

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

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**.

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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.

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.

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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.

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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.

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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Marketing and Sales Unit, Publishing Section
International Atomic Energy Agency
Vienna International Centre
PO Box 100
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fax: +43 1 26007 22529
tel.: +43 1 2600 22417
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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.

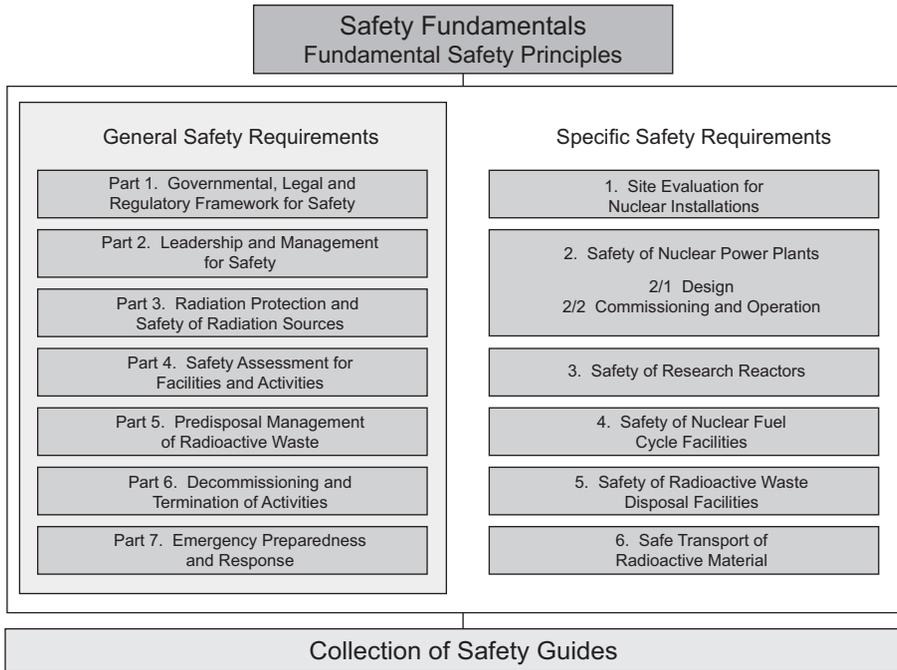


FIG. 1. The long term structure of the IAEA Safety Standards Series.

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

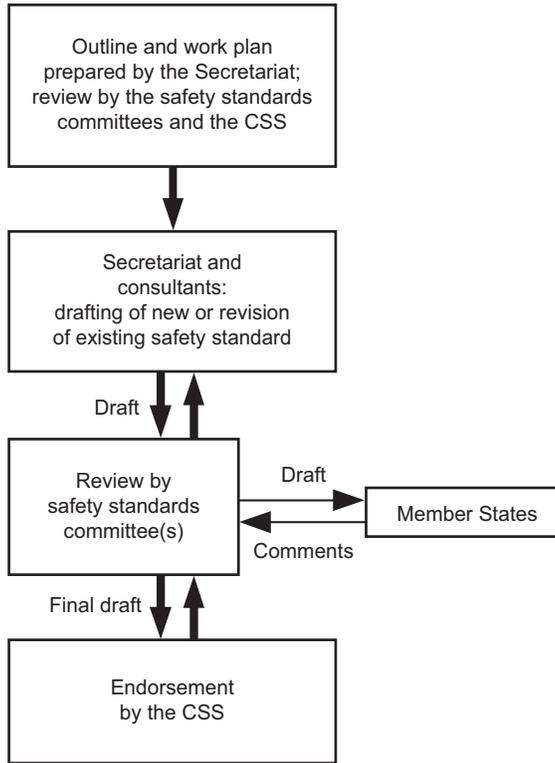


FIG. 2. The process for developing a new safety standard or revising an existing standard.

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

arrangements to comply with the safety requirements to become an authorized party.

- (b) The regulatory framework for dealing with requests for authorization should be clear, especially the process for applying for authorization.
- (c) The regulatory framework for the authorization process should be explicitly established by the regulatory body.
- (d) The authorization of a facility or activity should be based on a predefined list of documents that are to be submitted to the regulatory body by the person or organization responsible for the facility or activity. These documents should be reviewed by the regulatory body. Expenses associated with the authorization process and the person or organization that will be charged these expenses should be clearly specified.
- (e) A clear and explicit set of requirements, criteria and standards forming the basis for authorization should be defined.
- (f) A graded approach should be taken by the regulatory body when performing reviews, assessments or inspections throughout the authorization process.
- (g) Clear mechanisms should be established for public participation in the authorization process.
- (h) The authorization process should be transparent to the public, and authorizations should be published or made available to the public by other means, with account taken of the need for information security and protection of proprietary information.
- (i) The regulatory body should include conditions in the authorization, as appropriate.
- (j) The scope of the authorization (the site, the facility or activity, or parts of the facility or activity; or whether the authorization is one of a series of authorizations), its period of validity and any incorporated conditions should be clearly defined by the regulatory body.
- (k) Responsibility for safety may be transferred to a different authorized party, depending on national regulations; however, this may be done only with the agreement of the regulatory body, which may attach provisions and conditions to the new authorization (see para. 2.14 of GSR Part 1 (Rev. 1) [2]).
- (l) The applicant and the regulatory body should take into account good practices in other States, as appropriate, throughout the authorization process.
- (m) Regulatory review and assessment of reference or generic facilities and activities, and of similar facilities or activities in the State or other States, should be taken into account, if this would contribute to the authorization process.

- (n) The analysis approach to demonstrating safety should be clearly defined, including the use of deterministic and probabilistic methodologies and analytical tools, as appropriate.
- (o) Safety reviews should be carried out by the authorized party as required by the conditions in the authorization, and the results should be submitted to the regulatory body for review and assessment. Appropriate regulatory decisions may then follow.
- (p) The prime responsibility for safety is assigned to and assumed by the person or organization responsible for a facility or activity that gives rise to radiation risks. Compliance with regulations and requirements imposed by the regulatory body does not relieve the person or organization responsible for any facility or activity of the prime responsibility for safety (see Requirement 6 of GSR Part 1 (Rev. 1) [2]). The person or organization responsible for a facility or activity should demonstrate to the satisfaction of the regulatory body that this prime responsibility has been and will continue to be fulfilled.
- (q) The means of challenging or appealing against an authorization or part of an authorization should be made clear by the regulatory body and within the regulatory framework.

3.94. The legal and regulatory framework should include provisions for unrestricted access for designated staff of the regulatory body, at any time, to: the premises of an applicant or authorized party, any facility or activity already authorized or for which an application for authorization has been submitted, and any documents relating to safety and considered necessary for the authorization process.

3.95. The regulatory body should ensure that any interfaces between safety and nuclear security measures are addressed by the authorized party or applicant and are appropriately considered in conjunction with the competent authority with responsibility for nuclear security.

Information to be provided in the submission of a notification or application for authorization

Notification

3.96. The regulatory body should specify the minimum information to be submitted in support of notification by a person or organization intending to operate a facility or conduct an activity that involves the use of radiation sources, including the following:

- (a) Clear identification of the applicant submitting the notification;
- (b) Information on the provisions for justification of the facility or activity;
- (c) The location(s) of the facility and, if applicable, where the radiation source(s) will be stored and used;
- (d) Specification of the management system for the facility or activity;
- (e) Clear specification of the equipment to be used in the facility or activity, including the radiation source(s) and associated equipment.

Authorization

3.97. Requirement 24 of GSR Part 1 (Rev. 1) [2] states that:

“The applicant shall be required to submit an adequate demonstration of safety in support of an application for the authorization of a facility or an activity.”

3.98. The applicant should provide all relevant information describing the approach to safety in order to demonstrate that the facility or the activity will not present unacceptable radiation risks to people and the environment. This should include proposed objectives, principles, criteria, standards and analyses in relation to safety for all stages of the authorization process. The aim should be to provide all the relevant information such that the regulatory body can conduct its review and assessment process without needing to seek further information or clarification.

3.99. The documents submitted to the regulatory body in the framework of the authorization process should be updated, as appropriate, during the lifetime of the facility or activity, to ensure they cover relevant aspects. The documents submitted to the regulatory body (which may be divided or combined into different documents, as appropriate) should be incorporated as part of the authorization, if required by national regulations and the regulatory approach and practices.

3.100. For complex facilities or activities, before an applicant submits an application, the regulatory body should consider implementing a preparatory phase, in which basic safety requirements to be met and the authorization process to be followed are made clear to the applicant. This may include specification of, for example, the language, units, methodology and format of the proposed application. In this phase, it should be ensured that the staff of the regulatory body receive suitable training and have sufficient knowledge of the design of the facility or the proposed activity. Detailed and explicit design requirements for the

facility or characteristics of the activity should be developed in the early stages of the authorization process.

3.101. Early assessment of the competence and capability of the applicant should be conducted to ensure that the applicant will be able to manage all stages of the lifetime of the facility or the full duration of the activity. At a very early stage, the applicant should be encouraged to conduct a study to identify the staff and competences it will need in the different stages in the lifetime of the facility or the duration of the activity and should give consideration to how and from where it will recruit such staff.

3.102. The extent of the information to be submitted to support an application for authorization should take into account the type of facility or activity. The scope of the information required should depend on the stage in the lifetime for which the authorization is being considered. The information should include, as applicable:

- (a) Legal information:
 - (i) The formal name and address of the applicant and any additional contact information, such as the name of the individual(s) representing the applicant;
 - (ii) Details of any relevant existing authorizations;
 - (iii) Information on whether the facility or activity is fully or partly owned or controlled by a person from another State or by a foreign corporation, and, if so, details of the ownership structure.
- (b) Information on organizational matters:
 - (i) The applicant's organizational structure;
 - (ii) Evidence that the applicant has and will continue to maintain adequate financial resources to cover the necessary costs associated with safety, such as regulatory fees, liability insurance and funding for decommissioning or radioactive waste management, as applicable, depending on national legislation and regulation;
 - (iii) Evidence that the applicant has adequate human resources to ensure that regulatory requirements and safety standards are met and will continue to be met throughout the lifetime of the facility or activity.
- (c) Characteristics of the site and the facility or activity:
 - (i) The nature of the facility or activity that is the subject of the application;
 - (ii) A description of the relevant premises, including the layout of the facility, buildings and equipment;

- (iii) Where relevant, a description of the site in terms of geography, demography, topography, meteorology, hydrology, geology and seismology.
- (d) Staff qualification and training:
 - (i) Identification of the necessary qualifications and training of staff who will have safety related responsibilities;
 - (ii) For authorization of certain facilities or activities, the identification of persons by name may be required to be included in the application (e.g. the name of radiation protection officers or qualified experts);
 - (iii) Details of qualifications and training in radiation protection of workers engaged in activities that involve or could involve occupational exposure;
 - (iv) Evidence of trustworthiness of all staff who will be engaged in responsible or sensitive positions.
- (e) The management system:
 - (i) For relevant safety systems of facilities or activities with significant risk, the operating procedures and maintenance procedures that will be followed;
 - (ii) A description of the system for identification, traceability and preservation of documents and for control of records;
 - (iii) The system for the development of procedures;
 - (iv) Procedures for reporting on and learning from operating experience including accidents and other incidents;
 - (v) Procedures for learning from good practices in the State and in other States;
 - (vi) A description of the arrangements for establishing and sustaining leadership and management on the part of organizations and managers responsible for facilities and activities that give rise to radiation risks;
 - (vii) A procedure or description of the process for dealing with modifications of the facility or activity that may be subject to approval by the regulatory body, depending on national legislation, regulations and practices if requirements for dealing with modifications are not established directly in the regulations;
 - (viii) A description of the quality assurance arrangements established to ensure that all items to operate the facility or conduct the activity are designed, manufactured, constructed, assembled, tested, qualified, operated, maintained and replaced in compliance with the relevant safety requirements;
 - (ix) A description of the arrangements for ensuring the technical quality of information provided to the applicant by external organizations

- (e.g. contractors) for use during the operation of the facility or the duration of the activity;
- (x) Quality assurance arrangements, including internal and external audits.
- (f) Safety activities:
- (i) Applicable safety regulations, guides and industrial standards.
 - (ii) Safety assessments for exposures in normal operation and for potential exposures.
 - (iii) An appropriate prospective assessment of radiological environmental impacts, commensurate with the radiation risks associated with the facility or activity, as required by the regulatory body (see para. 3.9(e) of GSR Part 3 [3]).
 - (iv) The occupational radiation protection programme, including arrangements for designation of areas, local rules and procedures, monitoring of workers and the workplace, the health surveillance programme, and provision and maintenance of personal protective equipment.
 - (v) Safety assessments and other design related documents that address the optimization of protection and safety, the design criteria and the design features relating to the assessment of exposure and potential exposure of members of the public.
 - (vi) For activities involving medical exposure, information relating to the radiation protection of patients, including arrangements for the calibration of sources used for medical exposure and for clinical dosimetry and the description of the management system.
 - (vii) For new, unusual or complex activities, or for the provision of consumer products, a demonstration that the principle of justification for engaging in the activity is fulfilled.
 - (viii) Arrangements for ensuring safety, which will be maintained for all stages of the lifetime of the facility or the duration of the activity.
 - (ix) The safety concepts and criteria used in the design of the facility or for carrying out the activity, including the classification of equipment, systems and components; the application of the concept of defence in depth; the use of multiple barriers to prevent radioactive releases; and the approach to issues relating to the human-machine interface.
 - (x) A description of the items important to safety for operating the facility or conducting the activity (e.g. the facility's structures, systems and components, including their design criteria, the processes involved in their design, and the modes of operation and testing).
 - (xi) Arrangements for the management of radioactive waste generated throughout the lifetime of the facility or activity, including in

decommissioning and for the management of disused sources (disused sources should either be managed in the State concerned or be returned to the supplier or manufacturer), and information on the financial arrangements for such activities.

- (xii) The results of an analysis of the normal operation of the facilities and activities, and, for a radioactive waste disposal facility, of the long term period after closure, to demonstrate the acceptability of the design, including a demonstration that radiation protection criteria, radioactive waste management requirements and effluent limits are met by the design.
- (xiii) The results of a safety analysis to demonstrate how the design and related operational procedures of the facility or activity will contribute to the prevention of accidents and to the mitigation of the consequences of accidents if they do occur. The analysis should describe and evaluate the predicted response of the facility or activity to events, both internal and external, which could lead to anticipated operational occurrences and accident conditions. The analysis should include relevant combinations of such disturbances, malfunctions, failures, errors and events. Consideration should be given to aspects, such as the initial conditions assumed, the physical or mathematical models used and their correlation with experiments, and the method of presenting the results.
- (xiv) A safety analysis that shows the extent to which the authorized party addresses precursors to events and anticipated operational occurrences and accident conditions. The limits and conditions for safe operation should be derived from this analysis. If any part of the analysis has been independently reviewed, the results of this review should also be presented. Additional recommendations and guidance on safety analysis for nuclear power plants are provided in IAEA Safety Standards Series Nos SSG-2 (Rev. 1), Deterministic Safety Analysis for Nuclear Power Plants [18]; SSG-3, Development and Application of Level 1 Probabilistic Safety Assessment for Nuclear Power Plants [19]; and SSG-4, Development and Application of Level 2 Probabilistic Safety Assessment for Nuclear Power Plants [20].
- (xv) Information on other plans and programmes established by the authorized party in support of its safety activities. This includes areas such as:
 - The environmental monitoring programme;
 - Fire protection;
 - Research and development in relation to the safe design, operation, decommissioning or closure of the facility or the activity;

- Feedback of operating experience [21];
 - The decommissioning (or closure) strategy.
- (g) Emergency arrangements:
- (i) Emergency arrangements, including an emergency plan and financial arrangements for preparedness and response for a nuclear or radiological emergency, where appropriate, that address the general, functional and infrastructural requirements established in GSR Part 7 [7].
- (h) Interface with nuclear security:
- (i) In accordance with the national regulatory framework, relevant information on nuclear security needs to be provided to the competent nuclear security authority [10, 11].

Form of notification or authorization for a facility or activity

Notification for a facility or activity

3.103. The information required for notification (see para. 3.96) may be described in a notification form. The purpose of the notification form is to enable an applicant to provide information with respect to the provisions for justification of the activity and to demonstrate that notification is sufficient to allow operation of the facility or conduct of the activity. Depending on national requirements, the regulatory body might prefer to have separate notification forms for facilities, radioactive material and other radiation sources.

Authorization for a facility or activity

3.104. Authorization is “[t]he granting by a regulatory body or other governmental body of written permission for a person or organization (the operator) to conduct specified activities” [8]. Authorization also establishes, directly or by reference, conditions governing the safe performance of these activities.

3.105. Authorizations may be granted:

- (a) For a specific time period (e.g. 10 years, 40 years) or for a specific stage in the lifetime of the facility (e.g. construction, operation) or for the duration of an activity. In such a case, a mechanism should be put in place to ensure that the authorized party responsible for the facility or activity retains the prime responsibility for safety and for the implementation of security

measures at the facility or for the activity, even if the authorization has expired, unless the site has been removed from regulatory control.

- (b) For an indefinite period of time (a permanent authorization), under certain conditions and until the authorization is officially terminated by the regulatory body.
- (c) For a specific activity or a specific condition of the facility (e.g. the temporary storage of spent nuclear fuel).

