and authorization; the regulations should provide clarity and transparency in the notification and authorization process.
- (b) Review and assessment of facilities and activities; the regulations should require a demonstration of the safety of the facility or activity that enables

the regulatory body to make a decision or a series of decisions on the acceptability of the facility or activity in terms of safety.

- (c) Inspection of facilities and activities; the regulatory body should provide its inspectors with written guidelines in sufficient detail to ensure that facilities and activities are inspected to a common standard, based on a graded approach, and that there is a consistent level of safety.
- (d) Enforcement of regulatory requirements; the regulatory body should adopt clear administrative procedures and guidelines governing the use and implementation of enforcement actions.
- (e) The regulatory functions relevant to emergency exposure situations and existing exposure situations.
- (f) Provision of information to, and consultation with, parties affected by its decisions and, as appropriate, the public and other interested parties.

3.27. The government or the regulatory body should ensure that the following technical, administrative and procedural topics and requirements are included in the regulations, if appropriate, depending on the State's legal system and practices:

- (a) The name and location of the regulatory body;
- (b) The purpose of the regulations, their scope and their date of entry into force;
- (c) The powers of the regulatory body, such as powers of authorization, inspection and enforcement;
- (d) The relationship of a given set of regulations to other governmental regulations in force;
- (e) The criteria for exemption from some or all of the regulatory requirements;
- (f) Requirements for planned exposure situations, emergency exposure situations and existing exposure situations;
- (g) Requirements for occupational exposure, public exposure and medical exposure;
- (h) Requirements for construction, commissioning, operation and decommissioning (or closure) of facilities, management of radioactive waste and transport of radioactive material;
- (i) The financial arrangements for dealing with orphan sources and waste management (including decommissioning and waste disposal);
- (j) Acceptance criteria and performance criteria for any manufactured or constructed source, device, equipment or facility that when in use has implications for safety;
- (k) Criteria and methods for assessing the adequacy of the implementation of remediation following contamination;

- (l) Safety criteria and planning for radioactive waste management and discharge monitoring, as well as aspects of institutional controls at different stages of the authorized facility or activity's lifetime, including removal from regulatory control.

Notification and authorization

3.28. Requirement 7 of GSR Part 3 [3] states that: “**Any person or organization intending to operate a facility or to conduct an activity shall submit to the regulatory body a notification and, as appropriate, an application for authorization.**”

As part of the regulations, the regulatory body should clarify those facilities and activities for which only notification is required and those facilities and activities for which authorization is required, by providing criteria or lists of activities. The regulations and guides should cover all the major aspects to be dealt with at all steps of the authorization process.

3.29. Paragraph 4.34 of GSR Part 1 (Rev. 1) [2] states that:

“The applicant shall be required to submit or to make available to the regulatory body, in accordance with agreed timelines, all necessary safety related information as specified in advance or as requested in the authorization process.”

3.30. The regulatory body should issue detailed guidance for applicants on how to notify of the intention to conduct an activity or how to apply for authorization. The guidance for applicants for an authorization may include, as appropriate:

- (a) Guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization, including printed (or electronic) forms to be completed by authorized parties in a question and answer format, so that all relevant information is gathered. Guidance for nuclear power plants is provided in IAEA Safety Standards Series No. GS-G-4.1, Format and Content of the Safety Analysis Report for Nuclear Power Plants [14]; guidance for research reactors is provided in IAEA Safety Standards Series No. SSG-20, Safety Assessment for Research Reactors and Preparation of the Safety Analysis Report [15].
- (b) A list clearly stating the regulations and standards to be applied.
- (c) Advance information on the requirements for each major stage of authorization, in order to assist the authorized party in making sound plans

and decisions with respect to safety in the siting, design, construction, commissioning, operation and decommissioning or closure of a facility or conduct and termination of an activity.

Main contents of an authorization

3.31. The main contents of an authorization, as well as the objectives of possible authorization conditions, should be specified within regulations and guides. Detailed recommendations on notification and authorization are provided in paras 3.73–3.146.

Documentation to be submitted by the authorized party

3.32. The regulations and guides describing the authorization process should identify the essential documents to be prepared and submitted by the authorized party. Additional documents may be requested as necessary, depending on the type of facility or activity, in accordance with a graded approach and at specific steps in the authorization process.

3.33. The regulations and guides should indicate other documents that should be submitted to the regulatory body to confirm that the requirements established in the regulations and in the authorization conditions have been satisfied.