3.106. The format of an authorization will depend on the type of authorization and its content and, for complex facilities or activities, on the conditions deemed necessary by the regulatory body for a given stage of the authorization process in accordance with national legal procedures. For example, the authorization may incorporate by reference the underlying documents and only provide explanations of basic terms not defined elsewhere. Thus, the format of an authorization can differ not only among States, but also within a State, from stage to stage of the lifetime of the facility or activity, and from authorization to authorization for a given stage. However, the authorization should normally contain the following information:

- (a) Statutory authority. The authorization should have a unique identification and should explicitly refer to the laws and regulations on which it is based.
- (b) Issuing authority. The authorization should state the official designations of those who are empowered by law or regulation to issue the authorization, whose signature and/or stamp will appear on the authorization, and to whom the authorized party will be accountable under the terms of the authorization.
- (c) Fulfilment of requirements. The authorization should include a summary statement that all legal and technical requirements in respect of safety have been fulfilled and that the facilities can be operated and the activities can be conducted without unacceptable radiation risk to people or the environment.
- (d) Documentary basis. The authorization should identify the documents provided by the authorized party in support of the application, and those prepared by staff of the regulatory body in the review and assessment process, which together form the basis for issuing the authorization.
- (e) Relationship to other authorization(s). The authorization should indicate whether it is contingent upon a prior authorization or is a prerequisite for a future authorization.
- (f) The authorized party. The authorization should contain a precise identification of both the individual or organization legally responsible for the authorized facility or activity and the individual or organization responsible for the day to day control of the facility or the activity.

- (g) Period of authorization. The authorization should state an effective date of authorization. It may also include a termination date, which may be based on a fixed term. Alternatively, a period of validity may be stated over which the assumptions underlying the authorization decision will remain valid and at the end of which the basis for authorization will be re-examined.
- (h) Authorized activity. The authorization should clearly describe, in sufficient detail, the location of the facility or activity, including, as appropriate:
 - (i) A clear depiction and description of the site boundaries;
 - (ii) The facility design and its mode of operation and/or the conduct of activities;
 - (iii) The allowed inventory of radioactive material or radiation sources;
 - (iv) Other relevant information, as appropriate.
- (i) The authorized party's responsibility for compliance. The authorization should contain:
 - (i) An appropriate declaration that the authorized party has the responsibility for compliance with the legal requirements, regulations and conditions referenced or contained in the authorization or in other references, as applicable;
 - (ii) A statement that establishes that the responsibility for safety may be transferred to a different authorized party, subject to the approval of the regulatory body.

Form of authorization for individuals

3.107. In some States, legislation determines that an authorization in terms of individual qualification is required for a person to perform specific functions. In that case, the authorization should be the means of verifying the competences of the personnel to carry out those specific activities.

Form of notification and authorization for objects

3.108. Authorization for objects should be considered where it is effective for regulatory purposes. An example is the authorization (certificate of approval) of package design, special form radioactive material or low dispersible radioactive material as required in SSR-6 (Rev. 1) [17].

3.109. Requirement 33 of GSR Part 3 [3] states that:

“Providers of consumer products shall ensure that consumer products are not made available to the public unless their use by members of the

public has been justified, and either their use has been exempted or their provision to the public has been authorized.”

3.110. The regulatory body should require the manufacturer of consumer products to apply to the regulatory body and seek authorization to provide products to the public to ensure that consumer products meet all the requirements for design and performance that were taken into account in the safety assessment conducted by the manufacturer for the type of consumer product (see Appendix I).

3.111. For consumer products, notification is required only with respect to manufacture, assembly, maintenance, import, distribution and, in some cases, disposal (GSR Part 3 [3], para. 3.7).

Authorization conditions

3.112. An authorization should state explicitly, or should impose by reference or attachment, all conditions as determined by the regulatory body, which are obligations with which the authorized party is required to comply. Laws and practices relating to authorization differ between States. In some States, conditions are specified in the law and in regulations, and are merely referenced in the authorization, while in other States some or all conditions are stated explicitly in the authorization itself.

3.113. Authorization conditions should cover, as appropriate, safety aspects affecting the facility or activity throughout its lifetime, encompassing site evaluation, design, construction, installation, commissioning, operation and decommissioning of the facility or activity and its subsequent release from regulatory control. Authorization conditions should cover important aspects, such as design, radiation protection, the maintenance programme, emergency plans and procedures, modifications, the management system, operational limits and conditions, procedures and authorization of personnel. Furthermore, authorization conditions may refer to, but should not duplicate, regulations to avoid discrepancies or inconsistencies when the regulations are amended.

3.114. While authorization conditions may differ in format, they should exhibit certain basic qualities and characteristics to make them understandable and effective. Each authorization condition should be consistent with all other authorization conditions in that the fulfilment of one should not conflict with the fulfilment of another or with any other legal requirement. In the event that it is necessary to specify several authorization conditions addressing various technical

and administrative aspects, it may be useful to group the authorization conditions into categories, such as:

- (a) Authorization conditions that set technical limits and thresholds, such as:
 - (i) Any limits on operation and use, such as dose constraints or discharge limits;
 - (ii) Action levels;
 - (iii) Limits on the duration of the authorization.
- (b) Authorization conditions that specify procedures and modes of operation, such as:
 - (i) The obligations of the authorized party in respect of its facility, equipment, radiation source(s), management and personnel;
 - (ii) Requirements for minimization of the generation of radioactive waste;
 - (iii) Criteria for conditioning of radioactive waste for existing or foreseen radioactive waste management facilities;
 - (iv) Arrangements for emergency preparedness and response.
- (c) Authorization conditions pertaining to administrative matters, such as:
 - (i) Requirements for notifying the regulatory body of any modifications in accordance with their safety significance;
 - (ii) Any additional separate authorizations that the authorized party should obtain from the regulatory body, if necessary;
 - (iii) The reports that the authorized party should make to the regulatory body;
 - (iv) The means and procedures for changing any information stated in the authorization;
 - (v) Procedures for, information about and identification of the legal framework for challenging the conditions in the authorization or part of it.
- (d) Authorization conditions relating to inspection and enforcement, such as:
 - (i) The records that the authorized party should retain and the time periods for which they should be retained.
- (e) Authorization conditions pertaining to the response to abnormal conditions, such as:
 - (i) The requirements for reporting of events and the procedures for taking suitable corrective actions.

Steps in the authorization process

3.115. Although national practices differ, the regulatory body should carry out authorization in several steps for complex facilities or activities, with an application usually being required for each step (see Appendix II). For

nuclear facilities, industrial irradiation installations and facilities for industrial radiography, nuclear medicine and radiotherapy, the regulatory body may require a multistep process of authorization (e.g. it might require the submission of an application to construct the facility before construction can begin). The regulatory body might also prohibit the procurement of nuclear material or radiation sources (including their import) until a particular stage of construction has been completed and the safe and secure storage of the nuclear material or radiation sources can be ensured.

3.116. The authorization process should be understood by the parties concerned and should be predictable (i.e. well defined, clear, transparent and traceable). The authorization process should be such that the efficient conduct of regulatory activities is facilitated. The authorization process should be subdivided into steps (which may be based on the stage in the lifetime or be set at specific points within a particular stage) and the regulatory body should require additional information from the authorized party before the authorized party is granted an authorization to move from one step to the next. The steps of the authorization process should be discrete and should follow a logical order.

3.117. In developing the authorization process, consideration should be given to adoption or adaptation of pre-authorization processes; for example, steps that provide for the early approval of sites and the advance certification of standardized plant designs for authorization for construction and operation of a complex facility or activity. Such an authorizing process may help to minimize duplication of effort through the various steps and may allow for some steps to be conducted in parallel. It will also provide for a clear division of responsibilities at the various steps between the regulatory body, vendors, suppliers and authorized parties, will permit opportunities for early participation of the public, and will ensure that the most important safety issues are dealt with properly in the pre-authorization step.

3.118. The authorization process, including any processes for renewal of authorizations, should be carried out in a transparent manner, providing opportunities for communication and consultation with interested parties such as the public. The regulatory body should consider holding meetings with interested parties to provide information on the authorization renewal processes. Further recommendations on communication and consultation with interested parties are provided in paras 3.345–3.347.

Authorization process for a particular type of facility

3.119. If the national approach allows it, it may be appropriate for an authorized party or applicant to provide a submission to the regulatory body in terms of a ‘reference facility’ or a ‘generic design’, for example in cases where a particular type of facility (or parts thereof) is to be constructed many times. In such cases, the regulatory body should apply the same rigour in its review as for other submissions. A reference facility is a designated existing authorized facility of a type that will also be constructed in other locations, whereas the definition of a generic design is established by the regulatory body (see SSG-12 [5], para. 3.13) and relates to a type of facility that is to be constructed with relatively minor modifications in other locations. The review and assessment by the regulatory body of a submission in terms of a generic design in a pre-authorization assessment, if completed satisfactorily, means that it may be accepted as the basis for granting an authorization.

3.120. The use of generic designs or reference facilities will facilitate the authorization process. Not all the aspects that need to be considered can be dealt with on the basis of such a submission, and the regulatory body cannot grant an authorization in the same manner as for a single, specific facility; however, the authorized party will then generally only have to provide a limited submission for each particular facility. Such limited submissions should concentrate on those aspects for which the facility under consideration differs from the reference facility or the generic design; in particular, on those features that are specific to the chosen location or site. In providing a limited submission for a particular facility, the authorized party should clearly indicate which aspects of the limited submission differ from the earlier submission in terms of a reference facility or generic design, and should provide an explanation of why the other aspects of the limited submission are not affected. In addition, the regulatory body, in its comments on the generic design or reference facility, may identify particular aspects that should be addressed in the submission for the particular facility. In particular, authorization of the design of a facility that has been subjected to a pre-authorization assessment should consider the actual site characteristics and should ensure whether the site and the design are compatible. When moving forward from a pre-authorization step the regulatory body should require a submission by the applicant or authorized party detailing how it will manage and operate the facility.

Different steps of the authorization process for a complex facility or activity

3.121. The authorization process for a complex facility or activity should be considered to consist of a series of steps, each subject to the need for regulatory input to allow progress from one step to the next. These steps may depend on national legislation but are normally as follows:

- (a) Siting and site evaluation (which may include the environmental impact assessment);
- (b) Design;
- (c) Construction;
- (d) Commissioning;
- (e) Operation;
- (f) Decommissioning (or closure);
- (g) Release from regulatory control.

3.122. Each step of the authorization process may be divided into several substeps or may be merged or combined, as appropriate, to facilitate the regulatory process. Combining the authorizations (e.g. for construction and operation) may also give more predictability to the process for the authorized party, but will also require some information to be submitted earlier in the process.

3.123. In practice, review and assessment at each step of the authorization process may start at an earlier step and continue into subsequent steps. Also, depending on the arrangements made at the national level and the nature of the facility or the activity, review and assessment in some steps may be combined. The degree to which combination of the certain steps should be considered will depend on the nature of the facility or the activity and the risks associated with it.

3.124. Once an initial authorization has been issued, subsequent activities and arrangements should be undertaken by the authorized party and the regulatory body, as part of the authorization process.

3.125. On a particular site, there may be different facilities and/or activities at different stages of their lifetimes. Where there are different authorized parties on the same site, or on neighboring sites, the regulatory body should ensure cooperation between the authorized parties. The authorizations may have different licensing bases, depending on the type of regulatory control established in the State, and therefore a process for ensuring and maintaining consistency should be put in place. In cases where several authorized parties are permitted to

share common safety related items, arrangements should be reviewed to ensure that overall safety is not compromised.

Site evaluation

3.126. Site evaluation for many facilities or activities is initially determined by general processes rather than by highly prescriptive technical criteria. General requirements concerning remoteness, environmental concerns, local population density and transport arrangements may apply, which might not be within regulatory control. Geological and hydrogeological considerations should be major factors in site evaluation, particularly for radioactive waste disposal facilities. The regulatory body should consider being involved in the formulation of site selection criteria and in the process of determining the general suitability of a site. Further recommendations on site evaluation are provided in Refs [22–31].

3.127. For a facility or an activity that is to be operated or conducted at a permanent site, a decision should be reached on the acceptability of the specific site from a safety perspective after information on the site itself and preliminary information on the facility or activity and its interaction with the site have been reviewed and assessed by the regulatory body.

Design, construction, manufacture and installation

3.128. Construction, manufacture or installation of the facility should not be authorized until the initial design has been reviewed and assessed, including verification of the compatibility of the design and the site, as appropriate. The design requirements for nuclear power plants are established in IAEA Safety Standards Series No. SSR-2/1 (Rev. 1), Safety of Nuclear Power Plants: Design [32]. Guidance on the construction of nuclear installations consistent with the design requirements can be found in IAEA Safety Standards Series No. SSG-38, Construction for Nuclear Installations [33].

Commissioning

3.129. There is some overlap between the construction and commissioning stages, in that individual structures, systems and components might be commissioned before completion of the construction of the entire facility or the installation of all systems required for the activity. There are several steps in the commissioning process for which the regulatory body may require the authorized party to obtain prior approval and at which regulatory decisions may be made. However, the introduction of fissile material or other radioactive material into

the facility or activity marks a significant step within the commissioning stage and is often considered the main point at which regulatory decisions are made. The introduction of fissile material or other radioactive material should not be authorized until the proposed commissioning programme has been reviewed and assessed, preliminary operational limits and conditions have been established, the final design has been assessed and conformity of the construction with the design has been verified. Further recommendations on commissioning for nuclear power plants and research reactors are provided in IAEA Safety Standards Series No. SSG-28, Commissioning for Nuclear Power Plants [34] and IAEA Safety Standards Series No. NS-G-4.1, Commissioning of Research Reactors [35].

Operation

3.130. Commencement of operation should be authorized only once commissioning tests have been completed and their results assessed, and operational limits and conditions have been reviewed and assessed by the regulatory body.

3.131. Over the full operational lifetime of the facility or activity, the regulatory body should require the authorized party to provide evidence at appropriate intervals, in the form of a comprehensive safety review, such as a periodic safety review [36], that the facility or the activity is still fit to continue in operation. In many States, this reassessment period is around ten years for a complex nuclear installation such as a nuclear power plant. In such comprehensive safety reviews, account should be taken of significant changes in the potential nature and magnitude of the associated hazards, operating experience, significant changes to safety standards, technical developments and new safety related information from relevant sources. Depending on national laws and regulations and the outcome of the comprehensive safety review, the regulatory body may decide to renew the authorization of the authorized party.

3.132. Before bringing a facility back into operation following a major outage, the authorized party should be required to demonstrate to the satisfaction of the regulatory body that the facility will be able to continue to operate in compliance with the safety requirements until the next outage.

3.133. Throughout the lifetime of the facility or activity, modifications may be made to equipment, to management arrangements and to operational procedures. Where these modifications potentially affect safety they should be subjected to proper consideration by the authorized party. The regulatory body should ensure that proposed modifications are categorized by the authorized party in

accordance with their safety significance. This categorization should follow an established procedure, which may be subject to agreement or approval by the regulatory body. Modifications that are categorized as significant to safety should be submitted to the regulatory body for review and approval or agreement. The regulatory body should inspect the modifications for compliance with the established categorization procedure on a regular basis. Further recommendations on modification control at nuclear power plants are provided in IAEA Safety Standards Series No. NS-G-2.3, Modifications to Nuclear Power Plants [37].

3.134. Plans for radioactive waste management and decommissioning (including technical solutions, waste streams, the governmental and regulatory policies for disposal, and funding) should be reviewed and updated periodically during operation.

Decommissioning

3.135. Decommissioning or closure should be authorized only once the relevant, detailed plans and procedures to be used, the conditions to be observed during decommissioning or closure, and the proposed final state of the facility, including the radiological status, have been reviewed and assessed by the regulatory body and site inspections have been undertaken, as necessary.

3.136. The regulatory body should ensure that, before, during and after decommissioning, relevant documents and records are prepared by the authorized party, kept for an agreed time and maintained to a specified quality. Requirements for decommissioning are established in IAEA Safety Standards Series No. GSR Part 6, Decommissioning of Facilities [38] and further relevant requirements and recommendations are provided in WS-G-5.1 [6], SSG-47 [39], GSR Part 5 [40], SSR-5 [41], SSG-40 [42], SSG-41 [43] and SSG-49 [44].

Release from regulatory control

3.137. Before release from regulatory control, the authorized party should be required to demonstrate to the regulatory body that the site meets the release criteria. The regulatory body should review the evidence submitted by the authorized party, should confirm compliance with the criteria and only then should the site be released from regulatory control. Guidance on the release of sites from regulatory control is provided in WS-G-5.1 [6].

3.138. The regulatory body should ensure that an effective records system is put in place for sites to be released from regulatory control and is maintained for

future users of such sites. The responsibilities for maintaining site release records should be clearly assigned; these records could be maintained by a specific organization.

3.139. If the site does not meet the release criteria, restrictions should be imposed in relation to future use of the site (the 'restricted use' option). If after further remediation and site surveys it can be demonstrated that the site meets the release criteria and restrictions are not necessary, the selected option should be 'unrestricted use'.

3.140. For restricted use, the type, extent and duration of the restrictions and controls for release of the site can range from monitoring and surveillance to restriction of access to the site. The restrictions should be proposed by the authorized party on the basis of a graded approach, and after consideration of factors such as the type and level of residual contamination after the completion of remediation, the relevant dose constraints and release criteria, and the human and financial resources necessary to implement the restrictions and controls. The restrictions proposed by the authorized party should be submitted to the regulatory body for its agreement and should be enforceable. It should be clear which organization will be responsible for ensuring that the restrictions are maintained. In addition, the way in which the restrictions are to be removed when they are no longer necessary should be specified in the remediation plan.

Review and assessment of documents prepared by the authorized party in the authorization process

3.141. Essential documents to be prepared by the authorized party in the authorization process should be identified in the regulations and their content should be described in guides issued by the regulatory body. Additional documents may be requested as necessary, depending on the type of facility or activity concerned, and on the specific step of the authorization process.

Modification or revocation of authorizations

3.142. The granting of an authorization should not restrict or preclude the subsequent amendment, suspension or revocation of that authorization by the regulatory body within the period of its validity. A request for an amendment may be initiated by the authorized party, or an amendment may be imposed by the regulatory body in the interest of safety. A modification of the authorization may be desirable or necessary as a result of proposed changes relating to the facility or activity, experience from the facility or activity or from elsewhere, technological

advances, or as a consequence of research and development relating to nuclear or radiation safety.

3.143. Paragraph 4.37 of GSR Part 1 (Rev. 1) [2] states that:

“Any subsequent amendment, renewal, suspension or revocation of the authorization for a facility or an activity shall be undertaken in accordance with a clearly specified and established procedure, and shall make provision for the timely submission of applications for the renewal or amendment of the authorization.”

3.144. The regulatory body may require the renewal of an authorization after a set time interval, depending on national legislation. In such cases, a review and assessment of the safety documentation submitted by the authorized party should be conducted, which should include the findings of regulatory inspections and other information on performance. The results should be documented as part of the renewal process.

3.145. Proposals to change or modify the site, the facility, the activity, the organizational structure of the authorized party, associated management, and operational procedures and processes (including plans for future activities such as decommissioning) may be made. The regulatory body should require notification by the authorized party of any significant changes affecting safety and that the authorized party apply, where necessary, for an amendment to the authorization. Any modification affecting safety should be subject to an assessment by the authorized party in accordance with the graded approach. In addition, as stated in GSR Part 1 (Rev. 1) [2], para. 4.44:

“Any proposed modification that might significantly affect the safety of a facility or activity shall be subject to a review and assessment by the regulatory body.”

3.146. An authorization for an activity involving the use of radiation sources may be revoked because the radiation sources are no longer required or because the regulatory body has taken an enforcement action. The regulatory body should ensure that the radiation sources are transferred to an authorized party that possesses the necessary authorization, or are disposed of in an authorized radioactive waste disposal facility.

REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES

General

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

“The regulatory body shall review and assess relevant information — whether submitted by the authorized party or the vendor, compiled by the regulatory body, or obtained from elsewhere — to determine whether facilities and activities comply with regulatory requirements and the conditions specified in the authorization. This review and assessment of information shall be performed prior to authorization and again over the lifetime of the facility or the duration of the activity, as specified in regulations promulgated by the regulatory body or in the authorization.”

3.148. Furthermore, para. 4.45 of GSR Part 1 (Rev. 1) [2], also states that:

“In the process of its review and assessment of the facility or activity, the regulatory body shall take into account such considerations and factors as:

- (1) The regulatory requirements;
- (2) The nature and categorization of the associated hazards;
- (3) The site conditions and the operating environment;
- (4) The basic design of the facility or the conduct of the activity as relevant to safety;
- (5) The records provided by the authorized party or its suppliers;
- (6) Best practices;
- (7) The applicable management system;
- (8) The competence and skills necessary for operating the facility or conducting the activity;
- (9) Arrangements for protection (of workers, the public, patients and the environment) [see GSR Part 3 [3]];
- (10) Arrangements for preparedness for, and response to, emergencies;
- (11) Arrangements for nuclear security;
- (12) The system of accounting for, and control of, nuclear material;
- (13) The relevance of applying the concept of defence in depth to take into account inherent uncertainties (e.g. in the long term for the disposal of radioactive waste);
- (14) Arrangements for the management of radioactive sources, radioactive waste and spent fuel;

- (15) Relevant research and development plans or programmes relating to the demonstration of safety;
- (16) Feedback of operating experience, nationally and internationally, and especially of relevant operating experience from similar facilities and activities;
- (17) Information compiled in regulatory inspections;
- (18) Information from research findings;
- (19) Arrangements for the termination of operations.”

3.149. The review and assessment process is a critical appraisal, performed by the regulatory body, of information submitted by the authorized party or information that comes from inspection, information on events, feedback on operating experience at national and international levels or other specified reports (e.g. records, comprehensive safety reviews, dose records) relevant to the safety of the facility or activity. Review and assessment are undertaken in order to enable the regulatory body to make a decision or a series of decisions on the acceptability of the facility or activity in terms of safety. The process consists of examining the authorized party’s submissions, and other information as described above, on all aspects relating to the safety of the facility or activity. One of the initial tasks of the review and assessment is to confirm the completeness of submissions. When necessary, the review and assessment process should include checks on the site to verify the claims made in the submissions.

3.150. Various types of documents will need to be prepared by the authorized party in discharging its responsibilities with respect to the safety of the facility or the activity. Some of these documents will also form part of the formal submission to the regulatory body for review and assessment. Other documents to keep the regulatory body fully informed of the conditions prevailing at the facility or for the activity include routine reports periodically submitted to the regulatory body, and specific reports of events. Another type of documentation is for internal use by the authorized party, which should be made available upon request to the regulatory body to ensure its complete understanding of the design and operation of the facility or the activity, so that it can confirm that the requirements established in the regulations and authorization conditions have been fulfilled.

3.151. A fundamental feature of the process of review and assessment is for the regulatory body to consider the documents submitted by the applicant. For significant radiation risks or unusual or complex facilities or activities, the regulatory body should also verify the contents of the submitted documents by means of inspection of the site where the radiation sources are to be installed

or used. Such inspections will also allow the regulatory body to supplement the information and data necessary for review and assessment. Additionally, such inspections will enable the regulatory body to extend its practical understanding of the management, engineering and operational aspects contained within the application for authorization and to foster links with specialists from the authorized party.

3.152. The regulatory body should take into account assessments done in the past as well as assessments by other States for the same or similar facilities.

3.153. Paragraph 4.42 of GSR Part 1 (Rev. 1) [2] states that:

“In performing its review and assessment of the facility or activity, the regulatory body shall acquire an understanding of the design of the facility or equipment, the concepts on which the safety of the design is based and the operating principles proposed by the applicant, to satisfy itself that, among other factors:

- (a) The available information demonstrates the safety of the facility or the proposed activity and the optimization of protection [see SF-1 [1] and GSR Part 3 [3]];
- (b) The information provided in the applicant’s submissions is accurate and is sufficient to permit confirmation of compliance with regulatory requirements;
- (c) Operational and technical provisions, and in particular any novel provision, have been proved or qualified by experience or testing, or both, and will enable the required level of safety to be achieved.”

3.154. In addition, the justification for engaging in the activity or the need for the facility should be evaluated. (In some States justification is considered by other processes and is not the responsibility of the regulatory body.)

3.155. In undertaking the review and assessment, the regulatory body should not rely solely on safety assessments conducted by the authorized party, nor on those that the regulatory body has commissioned from external consultants or technical support organizations. Instead, the regulatory body should have sufficient full-time staff capable of either performing regulatory reviews and assessments, or evaluating assessments performed for it by consultants.

Objectives of review and assessment

3.156. The basic objective of regulatory review and assessment is to determine whether the authorized party's submissions demonstrate that, throughout the lifetime of the facility or duration of an activity, it will comply with all safety requirements stipulated or approved by the regulatory body.

3.157. The specific objectives of the review and assessment will depend on the stage of the lifetime of the facility or activity. Examples of specific objectives include the following:

- (a) To determine whether the authorized party has in place an appropriate management system that meets the regulatory body's requirements;
- (b) To determine whether the authorized party has put in place the necessary arrangements for establishing, sustaining and continuously improving leadership and management for safety;
- (c) To determine whether the operational limits and conditions are consistent with the regulatory body's requirements, the operational characteristics of the facility or activity, and up to date operational procedures and experience;
- (d) To determine whether an adequate level of safety is being maintained and improved;
- (e) To determine whether the authorized party's personnel meet the regulatory requirements, in terms of number, qualification and competence;
- (f) To determine whether, regardless of the stage of the lifetime of a facility or activity, proposed modifications have been designed and their implementation planned so that safety is not compromised;
- (g) To evaluate safety reviews performed by the authorized party;
- (h) To determine whether the authorized party's plans and commitments in respect of decommissioning meet the requirements of the regulatory body;
- (i) To determine whether the authorized party's plans and commitments in respect of the closure and post-closure stages for a radioactive waste disposal facility meet the requirements of the regulatory body;
- (j) To evaluate the final radiological survey documentation;
- (k) To determine, if relevant, whether the performance indicators proposed by the authorized party are appropriate;
- (l) To determine whether the programme proposed by the authorized party for confirmation of performance is acceptable (particularly important for radioactive waste disposal facilities);
- (m) To determine whether any additional requirements (or authorization conditions) have been fulfilled by the authorized party.

3.158. Even if the same or a similar design or a similar facility has been authorized in another State, the regulatory body should still perform its own independent review and assessment. The review and assessment performed by the regulatory body may take into account the review and assessment made by the other State, and also new experience and knowledge that have been gained since that review and assessment, and should also take into account the differences in the legal and regulatory framework of the States concerned. The regulatory bodies of the States concerned should establish close contact in order to facilitate the review and assessment process.

Information to be reviewed and assessed

Reporting by the authorized party

3.159. As appropriate (and for complex facilities, as a minimum), the following reports should be required from the authorized party for review and assessment at set times or upon the completion of specific activities during various steps in the authorization of the facility or the activity:

- (a) During the authorization steps of siting and construction, reports on:
 - The progress of site studies;
 - The progress of construction activities;
 - Results of the pre-operational environmental monitoring programme;
 - Relevant events occurring during construction and manufacturing.
- (b) During the authorization steps of commissioning and operation, reports on:
 - The results of commissioning tests;
 - Data from operation, including data on the facility's output and performance;
 - Modifications;
 - Results of the radiation protection programme;
 - Results of the environmental monitoring programme;
 - Radioactive waste management;
 - Relevant operational safety and performance events occurring during commissioning and during operation.
- (c) For the release of any facility or site from regulatory control, or for institutional controls for the post-closure stage of a radioactive waste disposal facility, reports on:
 - The types, amounts and destinations of radioactive waste resulting from the decontamination and dismantling programme;
 - Levels of residual activity in the facility;

- Results of the radiation protection programme and environmental monitoring programme, including the final radiological survey, and other relevant confirmatory programmes;
- Restrictions and institutional controls in the case of restricted release from regulatory control.

Information collected by the regulatory body

3.160. During its inspection activities, the regulatory body will collect on-site information, for example when examining records kept by the authorized party. Such information should be subjected to review and assessment by the regulatory body, in addition to any information associated with non-compliances with regulatory requirements or violations of the authorization conditions. Although this source of information may only represent a small part of the review and assessment, it is essential as it provides factual insights on how the authorized party complies with regulatory requirements.

Review and assessment process

3.161. In order to provide assurance that all topics significant to safety will be covered consistently with submissions for similar facilities or activities, review and assessment should be carried out by means of a systematic and formalized process implemented through specific procedures.

3.162. The review and assessment process should include the following steps:

- (a) Definition of the scope of the review and assessment process;
- (b) Specification of the purpose of and technical bases for the review and assessment process (these could be considered acceptance criteria for the review and assessment);
- (c) Identification of additional information, if necessary, for the review and assessment;
- (d) Performance of a step by step review and assessment procedure to determine whether the applicable safety objectives and regulatory requirements have been met for each aspect or topic;
- (e) Decisions⁸ on the acceptability of the authorized party's safety arguments or the need for further submissions;
- (f) Reporting and documentation.

⁸ Follow-up of review and assessment results is conducted through regulatory compliance activities.

Bases for review and assessment

3.163. At all steps of the authorization process, the regulatory body should have a clear understanding of the safety objectives and regulatory requirements that will be used in the review and assessment.

3.164. When collecting and structuring the applicable safety objectives and requirements to be used in its review and assessment process, the regulatory body should consider a broad range of sources, including the following:

- (a) National laws and regulations;
- (b) Advice obtained from external experts including consultants, dedicated support organizations and advisory bodies associated with the regulatory body;
- (c) Standards and guidance on nuclear, radiation, transport and radioactive waste safety as well as information issued by national and international organizations;
- (d) Requirements applicable in and experience gained in other relevant industries;
- (e) Technical results and experience from research and development;
- (f) Expertise and requirements used by others involved in reviewing and assessing similar facilities or activities in respect of technologies or safety.

3.165. The regulatory body might not have, in advance, detailed requirements covering all the areas that are subject to review and assessment since, even with a fairly comprehensive set of safety objectives and requirements, some aspects of safety might not be covered. The regulatory body should evaluate the acceptability of the proposals put forward by an authorized party or applicant on a case by case basis against general principles stated in laws and regulations. Consideration of the proposals may provide input for the development of additional regulations and guides or the modification of existing regulations and guides (see also paras 3.41–3.44).

3.166. In some instances, the authorized party may propose an alternative approach to that suggested in a guide to achieving a safety objective. In such cases, the authorized party should be required to demonstrate that its proposed approach will provide an equivalent level of safety.

3.167. The regulatory body should consider in what circumstances it might be appropriate to issue an authorization on the basis that a specific model of equipment has been ‘type approved’ or carries a certificate of compliance, in

accordance with industrial standards or other nationally recognized equivalent standards. In many cases, the safety of the facility or activity will depend on additional factors, such as the design and manufacture of equipment, qualification and training of the staff, and management and operational procedures and processes.

Major areas for review and assessment

3.168. Since this Safety Guide covers a wide range of facilities and activities, it is not possible to provide details of specific areas that should be subject to review and assessment at each stage of the lifetime of each type of facility or activity. A graded approach should be used to determine how the major areas for review and assessment should be considered, depending on the nature of the facility or activity and the risks associated with it.

3.169. Paragraphs 3.170–3.184 outline the areas on which review and assessment should concentrate for complex facilities or activities. It is not sufficient to review and assess these areas in isolation; all relevant areas from previous stages in the lifetime of the facility or activity should be considered at each step in the authorization process in order to ensure that the acceptability of the authorized party's submissions has not been compromised. A list of the topics that should be considered in the review and assessment process throughout the lifetime of a facility or activity is provided in Appendix III.

Site evaluation

3.170. The review and assessment should consider the potential interaction between the proposed facility or activity and the site, and assess the suitability of the site from the point of view of safety. The review and assessment of the site may be performed in parallel with the review and assessment of the design or may, as in some States, be performed at an earlier stage. Areas of particular significance are the possible impacts of the local environment (both natural and human-made aspects of the local environment) on the safety of the facility or activity, and the demands that the facility or activity would make on the local infrastructure. Natural phenomena to be considered should include earthquakes, high winds, flooding and other phenomena as appropriate for the geographical location of the facility or activity.

3.171. For radioactive waste disposal facilities, safety depends primarily on the properties of natural and engineered barriers. The review and assessment will require a detailed understanding of the features of the facility and its host

environment and of the factors that will influence its safety after closure. Such an understanding is unlikely to exist at this stage and so the outcome of review and assessment at the site evaluation stage should be reinforced and confirmed in the construction and operational stages to complete the technical basis and to gain the public's confidence. The process of review and assessment of the site characteristics may take a long time and continue into a period of institutional control following closure of the facility.

Design, construction, manufacture and installation

3.172. Before authorization of construction, review and assessment will concentrate on the applicant's or authorized party's approach to safety and to compliance with safety requirements, and how these have been applied in developing the design of the facility or activity. Features such as the physical layout and the construction, manufacture and installation of the systems of the facility or activity and the key elements of the process should be considered carefully, and their effects on the safety of the facility throughout its lifetime should be assessed at the design stage [32]. In addition, before authorizing construction or installation, the regulatory body should review and assess the authorized party's arrangements for the control of activities in construction, manufacture and installation. Once construction and installation has commenced, many features of the design can be changed only with great difficulty. An initial plan for decommissioning, covering issues such as the strategies to be used, the radiation doses to be expected and the amounts of waste expected to be generated, should be prepared by the applicant or authorized party early in the design stage. This plan should be subject to review and assessment by the regulatory body.

3.173. Review and assessment of the design should continue during construction, manufacture and installation as the details become finalized. Changes to the approved design at this stage should be analysed by the applicant or authorized party and reported to the regulatory body, which should carry out the necessary review and assessment.

Commissioning

3.174. Commissioning generally takes place in two stages: inactive commissioning, before fissile material and other radioactive material is introduced; and active commissioning, after fissile material and other radioactive material has been introduced. Radiation risks are present mainly in the second stage. Commissioning should be carried out in accordance with programmes that have been reviewed and assessed by the regulatory body. Before authorizing

commissioning, the regulatory body should determine whether the as-built facility meets the design requirements.

3.175. The inactive stage of commissioning is aimed at ensuring that the facility or systems for an activity have been constructed, manufactured and installed correctly and in accordance with the design documentation. If deviations from the approved design documentation have occurred, they should be recorded, and it should be shown by reconsideration of the safety documentation that safety has not been compromised. The results of inactive commissioning should also confirm the operational features and should lead to the finalization of detailed instructions for operators, which should be confirmed during the active commissioning stage.