Reporting of events

3.34. The regulations or the authorization conditions should specify the requirements for reporting to the regulatory body on events that are considered significant to safety. The regulations or the authorization conditions should specify the types of event that require reporting and the reporting procedures including the method of reporting and the time limit for reporting. They should also specify that an investigation is to be carried out by the authorized party and a report prepared and submitted to the regulatory body within a specified period of time, covering details of the event, details of associated doses and environmental impacts, the findings of the investigation performed and proposals for corrective actions. The requirements for such reporting should be applied in accordance with the severity of the event.

Reporting of design changes, modifications and non-conformances

3.35. The regulations and guides should specify the requirements for the reporting of changes to the design, prior to their implementation, and design deficiencies

and non-conformances identified during commissioning or operation. The requirements for such reporting should be applied in accordance with the safety significance of the change, modification or non-conformance.

Records to be kept by the authorized party

3.36. The regulations and guides should specify requirements for the authorized party to keep adequate records relating to the safety of facilities and activities. Such records, even if not formally requested by the regulatory body for review and approval, should be capable of being made available, as necessary. The regulations and/or the authorization conditions should establish the types of records to be kept and the periods for which they are to be retained. In specifying the retention period, account should be taken of the possible future need to refer to these records and of the difficulties of regenerating the information.

Records to be kept by the regulatory body

3.37. Requirement 35 of GSR Part 1 (Rev. 1) [2] states that:

“The regulatory body shall make provision for establishing, maintaining and retrieving adequate records relating to the safety of facilities and activities.”

3.38. Paragraph 4.63 of GSR Part 1 (Rev. 1) [2] states that:

“The regulatory body shall make provision for establishing and maintaining the following main registers and inventories:

- Registers of sealed radioactive sources and radiation generators;¹⁰
Records of doses from occupational exposure;
- Records relating to the safety of facilities and activities;
- Records that might be necessary for the shutdown and decommissioning (or closure) of facilities;
- Records of events, including non-routine releases of radioactive material to the environment;
- Inventories of radioactive waste and of spent fuel.

¹⁰ The regulatory body specifies which sources are to be included in the registers and inventories, with due consideration given to the associated risks.”

3.39. The regulatory body should also make provision for the establishment and maintenance of records by authorized parties of unsealed sources and records of airborne and liquid releases during normal operation.

3.40. Such registers and inventories may be held by the regulatory body or by the authorized party. If the regulatory body is not the sole entity responsible for the maintenance of such registers and inventories, it should ensure that the authorized party has arrangements for their proper retention and retrieval. The responsibility of the regulatory body to maintain safety related records at a national level should not diminish the responsibility of authorized parties to keep their own records.

Regulations and guides for review and assessment

3.41. Requirement 25 of GSR Part 1 (Rev. 1) [2] states that:

“The regulatory body shall review and assess relevant information... to determine whether facilities and activities comply with regulatory requirements...”

3.42. Further, Requirement 26 of GSR Part 1 (Rev. 1) [2] states that:

“Review and assessment of a facility or an activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.”

3.43. In order to fulfil these requirements, the regulatory body should issue regulations and guides that describe the safety assessments to be performed by the authorized party for the facility or activity, and how these should be submitted for review by the regulatory body prior to the granting of the authorization at each lifetime stage. Further requirements for safety assessment are established in paras 3.29–3.36 of GSR Part 3 [3] and in IAEA Safety Standards Series No. GSR Part 4 (Rev. 1), Safety Assessment for Facilities and Activities [16].

3.44. In carrying out its review and assessment, the regulatory body should refer to the relevant regulatory requirements when deciding on the acceptability of an authorized party’s submission.

Regulations and guides for enforcement

3.45. The regulations and guides governing the use and implementation of enforcement actions should include the policy for the use of regulatory and

enforcement measures and the associated authority delegated to inspectors and other regulatory body staff. Depending on national practices, the need to allow the authorized party to state a point of view on regulatory decisions, to respond to enforcement actions and to appeal against enforcement decisions should be recognized and taken into account in regulations and guides. In some States, the regulations and guides specify that a hearing with the authorized party be initiated before significant enforcement actions are taken.

3.46. Considering the level of detail of legislation and regulations, guides should describe the decision making approach of the regulatory body in determining the type and extent of the enforcement actions to be taken and the way in which the actions are to be taken, including how the failure of the authorized party to comply with requirements for regulatory enforcement is dealt with. Guides should also indicate which other governmental organizations, if any, are to be informed in the event of enforcement actions.

Exemption and clearance from regulatory requirements

3.47. Requirement 8 of GSR Part 3 [3] states that:

“The government or the regulatory body shall determine which practices or sources within practices are to be exempted from some or all of the requirements of [GSR Part 3]. The regulatory body shall approve which sources, including materials and objects, within notified practices or authorized practices may be cleared from regulatory control.”

3.48. In this respect, the government or the regulatory body is required to determine within the regulations:

- (a) Which activities and/or radiation sources are to be exempted from some or all of the legislative requirements, including the requirements for notification or authorization. The regulatory body is required to use as a basis for this determination the criteria for exemption specified in Schedule I of GSR Part 3 [3], or to specify any exemption levels on the basis of these criteria. The regulations should clearly state that exemption cannot be granted for activities deemed to be not justified (see paras 3.10 and 3.11 of GSR Part 3 [3]).
- (b) Which sources, including materials and objects, within notified or authorized activities may be cleared from further regulatory control. The regulatory body is required to use as the basis for this determination the criteria for clearance specified in Schedule I of GSR Part 3 [3], or to

specify any clearance levels on the basis of these criteria. By means of these arrangements, the regulatory body is required to ensure that sources that have been cleared from regulatory control do not again become subject to the requirements for notification or authorization unless the regulatory body so specifies (see para. 3.12 of GSR Part 3 [3]).

Regulations and guides on the release criteria for sites

3.49. The regulations and guides should specify generic release criteria for use in the evaluation of potential radiological consequences associated with a site after its release. In order to derive release criteria (in, for example, Bq/g or Bq/cm²), all relevant exposure pathways should be considered and dose assessment involving direct radiation, inhalation and ingestion pathways should be used.

3.50. Alternatively, the authorized party can derive site specific release criteria, on the basis of an optimization process, which the regulatory body should review and assess and then approve, if considered adequate.

Process for development, review and revision of regulations and guides

3.51. Paragraph 4.61 of GSR Part 1 (Rev. 1) [2] states that:

“The government or the regulatory body shall establish, within the legal framework, processes for establishing or adopting, promoting and amending regulations and guides. These processes shall involve consultation with interested parties in the development of the regulations and guides, with account taken of internationally agreed standards and the feedback of relevant experience. Moreover, technological advances, research and development work, relevant operational lessons learned and institutional knowledge can be valuable and shall be used as appropriate in revising the regulations and guides.”

Sources of information and general guidance

3.52. The nature of the national legal framework, more than any other single factor, will determine the form and content of the regulations and guides. As an initial source of information, the regulatory body should base its regulations and guides on national legislation and should make use of existing national regulations or technical standards in areas relating to, or adaptable to, facilities and activities. The degree to which the regulations are prescriptive will depend on

national approaches. In some States, for example, detailed guidance is preferred to prescriptive regulations.

3.53. While regulations may be established, in whole or in part, by the government, the regulatory body should be involved in the development process. The following paragraphs cover the role of the regulatory body in the development process.

3.54. In developing regulations and guides, consideration should be given to adopting, either directly or as a reference, the IAEA's safety standards. IAEA safety standards are established in the form of specific requirements and recommendations so as to facilitate their incorporation into regulations. Although IAEA safety standards may be adopted individually or collectively, adaptation, rewording and amendment may be necessary, depending on the national legal system. IAEA safety standards may be adopted into national regulations by the addition of appropriate specific requirements, or by referencing the safety standards, or by adapting the safety standards as necessary, or by issuing them as national guides or incorporating them into guides.

3.55. Consideration should be given to obtaining advice on and support in the development of regulations and guides from international organizations, such as the IAEA, and from the regulatory bodies of other States. When the design of a facility or the performance of an activity originates in another State, it may be particularly useful to seek advice and support from the regulatory body of that State. States embarking on a nuclear power programme should consider regulations developed by the State supplying the facility.

3.56. When regulations, guides and other relevant information issued by a regulatory body in another State are considered in the development of regulations, particular attention should be paid to the legal framework of that State. Owing to differences between States' legal and governmental infrastructures, and available resources, it is unlikely that the regulatory body will be able to adopt regulations issued in another State without revision. In adapting regulations and guides issued in another State, the regulatory body should ensure that it understands the regulations in terms of their technical background and significance and the legal and regulatory framework in the State that issued them.