3.176. Active commissioning, which takes place after the introduction of radioactive material, is a major step in the authorization process. The review and assessment of active commissioning should take into consideration: the final or as-built design of the facility or activity systems as a whole; the commissioning programme and its progress; the organizational structure; the qualifications of operating personnel; emergency preparedness; the preliminary operational limits and conditions; and the preliminary operating procedures. Whenever there are deviations from the design parameters, these should be analysed by the authorized party and reported to the regulatory body, which should carry out the necessary review and assessment.

3.177. As the active commissioning processes move closer to completion, review and assessment should concentrate on how the facility is operated or the activity is performed, on how the necessary safety systems, procedures and processes are maintained, and on the procedures for controlling and monitoring operations and responding to deviations or other occurrences. Before authorizing operation of the facility or conduct of the activity, the regulatory body should review and assess the consistency of the results of commissioning tests. If the regulatory body finds inconsistencies in these results, it should assess any corrections of non-conformances and modifications to the design and operational procedures that were made as a result of the commissioning. The regulatory body should review and assess any proposed changes to the operational limits and conditions.

Operation

3.178. For normal operation of the facility or conduct of the activity, the regulatory body should require the authorized party to report regularly on

adherence to safety objectives and compliance with specified regulatory requirements, and on efforts made to enhance safety. The regulatory body should review and assess the reports and should perform inspections to confirm compliance with regulatory requirements and to confirm that operation of the facility or conduct of the activity can continue.

3.179. While a need for reassessment may arise in a number of ways (see para. 3.189), a comprehensive safety review, such as a periodic safety review [36], should be carried out by the authorized party at intervals to assess the cumulative effects of ageing of the facility or activity systems and of modifications, and the implications of operating experience and technical developments. The nature of this review and the interval between reviews will depend on the nature of the facility or activity and the radiation risks associated with it. The objective of the review should be to assess the facility or activity against current national and/or international safety standards and operating practices and to determine whether adequate arrangements are in place to maintain safety. When the results of a review indicate that the facility or activity does not meet current standards and operating practices, the significance of the shortcomings should be assessed and the regulatory body should be notified. Possible ways of meeting the standards or operating practices should be considered. The comprehensive safety review should enable the regulatory body to judge whether it is acceptable for the facility to continue operation until the next comprehensive safety review is carried out.

3.180. The regulatory body should require the authorized party to provide evidence that in normal operation the facility is being operated or the activity is being conducted in accordance with the safety requirements, in particular the operational limits and conditions. Such evidence may be provided by means of reporting on operational parameters and occurrences relevant to safety. The regulatory body should review and assess the reports, and should perform inspections to ensure that the facility or activity complies with the safety requirements and is fit to continue operation.

3.181. From time to time, throughout the operation of the facility or the conduct of the activity, the initial decommissioning plan should be updated by the authorized party and reviewed by the regulatory body in the light of operating experience, new or revised regulatory requirements and technological developments.

Decommissioning

3.182. Aspects of decommissioning typically include planning for decommissioning, conducting decommissioning actions and terminating the authorization for decommissioning [38]. Decommissioning actions are the procedures, processes and work activities (e.g. decontamination, dismantling and removal of structures, systems and components) as described in the approved final decommissioning plan. Within a period agreed with the regulatory body (typically within two to five years prior to permanent shutdown of the facility or cessation of the activity), a detailed plan is required to be prepared by the authorized party and submitted to the regulatory body for authorization or approval, in accordance with Requirement 10 of GSR Part 6 [38]. The decommissioning plan is required to be reviewed and assessed by the regulatory body in order to ensure that decommissioning can be accomplished safely with a progressive and systematic reduction in radiological hazards. For all decommissioning strategies, it is required to be demonstrated that no undue burdens will be imposed on future generations. The arrangements for the management of waste from decommissioning should be a significant feature of the decommissioning plan. Large amounts of waste may be generated over short time periods, and the waste may differ greatly in type and activity from the waste generated during operation of the facility. In the review and assessment of the decommissioning plans, it should be ensured that such waste can be managed safely.

Closure of a radioactive waste disposal facility

3.183. To enable a radioactive waste disposal facility to proceed beyond the operational stage to closure, surface facilities should be decommissioned and the facility should be appropriately sealed. The safety case, including detailed proposals for closure and for assessment of the safety of the disposal facility in the long term, is required to be reviewed and assessed by the regulatory body. Further guidance is provided in SSG-29 [29], SSG-14 [30] and SSG-1 [31]. Particular consideration should be given to the provision of detailed information, including relevant operating records on the radionuclide content and physical properties of the waste and its packaging; geological and hydrogeological conditions; the performance of the facility's design (including backfill materials, engineered structures and the sealing arrangements); aspects of monitoring, surveillance and irretrievability; and the migration of radionuclides and potential exposure pathways.

3.184. If institutional control after closure of a waste disposal facility is deemed necessary, the arrangements for future control, including continuing

environmental monitoring programmes, should be subject to review and assessment by the regulatory body.

Release from regulatory control

3.185. Before an authorized party can be allowed to relinquish an authorization, it should be ensured that all responsibilities and liabilities that pertain to the authorization have been satisfactorily discharged and that there is no reasonable possibility that any future requirements will be placed on the authorized party. The authorized party should be required to provide evidence of this and, in particular, should be required to demonstrate that the site to be released from regulatory control will not pose unacceptable radiation risks in comparison with those that prevailed before the facility was built or the activity was started. The regulatory body should review and assess this evidence and should determine whether it is sufficient to allow the facility or site to be released from regulatory control.

Information exchange between the regulatory body and the authorized party

3.186. The process of review and assessment is conducted by means of exchanges between the regulatory body and the authorized party, which should be formally recorded. These records will mostly consist of:

- (a) Requests for additional information and questions by the regulatory body;
- (b) Responses from the authorized party (including responses provided by its contractors);
- (c) Records of meetings between staff of the regulatory body and staff of the authorized party.

3.187. This information should be kept in an organized way that permits retrieval in accordance with relevant criteria, such as subject, type, date or originator.

3.188. The regulatory body should request any necessary additional information and should be prepared to suspend or terminate its review and assessment if, in its judgement, such action is justified because of deficiencies in the information provided. The regulatory body should require that the documentation submitted for review and assessment be prepared by the authorized party in accordance with an effective management system, which should include proper quality assurance arrangements and an appropriate internal review process.

Reassessments

3.189. Throughout the lifetime of a facility or an activity, it may be necessary for the authorized party to make a reassessment of safety (or of an aspect of it). This reassessment could be at the initiative of the authorized party or at the request of the regulatory body, and may be prompted by one or more of the following reasons:

- (a) Experience relevant to safety that has been gained from the facility or activity, at similar facilities or activities or at other relevant nuclear and non-nuclear facilities or activities;
- (b) Information from relevant tests or from research and development programmes, and new knowledge of technical matters;
- (c) Proposed modifications to the facility or activity or to the way in which it is to be managed and operated;
- (d) Changes in the regulatory framework, regulations and guides;
- (e) A proposal to extend the lifetime of the facility or activity.

Specific aspects of review and assessment

3.190. To facilitate the review and assessment process for a facility or activity, the regulatory body should consider developing lists of approved equipment containing radiation sources, based on the submission of a certificate confirming compliance with international industry standards (e.g. of the International Electrotechnical Commission and the International Organization for Standardization). In such cases, the basis for approval should be documented, together with a summary of the conditions of use of the equipment and any appropriate limitations on its use.

Internal guidance

3.191. The regulatory body should provide internal guidance for its own staff on the procedures to be followed in the review and assessment process and on the safety objectives to be met. Internal guidance on specific topics for review and assessment should also be provided, as necessary.

3.192. The regulatory body should develop internal guidance on reporting on its review and assessment activities and on how it reaches its regulatory decisions. The regulatory body's internal guidance on review and assessment should be made available to other regulatory bodies worldwide.

Confirmatory calculations

3.193. The regulatory body may decide to perform confirmatory calculations to check that the authorized party has properly assessed a particular aspect of safety. Confirmatory calculations can provide information that can assist in:

- (a) Identifying weaknesses, if any, in the safety case;
- (b) Estimating safety margins or the degree of conservatism in the safety case;
- (c) Performing sensitivity analyses and uncertainty analyses in order to verify the authorized party's designation of the risk significance of various structures, systems and components;
- (d) Understanding complex process interactions between engineered features and natural features (this is particularly important for radioactive waste disposal facilities);
- (e) Verifying that the safety assessment is consistent with current data obtained from research and monitoring;
- (f) Gaining further confidence in its own decision making process;
- (g) Developing its in-house capacity for the resolution or further clarification of safety issues;
- (h) Extending the review and assessment process to include a quantitative evaluation of the design and operation of facilities and activities.

3.194. Where additional analyses are deemed necessary, the regulatory body should require the applicant or authorized party to perform them.

Verification of the safety analysis

3.195. The review and assessment process by the regulatory body consists of examination of the submissions from the authorized party on its management arrangements and operational procedures and verification of the safety analysis. For complex facilities and activities, additional submissions from the authorized party on engineered systems should also be examined by the regulatory body. This safety analysis should cover normal operation, anticipated operational occurrences and accident conditions in order to demonstrate that the safety of the facility or activity meets the safety objectives and requirements of the regulatory body. It is the responsibility of the regulatory body to determine whether these submissions have provided a sufficiently complete, detailed and accurate demonstration of this. In carrying out the review and assessment, the regulatory body may find it useful to perform its own analyses or research. The following subsections deal with major aspects of such verification; further details of these aspects are set out in Appendix III.

3.196. In the verification of the safety analysis for the facility or activity, the regulatory body should determine whether the authorized party has defined criteria that meet the safety objectives and requirements relating to:

- (a) Engineering design;
- (b) Operational and management aspects;
- (c) Normal operation, anticipated operational occurrences and accident conditions.

Structures, systems and components

3.197. For complex facilities and activities, the review and assessment by the regulatory body should confirm that the authorized party has performed a suitable and sufficient safety analysis of the structures, systems and components important to safety and has used the results to demonstrate that the regulatory requirements are met by the equipment and are reflected in operational procedures. Specific features that should be subject to review and assessment include the following:

- (a) Definition and categorization of the safety functions;
- (b) Identification and classification of structures, systems and components;
- (c) Ensuring the quality of engineered features as set out in the regulatory requirements or in terms of good engineering practice;
- (d) Demonstration of control of the facility or activity in normal operation, anticipated operational occurrences and accident conditions, with account taken of automatic systems, the human-machine interface and operating instructions;
- (e) Adequacy of the management system covering the structures, systems and components, and operational aspects, such as the training, qualification and experience of the authorized party's personnel and quality assurance procedures.

Operational safety performance

3.198. The regulatory body should review reports submitted periodically by the authorized party, in compliance with regulatory requirements, to monitor the operational safety performance of the facility or activity. Additionally, reports on safety significant events should be thoroughly reviewed by the regulatory body.

3.199. The regulatory body should ensure that an effective system for the feedback of operating experience, including events, is in place. If the severity of the event warrants it, the regulatory body may conduct or arrange for an

independent investigation, usually by a team with appropriately selected areas of expertise, to confirm that the event was adequately investigated, the root causes were correctly identified, and that adequate corrective and remedial actions were taken. The regulatory body's review should cover the identification of lessons to be learned and the sharing of safety related information. Operating experience feedback should not be restricted to consideration of the facility or activity itself but should consider a wide range of both radiation and non-radiation related facilities and activities from which lessons may be learned.

Organization and management

3.200. A well-engineered facility or activity will not achieve the required level of safety if it is not properly built, operated and managed. Review and assessment by the regulatory body should therefore include consideration of the authorized party's organization, management, procedures and safety culture [45], which may affect the operation of the facility or conduct of the activity. The authorized party should be able to demonstrate that there is a documented and effective management system in place that gives safety the highest priority.

3.201. Specific aspects that should be considered as part of review and assessment include the following:

- (a) Whether the authorized party's safety policy has been established by and is promoted by senior management and shows commitment at a high level to meeting regulatory requirements and states the means by which these requirements will be met.
- (b) Whether the authorized party's organization is such that it can achieve the aims and objectives in its safety policy. In particular, the following should be addressed:
 - (i) Adequate control of activities at the facility;
 - (ii) Fostering cooperation between staff members and between staff and managers;
 - (iii) A satisfactory system for communication both up and down the management chain and between managers;
 - (iv) Systems to ensure that staff are competent for the positions to which they are assigned.
- (c) Whether the authorized party has systems in place to ensure adequate planning of work and suitable performance standards so that staff and managers know what is expected of them in order to achieve the aims and objectives of the safety policy.

- (d) Whether the authorized party has systems in place to review and to audit periodically all the evidence on its performance, including consideration of operational events and other matters important to safety, in order to determine whether it is adequately achieving its aims and objectives, and to consider and make improvements where necessary.
- (e) Whether the authorized party has systems in place to ensure that it acquires and retains adequate capability within its organization to understand the nature, substance and detail of the advice given to it by contractors and is able to judge the soundness of that advice.

3.202. The review and assessment by the regulatory body should cover all aspects of the authorized party's management and organizational procedures and systems that have a bearing on safety, such as:

- (a) The development of operational limits and conditions;
- (b) The production and revision of safety documentation;
- (c) The planning and monitoring of maintenance, inspection and testing;
- (d) Control of contractors (see Appendix III for further details);
- (e) The procedures for the control and justification of changes to the authorized party's management and organizational procedures and systems that could have an impact on safety;
- (f) Feedback of operating experience.

Radiation risks in normal operation

3.203. Assessment and review of radiation risks in normal operation is directed towards the determination of occupational exposures and radioactive discharges to the environment [3]. These data will be compared with the safety objectives, requirements and limits approved by the regulatory body, including application of the principle of optimization of protection and safety. In the regulatory review and assessment, it should be determined whether the authorized party's submission meets the safety objectives, requirements and limits. In the review and assessment, particular attention should be devoted to those aspects that influence the radiological consequences for protection of people and the environment in normal operation, which include:

- (a) The inventory of radiation sources;
- (b) The occupational radiation protection programme and other matters relating to radiation protection of workers;
- (c) Radiation protection of the public, with all pathways of exposure taken into account;

- (d) Radioactive waste management;
- (e) Discharge, dilution and dispersion of radioactive effluents.

3.204. In considering these aspects, the regulatory body should satisfy itself that radiation doses to workers and the public and radioactive releases to the environment are below relevant limits, and are as low as reasonably achievable. Specifically, review and assessment should verify that:

- (a) The operational limits and conditions and the bases for these have been determined;
- (b) The radiation risks associated with operation at these limits have been considered;
- (c) Arrangements (including operating procedures) are in place to ensure that protection and safety is optimized.

3.205. The regulatory body should at all times require reasonably achievable improvements to be made in the design or operating procedures of the facility or activity with the aim of reducing radiation risks.

Safety analysis for abnormal operation, anticipated operational occurrences and accident conditions

3.206. A major part of the review and assessment effort should be directed to the safety analysis for abnormal operation, anticipated operational occurrences and accident conditions performed by the authorized party. The review and assessment of the safety analysis should be performed in accordance with the nature and magnitude of the risks associated with the particular facility or activity.

3.207. For the post-closure assessment of performance for waste disposal facilities, consideration should be given to all significant features, events and processes that may affect the performance of the facility. A comprehensive list of features, events and processes should be developed and criteria (with technical bases) should be clearly defined for screening to exclude those features, events and processes from further consideration that would have either a very small impact on the disposal system or a very low probability of occurrence. Scenarios to be considered for performance assessment should be determined in accordance with the features, events and processes selected for consideration.

Records of review and assessment

Records of the regulatory body's review and assessment

3.208. The review and assessment process will invariably involve the production of reports by the regulatory body and, where appropriate, by external experts. A document control system should be established for keeping records of the review and assessment process so that these documents and records can be readily retrieved. The bases for previous decisions should also be made accessible so as to achieve consistency and to facilitate any reassessment made necessary by new information.

Documentation produced by the regulatory body

3.209. Review and assessment should result in a decision on the acceptability of the safety of the facility or activity, which may be connected to a step in the authorization process. The basis for the decision should be recorded and documented in an appropriate form. This documentation should summarize the review and assessment performed and should present a clear conclusion about the safety of the authorized facility or activity. Typically, the following topics should be covered:

- (a) Reference to the documentation submitted by the authorized party;
- (b) The basis for the evaluation;
- (c) The evaluation performed;
- (d) Comparison with regulatory requirements, regulations and guides;
- (e) Comparison with another similar (reference) facility or activity, where appropriate;
- (f) Independent analysis performed by the regulatory body's staff, or by consultants or dedicated support organizations on its behalf;
- (g) Conclusions with respect to safety;
- (h) Additional requirements to be met by the authorized party.

INSPECTION OF FACILITIES AND ACTIVITIES

3.210. Requirement 27 of GSR Part 1 (Rev. 1) [2] states that:

“The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with

the regulatory requirements and with the conditions specified in the authorization.”

3.211. The regulatory body should verify the contents of the documents submitted by the applicant by means of inspection of the facility or activity where radiation sources are to be installed or used. Such inspections will also allow the regulatory body to supplement the information and data necessary for review and assessment.

3.212. The regulatory body should conduct inspections of manufacturers authorized to provide consumer products (see Appendix I).

3.213. Paragraph 4.49 of GSR Part 1 (Rev. 1) [2] states that:

“Regulatory inspection cannot diminish the prime responsibility for safety of the authorized party, and cannot substitute for the control, supervision and verification activities conducted under the responsibility of the authorized party.”