3.57. The regulatory body, as part of the drafting process, should consider performing comparisons of its national regulations and guides with international standards.

3.58. Consideration should also be given to other sources of information relevant to safety. This could include relevant industrial standards (in their entirety or in part), technical standards developed in other States, experience from the nuclear industry and from users of radiation sources, and the results of research in nuclear and radiation safety.

3.59. The regulatory body may find it useful to set up an advisory committee to advise on the need for regulations and on their technical content. The members of the advisory committee should be independent of the regulatory body and of authorized parties to ensure separate and unbiased reviews. Such an advisory committee can provide a valuable service to the regulatory body by helping to ensure that policies and regulations are clear, practicable and complete.

3.60. The regulatory body should follow a consistent process for establishing, reviewing and revising regulations and guides. The process should be well documented, comprehensive, cover all regulated activities and facilities, and should ensure a clear allocation of responsibilities. When establishing new regulations as well as revising existing regulations, careful consideration should be given to the cumulative effect of changes on safety.

3.61. The process of developing regulations and guides should be described in procedures and should be sufficiently flexible to permit timely revisions to be made to take account of changes in technological, legal and practical conditions.

3.62. Owing to variations in the legal systems and practices of States, it is impossible to provide detailed procedural guidance for establishing regulations and guides to be used by all States. However, certain basic steps for establishing regulations and guides can be specified, and are described in the following.

Process for establishing regulations and guides

3.63. The process used by the regulatory body to establish regulations and guides should include the following steps:

- (a) Determining the need for the regulations or guide. This need may arise from the regulatory body's activities and from the inventory of facilities and activities in the State. Alternatively, the need may be identified as a result of a request or enquiry by an authorized party, or an applicant for a new facility or activity. Additionally, the need for regulations may arise as a result of national debates or to meet international obligations.

- (b) Setting the priority for the development of the regulations or guide. The regulatory body should consider the advantages and disadvantages of the proposed regulations or guide, including such matters as: the risks associated with the facility or activity; the need for, and the costs associated with, improvements in safety; the number of authorized parties to be affected; the effects on the efficiency of the authorization process; and the feedback of information and experience from review and assessments, inspections, investigations and enforcement activities.
- (c) Determining the scope of the regulations or guide. This involves clear identification of the facilities and activities to which regulatory requirements or recommendations are to be applied, as well as the stage of the authorization process to be covered and the technical topic to be addressed.
- (d) Determining the resources necessary to develop the regulations or guide. The development of regulations and guides requires sufficient suitably qualified, competent and experienced people to be available, as well as adequate financial and other resources [4]. The need for the regulations or guide and the timescale required for its preparation and establishment will be a factor in determining the resources required.
- (e) Collection of information. The information necessary to prepare the proposed regulations or guide should be collected. In particular, the state of the art in technology should be taken into account.
- (f) Drafting of the regulations or guide. The staff of the regulatory body, assisted by technical support organizations, consultants, professional societies or advisory committees, drafts the initial version of the regulations or guide. Regulations and guides should be written in a style that is clear and easy to understand. Regulations and guides should be relevant, precise and unambiguous so as to be readily applicable and enforceable, as appropriate.
- (g) Review of the regulations or guide. Although practices differ widely, legal staff and special advisory committees, as appropriate, usually review the initial versions of proposed regulations or guides. In some States, authorized parties, professional societies or other organizations participate in these reviews. A draft version may also be published provisionally with an invitation for comment from the interested parties. Comments received as a result of the review should be analysed, evaluated and resolved, as appropriate. A review of the final draft for quality control should be carried out before formal approval. At this stage, consideration should also be given to the implications of the new regulations or guide for existing facilities and activities.
- (h) Establishing and issuing the regulations or guide. Regulations should be established and promulgated in a manner that makes them legally binding

in accordance with the national legal system, thereby ensuring that their provisions can be enforced by the regulatory body. The procedure for issuing guides should follow steps similar to those for regulations, but a guide can be formally issued with a lower level of approval, since its contents are only advisory in nature.