3.214. Paragraph 4.52 of GSR Part 1 (Rev. 1) [2] states that:

“Regulatory inspections shall cover all areas of responsibility of the regulatory body, and the regulatory body shall have the authority to carry out independent inspections. Provision shall be made for free access by regulatory inspectors to any facility or activity, at any time, within the constraints of ensuring operational safety at all times and other constraints associated with the potential for harmful consequences. These inspections may include, within reason, unannounced inspections.”

3.215. Paragraph 4.53 of GSR Part 1 (Rev. 1) [2] states that:

“In conducting inspections, the regulatory body shall consider a number of aspects, including:

- Structures, systems and components and materials important to safety;
- Management systems;
- Operational activities and procedures;
- Records of operational activities and results of monitoring;
- Liaison with contractors and other service providers;
- Competence of staff;
- Safety culture;

— Liaison with the relevant organization for joint inspections, where necessary.”

3.216. The regulatory body should also consider the following aspects in inspection, as appropriate:

- (a) Radiation risks associated with the facility or activity, including areas of higher risk;
- (b) Unintended or accidental medical exposure;
- (c) Arrangements for the control of radioactive material.

3.217. Requirement 29 of GSR Part 1 (Rev. 1) [2] states that:

“Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.”

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

3.219. In implementing the inspection programme, the regulatory body should also apply a graded approach in responding to unforeseen circumstances (see also paras 3.295–3.319).

Objectives of regulatory inspection

3.220. Regulatory inspection is performed to make an independent check on the authorized party and the state of the facility or activity, and to provide confidence that the authorized party is in compliance with the safety objectives prescribed or approved by the regulatory body. This should be achieved by confirming that:

- (a) The authorized party is in compliance with applicable laws, regulations and authorization conditions and all relevant codes, guides, specifications and practices;
- (b) The authorized party has in place an effective management system, a strong safety culture, and self-assessment systems for ensuring the safety of the facility or activity and the protection of people and the environment;

- (c) The required quality and performance are achieved and maintained in the items and activities important to safety throughout the lifetime of the facility or activity;
- (d) Persons employed by the authorized party (including contractors) possess the necessary competence for the effective performance of their functions throughout the whole lifetime of the facility or activity;
- (e) Deficiencies and abnormal conditions are identified and promptly evaluated and remedied by the authorized party and duly reported to the regulatory body as required;
- (f) Any other safety issue that is neither specified in the authorization nor addressed in the regulations is identified and appropriately considered;
- (g) Any safety lessons learned are identified and disseminated to other authorized parties and suppliers and to the regulatory body as appropriate.

Organization of regulatory inspection

3.221. Specific responsibilities of the regulatory body with respect to inspection should include the following:

- (a) Conducting planned inspections, at relevant steps of the authorization process;
- (b) Carrying out reactive inspections, as appropriate, in response to events;
- (c) Identifying and recommending necessary changes to the requirements approved by the regulatory body, as specified in the authorization or contained in the regulations;
- (d) Preparing reports to document inspection activities and their findings;
- (e) Ensuring that the authorized party has adequate, comprehensive and up to date information on the status of the facility or activity and information for demonstrating safety, and a procedure for keeping such information up to date;
- (f) Detecting degraded performance and potential non-compliances;
- (g) Tracking recurrent problems and non-compliances;
- (h) Verifying that corrective actions have been undertaken by the authorized party to resolve safety issues identified previously;
- (i) Developing procedures and directives as necessary for the effective conduct and administration of the inspection programme;
- (j) Determining and recommending suitable enforcement actions when non-compliance with regulatory requirements or a violation of the conditions of an authorization is encountered.

3.222. The major activities of the inspection programme are related to the steps of the authorization process. The regulatory body should organize and modify its inspection activities in accordance with the stage of the lifetime of the facility or activity. Specifically, as a facility or activity passes from one stage of its lifetime to another, the regulatory body will normally find it necessary:

- (a) To adjust the levels of attention given to particular inspection areas and to redeploy its human resources accordingly;
- (b) To alter the extent to which various inspection techniques and methods are employed;
- (c) To modify the rigour and frequency of the inspections.

Inspection programme

3.223. This Safety Guide focuses on technical aspects of the development of an inspection programme, while the organization and management of an inspection programme is addressed in GSG-12 [4].

3.224. Paragraph 4.50 of GSR Part 1 (Rev. 1) [2] states that:

“The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections), and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach.”

3.225. The regulatory inspection programme should be comprehensive and consistent with the overall regulatory strategy. The inspection programme should be thorough enough to ensure that the regulatory objectives and requirements are being met, thereby providing the regulatory body with a confidence that the authorized party is effectively maintaining the safety of the facility or activity. The inspection programme should also be developed so that the regulatory body can determine whether the authorized party conducts activities in accordance with previously established procedures, and has an effective self-assessment process capable of prompt identification and correction of actual and potential problems.

3.226. The regulatory body’s inspection programme should include the following key elements:

- (a) A system of prioritizing inspections based on a graded approach;
- (b) On-site inspections⁹;
- (c) The investigation and follow-up of events and deviations from normal operation;
- (d) The submission of information on key operational safety parameters by authorized parties.

3.227. On-site inspection is the element of the regulatory framework that gets closest to actual operations, and a significant proportion of the regulatory body's resources should be allocated to this task.

3.228. The regulatory inspection programme should give due consideration to leadership and the management system at the authorized party, and to human, technological and organizational factors. Accordingly, the inspectors' training and qualification programme should be tailored to develop competences in these areas. Independent external experts (e.g. technical and scientific support organizations) might also be engaged for inspections, as appropriate and as allowed by the regulatory system.

3.229. In addition to verifying compliance with regulatory requirements, the regulatory body's inspection programme should be able to obtain a general indication of safety performance at the facility or activity. Common performance indicators for safety include the following:

- (a) Housekeeping;
- (b) Financial stability;
- (c) Staffing, including turnover of staff;
- (d) Record keeping and retrieval systems;
- (e) Investigation levels set by the authorized party and the procedures to be followed in the event that investigation levels are exceeded;
- (f) Training, including arrangements for retraining of staff;
- (g) Occupational exposures for the type of facility or activity;
- (h) Recurring failures of structures, systems and components important to safety;
- (i) Unavailability of structures, systems and components;
- (j) Frequency of enforcement actions.

⁹ 'On-site' needs to be interpreted appropriately: some activities (e.g. well logging) do not take place on fixed sites so inspections may need to be carried out in a different location.

3.230. These indicators could be used as a basis for informing authorized parties of the need to make safety improvements, and as a basis for establishing the frequency of inspections for any particular authorized party. The regulatory body should require authorized parties to pay attention to indicators of degraded safety performance. This focus on indicators and the underlying performance issues should contribute to the enhancement of a strong safety culture in the authorized party.

3.231. Different methods may be used in establishing or modifying an inspection programme, and its associated priorities, to achieve the objectives of regulatory inspections. The regulatory body should consider the following:

- (a) The results of previous inspections;
- (b) The safety analysis performed by the authorized party and the results of regulatory review and assessment;
- (c) The use of performance indicators or any other systematic method for assessment of the safety performance of the authorized party;
- (d) Operating experience and lessons learned from operating the facility or conducting the activity, and from similar facilities and activities in the State and in other States, as well as results of research and development;
- (e) Inspection programmes of the regulatory bodies in other States.

3.232. The regulatory body should have the capability to undertake inspection activities when necessary; in particular, sufficient inspection resources should be available for reactive inspections. For verification of the overall performance of the authorized party, inspections of adequate depth should be conducted in a wide range of subject areas and at appropriate intervals. Each planned inspection should have objectives that have previously been specified by the regulatory body to serve to the extent practicable as guidance for inspectors.

3.233. The regulatory body should establish a process of periodically evaluating the findings of inspections, identifying generic safety issues and making arrangements to enable inspectors from various locations or projects to meet to exchange views and discuss the findings and issues.

3.234. The authorized party should be required to keep the regulatory body informed of its schedules for carrying out activities and tests of regulatory interest and should submit or make available to the regulatory body, in a timely manner, the procedures for these activities. To facilitate this process, the regulatory body should inform the authorized party well in advance as to which activities and tests it wishes to be kept apprised of and possibly inspect on the site.

3.235. As part of the inspection programme, on a regular basis the regulatory body should compile and assess data on the performance of authorized parties, the results of the regulatory inspection programme (inspection findings, corrective actions and inspection reports) and trends in these data and results. This information should be used to identify potential areas for improvement in the performance of authorized parties and regulatory processes. The reports of such assessments and analyses should be shared and communicated within the regulatory body.

Types of regulatory inspection

3.236. Requirement 28 of GSR Part 1 (Rev. 1) [2] states that: “**Inspections of facilities and activities shall include programmed inspections and reactive inspections, both announced and unannounced.**”

3.237. Regulatory inspection should include a range of planned and reactive inspections over the lifetime of the facility or activity and should include inspections of relevant parts of the authorized party’s organization and its contractors’ organizations to ensure compliance with regulatory requirements.

3.238. Inspections may be conducted by individuals or teams and may be announced or unannounced. Inspections may be made as part of a general inspection programme, or may have specific objectives.

3.239. The regulatory body should use the authorized party’s reports of safety related activities or events in preparing for both planned and reactive inspections. Matters to be included in reports from the authorized party should be clearly defined so that difficulties in interpretation are avoided.

Planned inspections

3.240. Planned inspections, either announced or unannounced, should be carried out in fulfilment of a predetermined inspection plan developed by the regulatory body to provide sufficient confidence that regulatory requirements are being met (baseline inspection plan). These inspections may be linked to authorized party schedules for the performance or completion of certain activities at the various steps of the authorization process. Planned inspections differ from reactive inspections in that they are scheduled in advance by the regulatory body and are not initiated because of unusual or unexpected circumstances. Planned inspections provide an opportunity for the examination of the authorized party’s

activities in order to confirm the authorized party's performance and to identify potential problems at an early stage.

3.241. In planned inspections, emphasis should be given to the observation and assessment of ongoing safety activities in order to assess the effectiveness of the authorized party's performance.

3.242. The regulatory body should consider conducting special inspections addressing specific issues that are of interest to the regulatory body, such as refurbishment, new findings from research and development work, and experience from other facilities or activities. Special inspections are usually planned inspections, since they are scheduled in advance; however, in certain circumstances they may be reactive inspections. Special inspections may range from a single inspector reviewing a specific work area or activity, to a team of inspectors reviewing different areas.

Reactive inspections

3.243. In addition to routine inspection activities, the regulatory body should carry out inspections at short notice if an abnormal occurrence warrants immediate investigation. Such reactive regulatory inspection does not diminish the responsibility of the authorized party itself to investigate any such occurrence immediately.

3.244. Reactive inspections, by individuals or teams, are usually initiated by the regulatory body in response to an unexpected, unplanned situation or incident in order to assess its significance, the implications for safety and the adequacy of corrective actions. A reactive inspection may be prompted by an isolated incident or a series of less significant events occurring at the particular facility or during the particular activity under consideration. Similarly, a reactive inspection may be made in response to a generic problem encountered at another facility or activity or identified by the review and assessment staff of the regulatory body. Unlike planned inspections, which are scheduled, reactive inspections are only partly subject to planning by the regulatory body and may disrupt regulatory programmes and schedules. The regulatory body should assume that there will be a need for reactive inspections and should plan to meet its needs for staff and external experts accordingly. All available resources may be necessary in responding to a serious event, whereas in simple cases only one inspector may be necessary. A pre-established, graded approach to responding to special circumstances will assist in determining the appropriate level of resources for use in reactive inspections.

3.245. For a more serious event (or a potentially serious event), or when operational parameters (e.g. doses) exceed regulatory limits or are significantly elevated, an independent investigation should be conducted by the regulatory body and in some cases by other governmental bodies, in addition to the investigation to be conducted by the authorized party. There are usually two main objectives in an investigation of a serious event by the authorities, which are not completely separable but which need to be distinguished:

- (a) Determination of the reasons why the event occurred so as to take measures to prevent its recurrence;
- (b) Consideration of the legal aspects concerning liability for the event.

3.246. Determining why the event happened is of central interest with regard to safety. Investigations should be carried out by, or in consultation with, a person with appropriate knowledge and experience of the facility or activity, the type of event and of investigation techniques. With regard to the regulatory investigation of the event, the following should be included:

- (a) The determination of the root causes, the sequence of events and the contributory factors;
- (b) The assessment of the consequences;
- (c) The identification of preventive and corrective actions;
- (d) The identification and documentation of lessons to be learned;
- (e) The recommendations for measures to be taken for the prevention of similar events in the future, including changes in the regulatory programme, as well as any adjustments to the authorized party's arrangements for safety;
- (f) The dissemination of the findings, lessons to be learned and recommendations to relevant authorized parties, manufacturers and suppliers, and other interested parties both in the State and in other States.

Announced and unannounced inspections

3.247. An announced inspection is an inspection of which the authorized party has been informed in advance by the regulatory body. The regulatory body should consider the timing of the announcement of the inspection, which may differ in accordance with the circumstances of the inspection to be performed. Inspections may be announced, for example, when the regulatory body wishes to observe a specific test or activity, to review a specific self-assessment by the authorized party while it is in progress or to interview a specific member of the authorized party's staff.

3.248. The main advantage of announced inspections is that the inspector is able to discuss plans and needs with the authorized party's personnel in advance in order to secure assurances that documentation will be available for inspection, personnel will be available for interview and activities can be inspected as scheduled. Hence, the announcement of inspections may enhance their effectiveness.

3.249. Unannounced inspections might not always be feasible, but they have benefits. The advantage of unannounced inspections is that the actual state of the facility and the way in which it is being operated can be observed. Inspections may be carried out at any time of the day or night so as to provide a more complete picture of the situation at the facility or activity. However, unannounced inspections need to take account of ongoing activities at the site.

Team inspections

3.250. Team inspections, which may require a multidisciplinary approach, provide an in-depth, independent and balanced assessment of the authorized party's performance. Team inspections may vary in both scope and complexity. Team inspections are of particular value once safety problems have been identified, since other inspections may cover only small samples of the authorized party's activities in any particular area. Team inspections should identify underlying causes of problems in order to determine whether a safety concern represents an isolated case or may signify a broader, more serious problem.

3.251. Different approaches may be used in planning team inspections. Some team inspections may be broad in focus and cover a wide subject area (a horizontal slice) in the programme or area of interest. For example, a team of inspectors may assess the performance of operations at a facility or the conduct of all relevant activities on a site, or a team of inspectors with maintenance and engineering competences may assess outage activities at a nuclear power plant. Other team inspections may be narrow in focus and cover a smaller subject area (a vertical slice). For example, a number of specialist inspectors may review, in depth, a single safety system in order to confirm that the system is in full compliance with the regulatory requirements or a team may inspect the same safety aspect at similar facilities or activities in the State.

Planning of regulatory inspections

3.252. The organization and management of planning for inspection and the allocation of resources for inspection are described in GSG-12 [4]; this Safety Guide focuses on technical aspects of the inspection plan.

3.253. The regulatory body should have an overall plan for the programme of inspection that it intends to undertake at a facility or during an activity.

3.254. For each technical area to be inspected, the intervals between inspections and the level of effort to be applied to the inspection will depend on the following factors:

- (a) The type of facility or activity;
- (b) The safety significance of the technical area to be inspected;
- (c) The inspection methods and approaches used (e.g. the use of resident inspectors may influence the intervals and the scope and depth of inspections);
- (d) The performance record of the authorized party and the facility; for example, the number of non-compliances with regulatory requirements, violations of conditions in the authorization, deficiencies, events and the number of reactive inspections;
- (e) The results of regulatory review and assessment;
- (f) The personnel and other resources available to the regulatory body;
- (g) The results of previous inspections.

3.255. To manage the allocation of resources for inspections, the regulatory body should develop specific inspection plans in which the factors listed in para. 3.254 are taken into account. The inspection plans should be recorded in such a way that they can be modified to take new activities or changes to ongoing activities into account. They should be reviewed periodically and modified as necessary.

3.256. The inspection plan for a specific facility or activity should be flexible enough to allow inspectors to respond to particular needs and situations. On major facilities, many States allow for 25% of the inspection time to be available for reactive inspections.

3.257. The planning of the programme of inspection will also be influenced by the locations of the regulatory body's offices and of the facility or activity to be inspected.

3.258. Arrangements should be made to ensure that all relevant staff of the regulatory body can fully contribute to the planning of inspections and, in particular, if the offices of the regulatory body are distributed over a wide area, that inspectors are involved in the planning process. This will ensure the best use of the skills and knowledge of the staff of the regulatory body.

Selection of inspection areas

3.259. This Safety Guide covers a wide range of types of facility and activity, and it is not possible to provide details of specific areas that would be subject to inspection at each lifetime stage for each type of facility and activity. The degree to which the areas should be considered will depend on the nature of the facility or activity and the risks associated with it. Major inspection areas for nuclear facilities are listed in Appendix IV.

3.260. Inspection should not be limited to the facility or activity itself and should cover any safety related services that may be provided at an authorized party's headquarters or other offices, such as activities relating to the development of safety assessments, outage planning or training.

3.261. Whenever the authorized party makes use of the safety related services or products of a contractor, the regulatory body should include the contractor's supervision by the authorized party and the contractor's activities in its inspection programme in all steps of the authorization process. This may comprise inspection of the design and manufacturing of components, including, where appropriate, activities performed in other States. Inspection of the authorized party's contractors should only be performed in conjunction with inspection of the authorized party, so that the authorized party is not relieved of the prime responsibility for safety.