3.64. Consideration should be given to grouping the guides, for example:

- (a) Detailed or specific recommendations, concerning specific facilities, activities, equipment, operating procedures and protocols, and the qualification and training of personnel, that can be adopted by authorized parties as a means of meeting regulations;
- (b) Practical protection and safety manuals covering various activities and procedures that serve as aids for the training of workers and for management in setting up local rules;
- (c) Procedural guides, such as those pertaining to instrument calibration, individual monitoring, environmental surveys and radioactive waste management, for use by authorized parties and/or technical service providers;
- (d) Guidance relating to the safety of persons undergoing medical exposure;
- (e) Guidance on developing safety assessments that identifies areas that need to be evaluated or reviewed for the authorization;
- (f) Guidance on the safe transport of radioactive material;
- (g) Procedures for the conduct of investigations;
- (h) Guidance on the development of emergency plans and emergency procedures.

Process for review and revision of regulations and guides

3.65. The regulatory body should ensure that the regulations and guides are kept up to date and should establish procedures, within its integrated management system, for their periodic review.

3.66. Experience from implementing the regulations should be examined and any problems or difficulties should be duly considered. The status of relevant requirements should also be examined in the light of new safety related developments. The possible effects of frequent changes in regulations and guides on the stability of the regulatory system should be taken into account. The reasons for revising regulations may include: changes in legislation; changes in the organization, responsibilities, policies or procedures of the regulatory body; experience gained by the regulatory body in the authorization process; feedback

of information and experience from events, as well as from relevant national and international good practices; technological advances; and the need to improve or eliminate any impractical, misleading, unenforceable or otherwise inadequate regulations.

3.67. The procedures applicable in the development of regulations may also be followed for making revisions. Authorized parties and other interested parties potentially affected by the revised regulations should be given adequate time to complete any preparations that may be necessary to enable them to comply with newly established requirements.

3.68. The process and procedures established for the revision of regulations and guides should not diminish the authority of the regulatory body to take immediate action if required for reasons of safety.

Impact of the revision of regulations

3.69. Paragraph 4.27 of GSR Part 1 (Rev. 1) [2] states that:

“The regulatory body shall...recognize the risks associated with making modifications to well established practices. Prospective changes in regulatory requirements shall be subject to careful scrutiny, to evaluate the possible enhancements in safety that are to be achieved. The regulatory body shall also inform and consult interested parties in relation to the basis for such proposed changes in regulatory requirements.”

3.70. In revising regulations, special care should be taken to ensure that no contradictions or inconsistencies arise between the retained parts and the revised parts of a regulation.

3.71. The extent to which the proposed changes are to be made applicable to facilities and activities that have already been authorized and the degree of back-fitting to be required should also be considered.

Internal guidance

3.72. In order to ensure a systematic and consistent approach, the regulatory body should develop internal guidance on the processes and procedures to be followed to carry out the regulatory functions in an effective and efficient manner as well as on the safety objectives to be met. Detailed guidance on specific topics is provided in the relevant parts of this section. Consideration should be

given to the extent to which the regulatory body's internal guidance may be made available to authorized parties and the public and other interested parties. Publication is an important aspect of communication with interested parties and openness demonstrates that the regulatory body is discharging its responsibilities in an appropriate manner.

NOTIFICATION AND AUTHORIZATION

General

3.73. Requirement 7 of GSR Part 3 [3] states that:

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

3.74. The notification and, as appropriate, the application for authorization should be submitted on forms prescribed by the regulatory body with information that is commensurate with the level of radiation risk associated with operating the facility or conducting the activity.

3.75. Requirement 23 of GSR Part 1 (Rev. 1) [2] states that:

“Authorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all those facilities and activities that are not either explicitly exempted or approved by means of a notification process.”

3.76. The concepts of notification, authorization by registration, and authorization by licensing broadly represent a graded approach to regulatory control based upon the levels of risk or the nature of the facility or activity.

3.77. The regulatory body is required to determine which facilities or activities are to be exempted from the requirements for notification or authorization, using as the basis for this determination the criteria for exemption specified in Schedule I of GSR Part 3 [3] or any exemption levels specified by the regulatory body on the basis of these criteria.

3.78. A notification is “[a] document submitted to the regulatory body by a person or organization to notify an intention to carry out a practice or other use of a source” [8].

3.79. For some activities that are suitable for exemption, there may be particular reasons why a notification should be submitted (e.g. to prevent uncontrolled waste disposal).

3.80. Paragraph 3.7 of GSR Part 3 [3] states that:

“Notification 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.”