Performance of regulatory inspection

Internal guidance

3.262. The regulatory body should issue internal guidance for its inspectors on performing regulatory inspections in order to ensure a consistent approach to inspection while allowing sufficient flexibility for inspectors to take the initiative in dealing with new concerns that arise. Each inspector should be given adequate training in following this guidance.

3.263. The guidance for inspectors should include the following:

- (a) Policies of the regulatory body regarding inspections.
- (b) The legal basis for regulatory inspection and the scope of the inspector's authority.
- (c) The use of regulatory requirements, regulations, guides and standards.
- (d) The development of an inspection programme.
- (e) The implementation of the inspection programme, including:
 - (i) Facilities (or areas of the facility) or activities to be subject to inspection;
 - (ii) Method of inspection to be used;
 - (iii) Methods for selection of inspection samples;
 - (iv) Use of relevant technical information;
 - (v) Use of inspection questionnaires;
 - (vi) Follow-up on inspection findings.
- (f) Reporting requirements and practices for inspectors.
- (g) Standards of conduct of inspectors.
- (h) The enforcement policy, procedures and practices.

3.264. The regulatory body should stress in the guidance the importance of objectivity and fairness on the part of inspectors, together with the need to respect the rules of the facility or activity as established by the authorized party provided these rules do not prevent inspectors from fulfilling their duty.

3.265. The authority vested in inspectors should oblige them to conduct themselves in a manner that inspires confidence in and respect for their competence and integrity. They should, for example, make adequate preparation by gathering and reviewing all relevant information and data before proceeding on assignment and should be knowledgeable about the area that they are required to inspect.

Preparation for an inspection

3.266. Before an inspection is carried out, inspectors should be thoroughly prepared for the task. The type of preparation will depend on the type (planned or reactive, announced or unannounced, individual or team) and method (see para. 3.268) of inspection. Preparation may include a review of the following:

- (a) Regulatory requirements relating to the authorized facility or activity, and conditions in the authorization issued to the authorized party;
- (b) Experience feedback relating to the inspection area;

- (c) Findings of previous inspections and enforcement actions relating to the inspection area, and any unresolved issues from previous inspections;
- (d) The analysis of accidents and other events in the past;
- (e) Past correspondence between the regulatory body and the authorized party relating to the inspection area;
- (f) The safety documentation and operational limits and conditions;
- (g) Documentation on operation and design for the facility or activity;
- (h) The authorized party's management system.

3.267. Preparations should be made by the individual or team (including any external experts) who will be conducting the inspection. It is generally useful to establish a specific plan for the inspection by compiling a questionnaire and a list of the documents to be reviewed with the authorized party. Preparation includes the identification of the necessary documentation and equipment for the inspection. Depending on the particular circumstances and the nature of the facility or activity these may include:

- (a) Relevant inspection procedures, questionnaires and checklists as well as other relevant documents;
- (b) The accreditation of the inspector;
- (c) Personal dosimeters;
- (d) Appropriate survey meters or other necessary measuring equipment;
- (e) Safety equipment, such as high visibility clothing, safety shoes and hard hats;
- (f) A camera for documentation.

Methods of inspection

3.268. The inspection procedures of the regulatory body should incorporate and use a variety of methods, as follows:

- (a) Monitoring and direct observation (such as of working practices and equipment);
- (b) Discussions and interviews with personnel of the authorized party and of the contractor, if necessary;
- (c) Examination of procedures, records and documentation;
- (d) Confirmatory tests and measurements.

In individual inspections, one or more of these methods should be employed, depending on the specific issues being considered.

Monitoring and direct observation

3.269. The inspection methods should include provision for direct observation of elements, such as human factors significant to safety (performance of personnel, attitudes of managers), tests and other safety related activities carried out by the authorized party.

3.270. The regulatory body may prescribe certain categories of structures, systems and components, tests and activities that should be directly observed by its inspectors in whole or in part. In some cases, the regulatory body may require regulatory monitoring of a specific structure, system, component, test or activity as a condition for the authorized party to be permitted to proceed to subsequent stages of work or operation. Monitoring is particularly useful during the commissioning stage, or as a means of verifying corrective action at any stage over the lifetime of the facility or activity as required by the regulatory body after an abnormal occurrence or a serious non-compliance.

3.271. The regulatory inspection programme should provide time for general surveillance of the facility or activity by regulatory inspectors. Such surveillance is aimed at gaining an overall impression of the authorized party's capabilities and performance and is not restricted to specifically designated components and systems or designated scheduled activities and tests. Examples of where such surveillance may be useful include the following:

- (a) Workplaces;
- (b) Transfer of jobs between persons;
- (c) Radiation protection arrangements including boundaries of controlled areas;
- (d) Items important to safety for the facility or activity;
- (e) Fire barriers;
- (f) Housekeeping;
- (g) The presence of management;
- (h) Internal and external interfaces and communications;
- (i) Arrangements for emergency preparedness and response.

Discussion and interviews with authorized party personnel

3.272. Regulatory inspectors should, as appropriate, communicate directly with the authorized party's personnel responsible for supervising and performing the activities being inspected. This is especially important in follow-up investigations

in which inspectors are involved in reconstructing events and assessing the authorized party's response.

3.273. The authorized party's personnel should be kept appropriately informed of inspection activities. These considerations can be partly satisfied by means of discussions and interviews. Interviews with workers, the facility or activity manager and, as appropriate, with other senior managers should be standard features of most inspection visits. In interacting with the authorized party's staff, the inspector should exercise mature judgement concerning the prerogatives and responsibilities of the facility's management. Generally, the focus of interviews should be to gain insights about technical, human or organizational topics and processes.

Examination of procedures, records and documentation

3.274. Examination of the authorized party's documentation contributes to the regulatory body's verification of the authorized party's compliance without unduly disrupting work schedules or interfering with the authorized party's prime responsibility for safety. Documentation examined by regulatory inspectors may include the following:

- (a) Procedures and schedules for maintenance and testing;
- (b) Quality assurance records;
- (c) Test results and data;
- (d) Operational and maintenance records, and results of workplace monitoring;
- (e) Records of deficiencies and incidents;
- (f) Modification records, including records of modifications to management and operating procedures;
- (g) Training records;
- (h) Shift schedules;
- (i) Dose records.

3.275. The regulatory body should examine the authorized party's documentation in a manner sufficient to satisfy itself that the authorized party is fulfilling the requirements for authorization and is operating in accordance with the practices proposed by the authorized party and approved by the regulatory body and that any deviations or deficiencies that have been detected have been adequately addressed.

3.276. The examination of documentation by regulatory inspectors may in some cases take place, in part, off the site — for example, at the regulatory

body's headquarters or the authorized party's headquarters — and can contribute towards the preparation for the inspection of the facility or activity.

Tests and measurements

3.277. The regulatory body should have the authority and resources [4] to be able to carry out confirmatory tests and measurements as necessary, at fixed points or in places of special interest, as applicable, using its own equipment.

3.278. The extent to which the regulatory body conducts its own confirmatory tests and measurements independently of the authorized party differs greatly between States, depending upon factors such as the qualifications of personnel available to the regulatory body, its regulatory approach, and the experience and demonstrated performance of authorized parties. The regulatory body should not engage in the conduct of confirmatory tests or measurements that would necessitate its assuming direct operational control of the facility or activity or any of its systems.

3.279. Tests of components and systems of the facility should only be undertaken after consultation with the facility's management. In most instances, confirmatory tests and measurements replicate and serve as an independent verification of tests and measurements performed by the authorized party. The conduct of such confirmatory tests and measurements by the regulatory body does not relieve the authorized party of the prime responsibility for safety. The confirmatory tests undertaken by the regulatory body should not place the facility in an unsafe condition nor contribute to risks of any kind.

3.280. Since the regulatory body itself conducts only limited testing, a detailed review should be carried out of a sample of the authorized party's procedures for tests and its interpretation of their results. If external experts are used by the regulatory body to monitor the confirmatory tests and measurements undertaken by the authorized party, their reports should also be reviewed. Where further confirmatory tests or measurements are necessary, the regulatory body should request that they be performed by the authorized party.

Conduct of inspections

3.281. Inspections should be conducted in accordance with an approved inspection programme, plan, guidelines, procedures and checklists. The techniques utilized for the inspections should be commensurate with the inspection requirements and the activity or area being inspected. Certain activities

may require the inspectors to avoid immediate discussions with the personnel performing the activity, and some inspections may not provide the opportunity for direct observations.

3.282. Inspectors should write down their observations while conducting the inspections. Upon completion of the inspection, the inspectors should conduct an exit briefing with the authorized party's senior management and should share the details about the inspection activities, observations, good practices, deficiencies and deviations with the inspected organization. Inspectors should also seek feedback from the authorized party about the conduct of inspections.

Records of regulatory inspections

3.283. Paragraph 4.51 of GSR Part 1 (Rev. 1) [2] states that:

“The regulatory body shall record the results of inspections and shall take appropriate action (including enforcement actions as necessary). Results of inspections shall be used as feedback information for the regulatory process and shall be provided to the authorized party.”

Inspection reports and findings

3.284. A report of each regulatory inspection should be prepared by the inspector(s) who performed the inspection. The report should be reviewed and approved in accordance with established internal procedures of the regulatory body. The scope, layout, content, timing and distribution of inspection reports may differ in accordance with:

- (a) The general administrative and legal structure in the State and the requirements established by the regulatory body;
- (b) The type of facility or activity and its steps of authorization;
- (c) The location of the inspection;
- (d) The type of inspection, whether planned or reactive, announced or unannounced, individual or team;
- (e) The purpose of the inspection (e.g. team inspection, special inspection, site visit by non-resident site inspectors, weekly inspection activities carried out by resident inspectors).

3.285. The purposes of inspection reports are:

- (a) To record the results of all inspection activities relating to safety or of regulatory significance;
- (b) To document and record an assessment of the authorized party's activities in relation to safety;
- (c) To record discussions held with authorized party's staff, management and other concerned persons;
- (d) To provide a basis for informing the authorized party of the findings of the inspection and of any non-compliance with regulatory requirements, and to provide a record of any enforcement actions taken;
- (e) To record any findings or conclusions reached by inspectors;
- (f) To record any recommendations by inspectors for future actions by the authorized party or the regulatory body and to record progress on recommendations from previous inspections;
- (g) To inform other staff of the regulatory body of inspection results;
- (h) To contribute to maintaining an organizational memory.

Content of inspection reports

3.286. Inspection reports should typically contain:

- (a) Details of the authorized party inspected, the purpose and date of the inspection and the inspectors' names;
- (b) The methods used in the inspection (interviews, observations, review of documents);
- (c) Reference to applicable requirements;
- (d) Criteria used in the assessment of safety performance;
- (e) Details of areas, activities, documents, processes, items, and qualification and training of personnel that have been inspected, assessed or reviewed;
- (f) A record of actual or potential problems relating to safety;
- (g) A record of the results of any checks for compliance with regulatory requirements and the conditions of the authorization;
- (h) A record of any deficiency or non-compliance with regulatory requirements or violation of conditions of the authorization found in regulatory inspections, including a record of which requirements or authorization conditions have been contravened;
- (i) A record of discussions held with the authorized party's staff, managers and other persons, including a record of discussions with the authorized party's managers about points of concern;

- (j) A record of the inspectors' opinion about the response of the authorized party's management to any matter of concern to which their attention was drawn after a regulatory inspection;
- (k) A record of any regulatory action taken by inspectors and any consequent action taken by the authorized party in the period covered by the report;
- (l) A record of the findings or conclusions of the inspectors, including corrective actions that should be taken;
- (m) A record of recommendations made by inspectors for future action, such as a need to advise other inspectors or authorized parties about particular problems, proposals for further inspections or proposals for enforcement actions.

Distribution and use of inspection reports

3.287. Inspection reports should be distributed, or made available electronically, in accordance with established procedures in order to provide the following:

- (a) A basis for future regulatory action;
- (b) A contribution to maintenance of the regulatory history by providing a record of inspections, discussions and associated findings and conclusions;
- (c) A basis for identifying major or generic issues that necessitate special inspections, changes to inspection plans or generic regulatory action;
- (d) Information to other staff of the regulatory body, for example those staff responsible for the development of regulations and guides, for review and assessment, and for the development of requirements for authorization;
- (e) A means of sharing information with other inspectors;
- (f) Information to regulatory staff responsible for the analysis of reportable events;
- (g) A basis for periodic reviews of inspection findings, including trends and root causes;
- (h) A means of passing information to interested parties or governmental bodies;
- (i) Self-assessment activities.

3.288. Inspection findings should be discussed at regular meetings attended by groups of inspectors. It is also a good practice in many States to include those regulatory body staff involved in review and assessment activities or authorization activities in such meetings.

3.289. Inspection findings should be forwarded to the authorized party for its information and records, as well as for necessary corrective actions. Whenever

corrective action is necessary, a formal communication including the findings from inspection reports should be sent to the authorized party. In some States, the full inspection report is forwarded to the authorized party. In communications with the authorized party, caution should be exercised in identifying individuals by their name or their post because of the possible implications (including those of a legal nature) for the individuals concerned.

3.290. Documents that are made available to the inspector by the authorized party during an inspection should be referenced in the inspection report. Inspection reports and copies of relevant documents received in connection with the inspection should be stored in a manner that permits ready retrieval and that follows applicable document classification procedures.

3.291. From time to time the regulatory body may find it useful to produce a composite report covering a type of facility, activity or a specific aspect of inspection, drawing together findings from a number of relevant inspection reports.

Publication of inspection findings

3.292. In order to inform the public of the safety of facilities and activities and of the effectiveness of the regulatory body, findings of inspections and the associated regulatory decisions may be made publicly available. The extent to which such information is made publicly available will depend on the legal provisions in the State concerned. Although it may be the practice in some States to publish individual inspection reports or inspection follow-up letters sent to the authorized party, such reports and letters may contain confidential information, such as nuclear security information, information that the regulatory body may wish to use in connection with future regulatory actions, proprietary information, or personal or medical information relating to individuals. Such information should be processed in accordance with the relevant national requirements.

3.293. All information exchanged between the regulatory body, other governmental bodies, the authorized party, its contractors, advisory committees and the regulatory body's consultants and, as appropriate, members of the public should be formally recorded upon receipt by the regulatory body and should be stored in a manner that permits ready retrieval.

Follow-up of inspection findings

3.294. A programme to systematically analyse and follow-up on inspection findings should also be established. The programme should include provisions for periodic review and surveillance of the follow-up actions to verify that the authorized party is taking the necessary actions in response to inspection findings. Upon satisfactory completion of the actions, the inspection findings should be formally closed and necessary documents and records should be maintained.

ENFORCEMENT

3.295. Paragraph 2.5 of GSR Part 1 (Rev. 1) [2] requires that the government promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety, including provision for the enforcement of regulations, in accordance with a graded approach.

3.296. Requirement 30 of GSR Part 1 (Rev. 1) [2] states that:

“The regulatory body shall establish and implement an enforcement policy within the legal framework for responding to non-compliance by authorized parties with regulatory requirements or with any conditions specified in the authorization.”

3.297. Paragraph 4.55 of GSR Part 1 (Rev. 1) [2] states that:

“Enforcement actions by the regulatory body may include recorded verbal notification, written notification, imposition of additional regulatory requirements and conditions, written warnings, penalties and, ultimately, revocation of the authorization. Regulatory enforcement may also entail prosecution, especially in cases where the authorized party does not cooperate satisfactorily in the remediation or resolution of the non-compliance.”

3.298. The authorization process itself is a form of enforcement as refusal of an application for an authorization effectively means that operation of the facility or conduct of the activity is prohibited and legal sanctions can be used if the prohibition is not complied with. However, in most States the term ‘enforcement process’ refers to the actions taken by the regulatory body in response to non-compliances with regulatory requirements and violations of authorization conditions that occur during the operation of a facility or conduct of an activity.

3.299. Regulatory enforcement activities should cover all areas of regulatory responsibility. Enforcement actions should be applied as necessary by the regulatory body using a graded approach appropriate to the legal system and the authorization practices of the State.

Objectives of enforcement

3.300. The principal objectives of enforcement should be to provide a high level of assurance that the authorized party complies with all safety requirements at all steps of the authorization process and all stages of the lifetime of the facility or duration of the activity meet the safety objectives and authorization conditions, and that the authorized party promptly identifies and corrects non-compliances with safety requirements.

3.301. Regulatory enforcement actions are taken by the regulatory body to address non-compliance by the authorized party with specified conditions and requirements. Such actions should be taken to ensure that the authorized party modifies or corrects aspects of its procedures and practices, or of a facility or activity's structures, systems and components important to safety.

Methods of enforcement

3.302. The main purpose of enforcement is to ensure safety by deterring non-compliance, encouraging prompt identification of non-compliances, and ensuring that appropriate corrective actions are taken. Enforcement actions should be chosen to achieve this end. However, the method chosen should also be appropriate to the severity of the non-compliance with regulatory requirements or the violation of authorization conditions, and the regulatory body's policy on this should be documented. Paragraphs 3.303–3.307 describe some of the main enforcement methods; para. 3.308 describes the factors affecting the choice of method.

Verbal or written notification of non-compliance

3.303. In many cases it may be possible to resolve unsatisfactory situations with minor safety significance by means of discussion with the authorized party. If necessary, such a verbal notification should be formalized in a written notification, in accordance with the legal system of the State.

Written warnings or directives

3.304. Deviations from, or non-compliance with, the regulatory requirements as set out in regulations, or unsatisfactory situations that have more than minor safety significance, may be identified at facilities or in the conduct of activities. In such circumstances, the regulatory body should issue a written warning or directive to the authorized party, which should specify the nature and regulatory basis for each case and the period of time permitted for taking remedial action, and may provide guidance on the required corrective action(s). This is the most common form of enforcement action and will, in most cases, be sufficient to remedy the safety issue.

Penalties

3.305. The regulatory body should have the authority to impose or to recommend penalties; for example, fines on the authorized party, whether a corporate body or an individual; or to institute prosecution through the legal process, depending on the legal system and the authorization practices of the State. The use of penalties is usually reserved for serious non-compliances with regulatory requirements and for repeated violations of the authorization conditions of a less serious nature. Experience in some States suggests that imposing penalties on the authorized party rather than on individual workers is preferable as it is more likely to lead to improved safety performance.

Restriction or suspension of activities

3.306. If there is evidence of a deterioration in the level of safety, or in the event of a serious violation of the authorization conditions that, in the judgement of the regulatory body, poses an imminent radiological hazard to people or the environment, the regulatory body should require the authorized party to restrict or suspend the operation of specified facilities or activities and to take any further action necessary to restore an adequate level of safety.

Modification, suspension or revocation of the authorization

3.307. In the event of a persistent or extremely serious or willful non-compliance with regulatory requirements or violation of the authorization conditions, or a significant release of radioactive material to the environment due to serious malfunctioning of equipment, damage to structures, systems and components or incorrect operation of a facility or conduct of an activity, the regulatory body should direct the authorized party to cease the operation of a

facility or the conduct of an activity and may suspend or revoke the authorization. The authorized party should be directed to eliminate any unsafe conditions. In considering the withdrawal of an authorization, the regulatory body should ensure that operations or activities important to maintain safety continue to be performed by the authorized party.

Factors in determining enforcement actions

3.308. The factors to be taken into account by the regulatory body in deciding which type of enforcement action is appropriate in each case include the following:

- (a) The safety significance of the non-compliance or of the violation and the complexity of the corrective action necessary;
- (b) Whether the non-compliance or violation is repeated;
- (c) Whether there has been a willful violation or a willful non-compliance;
- (d) Whether or not the authorized party identified and/or reported the non-compliance or the violation;
- (e) Whether the non-compliance or violation impacted the ability of the regulatory body to perform its regulatory oversight function;
- (f) The past safety performance of the authorized party and the performance trend;
- (g) The need for consistency and openness in the treatment of authorized parties.

Implementing enforcement

The inspector's authority in relation to enforcement

3.309. The extent of the authority of regulatory inspectors to take immediate enforcement actions should be determined by the regulatory body, in accordance with the national legal framework and regulations. The authority given to an inspector may depend on the structure of the regulatory body and on the inspector's duties and experience.

3.310. In many States, inspectors are empowered to implement immediate enforcement actions for non-compliances with regulatory requirements or violations of authorization conditions, to enable a more rapid response and improvement in safety. Where immediate enforcement authority is not granted to individual inspectors, the transmission of information to the regulatory body should be commensurate with the urgency of the situation so that necessary actions are taken in a timely manner. Information should be transmitted

immediately if an inspector judges that the health and safety of workers or the public are at risk, or that the environment is endangered.

3.311. Significant enforcement actions, particularly those involving penalties, the curtailment of activities or the suspension of the authorization, are not taken immediately by regulatory inspectors except in unusual situations. Normally, decisions concerning these types of enforcement action should be taken by the regulatory body in accordance with its established procedures.

Use of the enforcement process

3.312. The regulatory body should adopt clear administrative procedures governing the taking of enforcement actions, which should be documented in internal guidance. All inspectors and other staff of the regulatory body should be trained in, and knowledgeable about, the procedures.

3.313. If there is no immediate risk to safety, the regulatory body should allow the authorized party a reasonable period of time in which to complete a corrective action. The time period should reflect the safety significance of the issue and the complexity of the corrective action required as well as other relevant factors (e.g. the proximity to a maintenance outage). However, in an integrated approach to safety, the contribution to the total risk of each non-compliance requiring a corrective action should be considered.

3.314. Procedures should stipulate which other governmental bodies, if any, should be informed in the event of enforcement actions being taken.

3.315. Regulatory procedures should state the circumstances under which it is appropriate to carry out further inspections to check whether the authorized party has responded to regulatory enforcement measures. The purpose of such inspections should be to confirm that the authorized party has complied with the enforcement measures within the periods of time specified.

Records of enforcement

3.316. Paragraph 4.56 of GSR Part 1 (Rev. 1) [2] states that:

“At each significant step in the enforcement process, the regulatory body shall identify and document the nature of non-compliances and the period of time allowed for correcting them, and shall communicate this information in writing to the authorized party.”

3.317. All enforcement actions should be recorded in accordance with an established procedure and with legal and regulatory practices. Whenever an enforcement action has to be taken urgently to ensure the protection of people and the environment, the action should be confirmed in writing as soon as possible.

3.318. Internal records of decisions relating to enforcement actions and any supporting documentation should be kept by the regulatory body in such a way that they are easily accessible and retrievable when required.

3.319. Moreover, para. 4.65 of GSR Part 1 (Rev. 1) [2] requires that the regulatory body use such internal records in support of its regulatory functions and to support the enforcement of regulatory requirements.

EMERGENCY PREPAREDNESS AND RESPONSE

3.320. The responsibilities of the government in the area of emergency preparedness and response are set out in Requirement 8 of GSR Part 1 (Rev. 1) [2] and Requirement 43 of GSR Part 3 [3]. Furthermore, Requirement 2 of GSR Part 7 [7] states that:

“The government shall make provisions to ensure that roles and responsibilities for preparedness and response for a nuclear or radiological emergency are clearly specified and clearly assigned.”

3.321. Paragraph 4.13 of GSR Part 7 [7] states that:

“The regulatory body shall require 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.”

3.322. The above roles, responsibilities and arrangements should address coordination and integration of on-site emergency arrangements with other relevant plans (e.g. those of other response organizations and the nuclear security plans of the authorized party).

3.323. The government may assign the regulatory body other roles and responsibilities in emergency preparedness and response; the precise nature of these roles and responsibilities will depend on the specific legal and organizational structures in the State. Consequently, in the following text it is only

possible to describe in a generic manner the necessary functions and processes that the regulatory body should perform in relation to emergency preparedness and response.

3.324. The functions and processes in which the regulatory body will have a role can be considered under the following four general headings:

- (a) Ensuring that on-site emergency arrangements are in place;
- (b) Ensuring coordination with off-site response organizations;
- (c) Establishing and maintaining internal arrangements for emergency preparedness and response;
- (d) Discharging its assigned responsibilities in emergency response.

3.325. Many of the roles and responsibilities of the regulatory body in respect of emergency preparedness and response will be conducted through the functions and processes described in earlier sections of this Safety Guide, but additional processes within the integrated management system may also need to be considered [4].

3.326. While much of the effort by the regulatory body and the authorized party in emergency preparedness and response for a nuclear or radiological emergency will be devoted to incidents including accidents occurring at a facility or activity within the State, a nuclear or radiological emergency in another State may have an impact on the State concerned. Such impacts should be considered in the hazard assessment carried out for the facility or activity by the authorized party and should be addressed, as appropriate, in the emergency arrangements.

Ensuring on-site emergency arrangements are in place

Regulations and guides

3.327. Paragraph 4.12 of GSR Part 7 [7] states that:

“[The] regulations and guides shall include principles, requirements and associated criteria for emergency preparedness and response for the operating organization.”

The regulations and guides should include requirements for the following:

- (a) Performing a hazard assessment;

- (b) Provisions for establishing and maintaining adequate infrastructure to support the performance of emergency response actions (e.g. plans, procedures, training and exercise programmes, staffing, equipment, tools, facilities, quality management programme and record keeping);
- (c) The timely notification of a nuclear or radiation emergency to the appropriate authorities;
- (d) The timely activation of the necessary emergency response actions on-site and, as relevant, off-site;
- (e) Provisions for obtaining off-site support and coordination with off-site authorities;
- (f) Provisions for protecting emergency workers (including health surveillance, medical follow-up, monitoring and control of exposure during the response);
- (g) Provisions for terminating the emergency;
- (h) Conducting a subsequent analysis of the emergency and the emergency response.

Review and assessment

3.328. The regulatory body should review and assess the on-site emergency arrangements developed by the authorized party, to verify compliance with regulatory requirements. This review and assessment should ensure that the on-site emergency arrangements provide, to the extent practicable, assurance of an effective response to the full range of postulated nuclear or radiological emergencies, including those of very low probability [7].

3.329. The review and assessment should consider whether the on-site emergency arrangements:

- (a) Are based on a hazard assessment that identifies all postulated nuclear or radiological emergencies that might occur in relation to the facility or activity, including those of very low probability;
- (b) Include arrangements for managing the on-site emergency response and for coordination with off-site response;
- (c) Address, as applicable, the operability and habitability of emergency response facilities (e.g. the emergency centre, technical support centre, operational support centre) under the range of postulated emergency conditions identified in the hazard assessment;
- (d) Include emergency procedures covering all postulated nuclear or radiological emergencies, including, where necessary, severe accident management guidelines [46], and which satisfactorily cover the necessary

operator actions and functions in emergency response (including procedures for notification and activation of off-site emergency response);

- (e) Identify tools, instruments, supplies, equipment and communication systems necessary for response to a nuclear or radiological emergency that are adequate for the usage expected;
- (f) Include a specific training programme (which includes drills) and instructions for all staff of the authorized party on how to respond to a nuclear or radiological emergency and on the discharge of their expected duties;
- (g) Include sufficient suitably qualified staff to be available at all times to implement the emergency plans and procedures;
- (h) Include arrangements for obtaining support from off-site response organizations;
- (i) Describe the coordination with other plans, such as plans for nuclear security and plans for firefighting;
- (j) Include an exercise programme to ensure that all the emergency arrangements are tested satisfactorily within a specific period.

Inspection

3.330. As part of its inspection plan, the regulatory body should inspect and evaluate the on-site emergency arrangements against predetermined criteria and checklists. In addition, it is required that the regulatory body evaluate some of the emergency exercises carried out by the authorized party (see GSR Part 7, para. 6.30 [7]). To do so, the regulatory body should develop necessary evaluation guidelines and checklists. As appropriate, this evaluation should assess the adequacy of coordination and integration of the on-site emergency arrangements with those off-site.

3.331. The regulatory body should ensure that the authorized party demonstrates the effectiveness of the on-site emergency arrangements as a prerequisite to issuing the authorization to bring nuclear and radioactive material onto the site and that this is completed before the start of commissioning or operation of a facility or commencement of the activity.

Enforcement

3.332. Enforcement, as described in paras 3.295–3.319, should also be applied with regard to the on-site emergency arrangements.

Ensuring coordination with off-site response organizations

3.333. The regulatory body is part of the coordinating mechanism that is required to be established by the government in accordance with para. 4.10 of GSR Part 7 [7]. The coordinating mechanism ensures that emergency arrangements are coordinated, consistent and are in place for all postulated nuclear or radiological emergencies, including those beyond State borders. The regulatory body should ensure that the authorized party provides the information necessary for establishing and maintaining adequate and coordinated off-site emergency arrangements at all levels, as appropriate.

3.334. The regulatory body will usually be either a source of advice during the preparation of the national radiation emergency response plan or a lead organization for its preparation. In many States, the regulatory body may be assigned the responsibility to provide advice in an emergency to the government and other response organizations. In some States, the regulatory body may also provide expert services (e.g. services for radiation monitoring and risk assessment for actual and expected future radiation risks) in accordance with the responsibilities assigned to it. Irrespective of its assigned responsibility in emergency response, the regulatory body should develop and maintain necessary arrangements (e.g. plans, procedures, tools, equipment, training, exercises) to effectively discharge this responsibility.

3.335. The regulatory body should take part in the regular exercises for emergency response, including national exercises, and should evaluate its own performance against pre-established objectives associated with its duties in emergency response. The results of this self-evaluation should be used to identify where and what further improvements are necessary in its emergency arrangements.

3.336. As an important aspect of the regulatory body's evaluation of the national exercises, the regulatory body should assess the interface between the authorized party, off-site response organizations and itself.

Establishing and maintaining internal emergency arrangements

3.337. The regulatory body should set up internal processes and procedures to ensure that it will fulfil the duties set out in previous paragraphs, both at the preparedness stage and during an emergency response.

3.338. The regulatory body, within its sphere of responsibility, should coordinate its emergency arrangements with those of authorized parties, with emergency arrangements at national and local levels and with its related international agreements and obligations.

3.339. GSG-12 [4] describes the management provisions and organizational and training provisions necessary for regulatory body staff with appropriate training to carry out their responsibilities in emergency preparedness and response. The regulatory body should, as applicable, put mechanisms in place to:

- (a) Send staff to appropriate locations during a nuclear or radiological emergency;
- (b) Collect data on the progress of the emergency either directly or remotely, which may require having access to the authorized party's systems;
- (c) Analyse and draw conclusions on the likely progression of the emergency;
- (d) Advise the appropriate response organizations, which includes the authorized party, of its findings;
- (e) Ensure secure and reliable communication between its staff and other organizations.

3.340. The regulatory body should develop and implement internal training and exercise programmes to ensure that the emergency arrangements are tested and that staff are familiar with the roles they will be expected to undertake in the event of a nuclear or radiological emergency.

Discharging its assigned responsibilities in emergency response

On-site responsibilities

3.341. The prime responsibility for safety remains with the authorized party during a nuclear or radiological emergency confined to the site of the facility or where the activity is taking place. The role of the regulatory body should be to observe the actions the authorized party takes; the regulatory body should not impede the authorized party from taking the necessary pre-planned emergency response actions on the site in a timely manner (see paras 4.15 and 5.23 of GSR Part 7 [7]).

3.342. The regulatory body should collect information, analyse the situation and compare its findings with that of the authorized party. In addition, without interfering with the authorized party's responsibilities for safety, the regulatory body should consider the actions that the authorized party takes. To do this

effectively, the regulatory body may assign staff to a position on the site or to other locations. These staff should record how decisions regarding on-site emergency response actions are taken and implemented by the authorized party.

Off-site responsibilities

3.343. The regulatory body's responsibilities should be clearly described in the government's provisions for dealing with a nuclear or radiological emergency. In preparing an emergency plan and in the event of an emergency, the regulatory body is required to advise the government and response organizations and to provide expert services in accordance with the responsibilities assigned to it (see GSR Part 1 (Rev. 1), para. 2.24 [2]).

3.344. Where applicable, the regulatory body should make information on incidents, including accidents, available to authorized parties, governmental bodies and international organizations, and the public, as appropriate, in accordance with the pre-planned arrangements.

COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

3.345. Paragraph 3.10 of SF-1 [1] states that:

“The regulatory body must: ...[s]et up appropriate means of informing parties in the vicinity, the public and other interested parties, and the information media about the safety aspects (including health and environmental aspects) of facilities and activities and about regulatory processes; [and] [c]onsult parties in the vicinity, the public and other interested parties, as appropriate, in an open and inclusive process.”

3.346. Requirement 36 of GSR Part 1 (Rev. 1) [2] states that:

“The regulatory body shall promote the establishment of appropriate means of informing and consulting interested parties and the public about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body.”

3.347. The regulatory body should develop and implement a communication and consultation strategy and should be committed to a high level of transparency and openness, while ensuring an adequate level of protection of

sensitive information, in order to address the legitimate concerns of interested parties in nuclear and radiation safety matters, to enable the regulatory body to make informed decisions and to contribute to ensuring its freedom from undue influences that might adversely affect safety. Recommendations and guidance covering the communication and consultation with interested parties are provided in IAEA Safety Standards Series No. GSG-6, Communication and Consultation with Interested Parties by the Regulatory Body [47].

Appendix I

PROVISION OF CONSUMER PRODUCTS

AUTHORIZATION FOR THE PROVISION OF CONSUMER PRODUCTS

I.1. Requirement 33 of GSR Part 3 [3] states that:

“Providers of consumer products shall ensure that consumer products are not made available to the public unless their use by members of the public has been justified, and either their use has been exempted or their provision to the public has been authorized.”

I.2. The aim of authorization is to ensure that consumer products meet all the requirements for design and performance that were taken into account in the generic safety assessment conducted by the manufacturer for the type of consumer product. The manufacturer should provide the regulatory body with sufficient documentation and certification to enable it to review and assess the proposed consumer product. The documentation should include the following:

- (a) A description of the consumer product, its intended uses and benefits, the radionuclide(s) incorporated and the function served by the radionuclide(s). Documentary evidence that the radioactive substance fulfils its function should also be provided.
- (b) The activity of the radionuclide(s) to be used in the consumer product.

I.3. The following additional information should be provided, as may be appropriate or as required by the regulatory body. See IAEA Safety Standards Series No. SSG-36, Radiation Safety for Consumer Products [48]:

- (a) Justification of the choice of radionuclide(s), particularly in relation to other radionuclide(s) that could be of lower risk to the public (e.g. radionuclides that emit less penetrating radiation and/or have a shorter half-life). The reason for choosing the radioactive substance in preference to a non-radioactive alternative should also be provided.
- (b) The chemical and physical forms of the radionuclide(s) contained in the consumer product.
- (c) Details of the construction and design of the consumer product, particularly with regard to the containment and shielding of the radionuclide in normal

and abnormal conditions of use and disposal, and the degree of access to the radionuclide(s).