3.81. Where notification alone is insufficient (i.e. because the exposures expected to be associated with the facility or activity have the potential to exceed the small fraction of the limit specified by the regulatory body) an application for authorization should be submitted to the regulatory body. An application for authorization may also serve as notification. Where a notification has been submitted, but the regulatory body determines that the potential exposures can exceed the specified limit for notification, an authorization should be required.

3.82. The authorization process is the principal means by which the regulatory body is able to initially apply the legal and regulatory framework and by which the responsibilities of the applicant or authorized party are clearly connected to the legal framework.

3.83. Authorization is required to take the form of either registration or licensing [3]. Other terms are used for authorization, including certification, granting of a permit, agreement, consent, approval or granting of another similar regulatory instrument, depending on the governmental and regulatory framework of the particular State. For complex facilities or activities and where the radiation risks are significant, the authorization process is usually referred to as a licensing process, which results in a licence in the form of a legal document issued by the regulatory body granting authorization to perform specified activities relating to operation of a facility or conduct of an activity.

3.84. Registration is “[a] form of authorization for facilities and activities of low or moderate risks whereby the person or organization responsible for the practice

has, as appropriate, prepared and submitted a safety assessment of the facilities and equipment to the regulatory body” [8]. The regulatory body should determine which facilities and activities require authorization by registration only and for which a licensing process is required. In either case, the facility or activity should be authorized with conditions or limitations as appropriate. The requirements for safety assessment and the conditions or limitations applied to the facilities or activities would be less severe for registration than those for issuing a licence.

3.85. With regard to material being transported in accordance with IAEA Safety Standards Series No. SSR-6 (Rev. 1), Regulations for the Safe Transport of Radioactive Material [17], the requirements established in GSR Part 3 [3] for notification and authorization are fulfilled by means of compliance with SSR-6 (Rev. 1) [17].

3.86. Authorizations should be granted or denied in accordance with the governmental, legal and regulatory framework and should cover all stages of the lifetime of a facility or activity. For a nuclear facility, for example, this encompasses site evaluation, design, manufacturing, construction, installation, commissioning, operation, decommissioning (or closure) and subsequent release of the site from regulatory control.

3.87. The legal framework of the State should set out the responsibilities for issuing an authorization and, in particular, should determine who is empowered to issue authorizations. Depending on the system used in the particular State, different authorizations may be issued by different authorities. Requirement 7 of GSR Part 1 (Rev. 1) [2] states that:

“Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties.”

3.88. Paragraph 3.9(b) of GSR Part 3 [3] states that:

“Any person or organization applying for authorization...[s]hall refrain from carrying out any of the actions [covered by the application] until the registration or the licence has been issued”.

3.89. The authorized party is the legal person or organization that has prime responsibility for safety and retains this responsibility even if the validity of an

authorization expires or lapses, or if the authorization is revoked by the regulatory body. However, the responsibilities conferred by the authorization may be transferred to a different authorized party (e.g. upon change of ownership, where this has been approved by the regulatory body).

3.90. After having determined that the justification principle has been implemented, the regulatory body should specify the conditions under which consumer products that contain radioactive material may be made available to the public, who have no regulatory obligation with respect to the product. In this context, the presumption is that the consumer product can be used and disposed of without any special safety measures being required. The provision of consumer products to the public is subject to authorization by the regulatory body unless their use has been exempted (see Requirement 33 of GSR Part 3 [3]).

Objectives of notification and authorization

3.91. The objective of notification is to provide initial information to the regulatory body that a person or organization is intending to operate a facility or conduct an activity. The regulatory body should use the information received in the notification process to update the registers of sources, facilities and activities and to decide on the level of regulatory control to be applied. The notification should be reviewed and, if necessary, the regulatory body should inform the person or organization as to what further regulatory interactions will be required.

3.92. The objective of granting authorizations is for the regulatory body to establish effective regulatory control for safety throughout the lifetime of a facility or activity. The authorization process should require assurance by the applicant that it can comply with all safety requirements.

General principles for authorization

3.93. Principles for authorization should be established in the regulatory and legal framework. Examples of principles for authorization include the following:

- (a) A facility or activity should be authorized only when the regulatory body has confirmed, by review and assessment of the submitted documentation, that the facility or activity is going to be used or conducted in a manner that does not pose an unacceptable radiation risk to people or the environment. This should include confirmation that the applicant has the organizational capability, the organizational structure, adequate resources, adequate competence of managers and staff, and appropriate management