- (d) The quality assurance and verification procedures to be applied to radioactive sources, components and finished products to ensure that the maximum specified quantities of radionuclides or the maximum specified radiation levels are not exceeded, and to ensure that the consumer product is constructed in accordance with the design specifications.
- (e) A description of the prototype tests for demonstrating the integrity of the consumer product in normal use and in the event of possible misuse and accidental damage, and the results of these tests.
- (f) External radiation levels arising from the consumer product and the method of measurement.
- (g) Safety assessments, including estimates of individual doses and, if appropriate, collective doses arising from normal use, possible misuse and accidental damage and disposal and, if applicable, servicing, maintenance and repair.
- (h) The anticipated useful lifetime of the consumer product and the total numbers expected to be distributed and/or made available annually.
- (i) Information about any advice to be provided on the correct use, installation, maintenance, servicing and repair of the consumer product.
- (j) An analysis to demonstrate that the consumer product is inherently safe (i.e. it will not give rise to significant doses to individuals in the event of foreseeable accidents).
- (k) Information on how the consumer product is intended to be labelled.
- (l) The provisions foreseen for recycling or disposal of the consumer product at the end of its useful lifetime.

REGULATORY INSPECTION FOR THE PROVISION OF CONSUMER PRODUCTS

I.4. Periodic inspections of the facilities authorized to manufacture consumer products should be undertaken to confirm that the consumer products are being manufactured and distributed in accordance with the product specifications, regulatory requirements and conditions of the authorization. The regulatory body should also conduct investigations, or review the results of investigations, of any accidents or instances of misuse. If the regulatory body receives new information that casts doubt on part or all of the original safety assessment, then appropriate enforcement actions should be taken.

Appendix II

AUTHORIZATION CONDITIONS RELEVANT FOR CERTAIN STEPS OF THE AUTHORIZATION PROCESS FOR COMPLEX FACILITIES OR ACTIVITIES

II.1. In addition to general authorization conditions that are applicable to all authorizations, there are some specific conditions that are relevant only at certain steps of the authorization process. The following list of conditions is not all-inclusive, nor is it the only possible arrangement, but it may be helpful in determining which conditions are relevant.

SITE PREPARATION

II.2. The regulatory body should specify the controls that the authorized party is required to exercise over the use of the site and the degree to which the authorized party may prepare the site without conducting activities which, under the laws and regulations of the State, require an authorization for construction.

CONSTRUCTION

II.3. In authorizing construction, the regulatory body should ensure that certain conditions are fulfilled so that this step can proceed in a manner that ensures safe operation of the facility. These conditions include the following:

- (a) The facility should be designed and constructed in accordance with the relevant site parameters approved by the regulatory body.
- (b) The facility should be constructed in accordance with the design that has been justified in a safety case. The authorized party should not deviate from this design in any way that might affect safety without following a modification process that requires categorization of the modification according to safety significance. This modification process may require approval or agreement from the regulatory body depending upon the safety significance of the modification.
- (c) The authorized party should initiate a radiological study of the region, including an appropriate baseline survey, prior to the start of operation.
- (d) The authorized party should prepare reports during the stages of site evaluation and construction to keep the regulatory body informed of the

progress of the project, covering the progress of site studies, the progress of construction and results of the pre-operational environmental monitoring programme.

- (e) The authorized party should keep records of site evaluation and construction of the facility (as appropriate), such as the results of site evaluation studies (geological, meteorological and hydrological data, as well as results of the pre-operational environmental monitoring programme), design records, manufacturing records (including results from quality control activities) and erection records (including quality control results and as-built design records). Such records may be useful later in the investigation of events or generic problems and in decommissioning.

II.4. Furthermore, at the time of authorizing construction, conditions may be imposed on the authorized party requiring that it obtain from the regulatory body additional approvals relating to the design of certain parts of the facility.

COMMISSIONING

II.5. In authorizing the commissioning of a facility, the regulatory body should specify a number of conditions, including the following:

- (a) Commissioning should be carried out in accordance with a programme approved by the regulatory body.
- (b) Completed structures, systems and components important to safety should be put into service only once they have been inspected, tested and approved as being in accordance with the terms of the authorization.
- (c) Commissioning records, including records of equipment and system tests, test procedures and test results should be kept to demonstrate to the regulatory body the continuing safety of the facility. Commissioning records should cover the following:
 - The results of the commissioning tests and their evaluations;
 - Operational data, including data on the facility's output and performance;
 - Modifications performed;
 - Results of the radiation protection programme;
 - Results of the environmental monitoring programme;
 - Radioactive waste management.
- (d) The authorized party should provide approved storage facilities for nuclear or radioactive materials. The competent authority responsible for nuclear

security may require that appropriate nuclear security measures be in effect before nuclear or other radioactive material is brought into the facility.

- (e) Fissile material or other radioactive material should not be brought onto the site without a regulatory authorization.
- (f) From the introduction of radioactive material into the facility, the authorized party should operate the facility only under the control and supervision of authorized personnel using written procedures, in accordance with the operational limits and conditions approved by the regulatory body. Any changes made to the operational limits and conditions should be approved by the regulatory body prior to their implementation.
- (g) The authorized party should have an approved emergency plan, coordinated with the other authorities involved in emergency preparedness and response.

OPERATION

II.6. In authorizing operation, the conditions imposed for commissioning should be amended appropriately in the light of commissioning results. The regulatory body should add conditions to the authorization, as necessary, such as the following:

- (a) The authorized party should not operate the facility or conduct the activity outside the limits authorized by the regulatory body.
- (b) The authorized party should have a procedure for modifications to be approved by the regulatory body in order to ensure that no part of the approved facility that is important to safety will be modified without the prior approval of the regulatory body.
- (c) The authorized party should ensure that the facility is subjected to in-service inspection and testing, to be carried out as specified for structures, systems and components important to safety, in accordance with a schedule approved by the regulatory body.
- (d) The authorized party should keep operational records to be used in the regulatory oversight for possible examination by the regulatory body. Operational records should cover:
 - Operational data and performance records of the facility or activity;
 - Operating log books;
 - Inventories of fissile material and other radioactive material;
 - Periodic calibration of equipment;
 - Periodic testing of equipment and systems;
 - Internal reviews or inspections;
 - Preventive maintenance and repairs;

- Personnel training;
 - Monitoring of occupational exposures;
 - Records of workplace monitoring for the facility or activity;
 - Radioactive waste management;
 - Effluent discharges and the environmental monitoring programme;
 - Anticipated operational occurrences and accidents.
- (e) The authorized party should ensure that the maintenance of equipment and systems important to safety is carried out in accordance with a schedule approved by the regulatory body.
- (f) Only changes given prior approval by the regulatory body should be made to the approved arrangements, schedules, procedures and rules.
- (g) The authorized party should ensure that the facility is operated or the activity is carried out only under the control and supervision of authorized personnel in adequate numbers that are acceptable to the regulatory body.

II.7. Authorization conditions relating to liability of the authorized party in the event of an accident are outside the scope of this Safety Guide.

DECOMMISSIONING

II.8. In authorizing the decommissioning of a facility, the regulatory body should take particular care in specifying conditions, since the sanctions of shutting down the facility or revoking the authorization are unlikely to be effective at this stage. The regulatory body should examine the results of the final radiological survey conducted by the authorized party. The final radiological survey should be conducted after the completion of decommissioning activities to ensure that regulatory requirements are met prior to release of the facility from regulatory control.

CLOSURE

II.9. Following the closure of a radioactive waste disposal facility, continuing institutional control, including environmental monitoring, may be necessary. Depending on national legislation, conditions may be specified in a post-closure authorization held by the authorized party or responsibilities may be taken by a relevant national authority prior to agreeing to closure of the facility.

Appendix III

TOPICS TO BE COVERED BY REVIEW AND ASSESSMENT

III.1. This appendix provides a generic list of topics that should be considered in the review and assessment process by the regulatory body throughout the lifetime of a facility or activity, from site selection to decommissioning or closure. Each topic has been itemized; however, addressing all items does not necessarily mean that every aspect of safety has been fully addressed. Also, depending on the facility or activity and on the particular stage of the lifetime, some topics will be more important than others and the degree of detail necessary in the review and assessment may differ. This Appendix focuses on complex facilities and activities. For less complex facilities and activities, the review and assessment process should follow a graded approach.

THE PHYSICAL NATURE OF THE FACILITY OR ACTIVITY AND ITS ENVIRONMENT

III.2. The following information on the facility or activity and on the processes conducted should be provided by the authorized party at various stages and used as a basis for review and assessment:

- (a) A detailed description of the facility or activity, supported by drawings of the layout, the systems and the equipment;
- (b) Information on the functional capability of the facility and the nature of the activity, its systems and major items of equipment (including radiation protection equipment and waste management systems and equipment);
- (c) The findings of tests that validate the functional capability of equipment and systems;
- (d) The results of inspections of components;
- (e) Maintenance records;
- (f) A description of the physical condition of structures, systems and components on the basis of inspections or tests;
- (g) A description of the support facilities available both on and off the site, including maintenance and repair workshops;
- (h) Geological, hydrogeological and meteorological conditions at the site;
- (i) A description of off-site characteristics, including population densities, land use, industrial structures and facilities (including pipelines) and transport arrangements (such as airports, roads and railways).

INFRASTRUCTURAL ASPECTS

III.3. Throughout the lifetime of a facility or activity, the authorized party will have to propose and implement arrangements for radioactive waste management. The regulatory body should review and assess any proposals in the safety case for on-site processing (i.e. pretreatment, treatment and conditioning) and storage of radioactive waste, to ensure that the characteristics of the processed waste and the waste packages are compatible with the national strategy for radioactive waste management, any subsequent waste acceptance requirements and regulatory requirements. Specifically, the regulatory body should satisfy itself that the radioactive waste and waste packages:

- (a) Are properly characterized and compatible with the anticipated nature and duration of storage pending disposal;
- (b) Can be subjected to regular surveillance;
- (c) Can be retrieved for further steps in radioactive waste management.

III.4. Adequate arrangements should be made for the transport of radioactive material, waste and equipment both on and off the site. The regulatory body should review and assess these arrangements and should satisfy itself that all national and regulatory requirements have been met.

SAFETY ANALYSIS

III.5. Throughout the lifetime of the facility or activity, the regulatory body should review and assess the information on the facility or activity provided by the authorized party to determine whether the facility or activity is in compliance with the relevant safety and regulatory requirements, and, in particular, information covering the following:

- (a) Specification of the safety standards and design codes used.
- (b) A compilation of the safety analyses and their assumptions.
- (c) Structures, systems and components important to safety.
- (d) Limits and permitted operational states.
- (e) Anticipated operational occurrences.
- (f) Postulated initiating events for the safety analyses:
 - External hazards (e.g. external floods, earthquakes, aircraft crashes, transportation accidents, explosions, external fires and meteorological hazards);
 - Internal failures (e.g. mechanical and electrical failures);

- Internal hazards (e.g. internal fires, internal floods and internally generated missiles).
- (g) Features, events and processes:
 - A list of barriers with their relative contributions;
 - A description of how requirements for defence in depth are met;
 - Anticipated activities for confirmation of performance.
- (h) Analytical methods and computer codes used in the safety analyses and the verification and validation of such codes.
- (i) Radioactive releases and radiation exposures in normal operation, anticipated operational occurrences and accident conditions.
- (j) The authorized party's safety criteria for analyses of authorized party actions, common cause failures, cross-link effects, the single failure criterion, redundancy, diversity and separation.

III.6. The impacts of the facility or activity on its surroundings should be assessed. Societal and economic issues, land use issues, technical issues such as detailed considerations of geology and hydrogeology, transport routes for the facility and protection of the environment should be taken into account in such an assessment. Both the anticipated impacts and the consequences of anticipated operational occurrences and accident conditions, which are the subject of safety analysis, should be considered.

THE AUTHORIZED PARTY AND THE MANAGEMENT SYSTEM

III.7. At all stages of the facility's lifetime, the authorized party should be required to demonstrate that:

- (a) It will be in control of the facility or activity;
- (b) It has resources available to meet its obligations and liabilities in connection with an authorization.

III.8. The authorized party should be required to demonstrate that it has a management system in place, whereby all activities are controlled, so as to provide an assurance that requirements for quality assurance, safety and protection of people and the environment will be met. This will include having operational procedures in place.

III.9. For some facilities (notably waste disposal facilities) this demonstration may need to apply for an extended period, perhaps covering several generations, over which control will need to be maintained.

III.10. The information to be provided by the authorized party to the regulatory body for review and assessment should include:

- (a) Details of the organizational structure of the authorized party, showing that it has adequate control over the activities of its own staff and its contractors;
- (b) A demonstration of the adequacy of resources in terms of sufficient and appropriately trained and experienced staff, ensuring in-house expertise;
- (c) A demonstration of the adequacy of the procedures for controlling changes to the organizational structure and resources;
- (d) The specification and documentation of the duties of staff, demonstrating the integration of responsibilities for safety into their duties;
- (e) A demonstration of the provision of, or access to, a high level of expertise in safety to carry out safety and engineering analyses and to perform associated audit and review functions;
- (f) A demonstration of the adequacy of the provisions for financing of continuing liabilities for nuclear damage and of decommissioning;
- (g) Provisions for the use of contractors.

III.11. The authorized party should be required to demonstrate that it has in place:

- (a) A mechanism for setting operating targets and safety targets;
- (b) A policy that states that the demands of safety take precedence over those of production;
- (c) Documented roles and responsibilities for individuals and groups;
- (d) Procedures for the control of modifications to the facility;
- (e) Procedures for the feedback of operating experience to staff, including experience relating to organizational and management aspects;
- (f) Mechanisms for maintaining the configuration of the facility and its documentation;
- (g) Formal arrangements for employing and controlling contractors;
- (h) Staff training facilities and programmes for initial, refresher and upgrade training, including the use of simulators, where appropriate;
- (i) A quality assurance programme and regular quality assurance audits with independent assessors;
- (j) A system for ensuring compliance with regulatory requirements;
- (k) Comprehensive, readily retrievable and auditable records of baseline information and operational and maintenance history;
- (l) Staffing levels for the operation of the facility or conduct of the activity that take account of absences, shift working and overtime restrictions;
- (m) Sufficient and qualified staff available and on duty at all times;

- (n) Systematic and validated methods for the selection of staff, including testing for aptitude, knowledge and skills;
- (o) A systematic approach to fostering leadership and management for safety, including training in safety culture, particularly for managers;
- (p) Guidelines on fitness for duty in relation to hours of work, health and use of drugs or alcohol;
- (q) Competence requirements for operating, maintenance and technical staff and managers;
- (r) A system for consideration of the human-machine interface and its design and for the analysis of information needs and task workload for operators in the control room and at other workstations.

OPERATIONAL PROCEDURES

III.12. The authorized party should be required to demonstrate that the operation of the facility or conduct of the activity is in accordance with the relevant safety objectives and safety and regulatory requirements, and that it has developed or obtained the following:

- (a) Formal approval and documentation where required by regulatory body;
- (b) A formal system for modification of a procedure;
- (c) Understanding and acceptance of the procedures by management and staff;
- (d) Verification that the procedures are being followed;
- (e) Procedures that are adequate in comparison with international good practices;
- (f) Arrangements for regular review and, if necessary, revision of the procedures;
- (g) Clear procedures in which principles relating to human factors have been taken into account;
- (h) Procedures that comply with the assumptions and findings of the safety analysis and with experience from design and operation;
- (i) Adequate emergency operating procedures.

EQUIPMENT QUALIFICATION

III.13. The authorized party should be required to maintain:

- (a) A list of equipment covered by the equipment qualification programme, including documentation of the analyses used to derive this list of equipment, and a list of control procedures;
- (b) A qualification report and other supporting documents (such as equipment qualification specifications and a qualification plan);
- (c) Verification that the installed equipment matches the qualification requirements;
- (d) Documentation of procedures to maintain qualification over the lifetime of the installed equipment;
- (e) Information on mechanisms for ensuring compliance with these procedures;
- (f) Documentation of a maintenance, testing and inspection programme and a procedure for providing feedback to ensure that ageing degradation of qualified equipment remains insignificant;
- (g) A list of appropriate corrective actions to maintain equipment qualification;
- (h) Information on the physical integrity and functionality of qualified equipment;
- (i) Records of all qualification measures taken over the installed lifetime of equipment.

III.14. In the selection of equipment for measurements, the minimum detection limit should be commensurate with the compliance level such that the minimum detection limit is around 10% of the level to be measured for demonstration of compliance.

MANAGEMENT OF AGEING

III.15. The authorized party should be required to establish and maintain a programme for the management of ageing of equipment that includes the following:

- (a) Documented methods and criteria for identifying structures, systems and components covered by the ageing management programme;
- (b) A list of structures, systems and components covered by the ageing management programme and records that provide information for use in the management of ageing;

- (c) An evaluation of and documentation of potential ageing related degradation that may affect the safety functions of structures, systems and components;
- (d) Details of the extent of understanding of the dominant mechanisms of ageing for structures, systems and components;
- (e) Details of the programme for the timely detection and mitigation of ageing processes and/or ageing effects;
- (f) Acceptance criteria and required safety margins for structures, systems and components;
- (g) Awareness of the physical condition of structures, systems and components, including actual safety margins.

AUTHORIZED PARTY'S SAFETY PERFORMANCE

III.16. The authorized party should be required to provide details of:

- (a) The system used for identifying and classifying safety related events.
- (b) The arrangements made for root cause analysis of events, the results and lessons learned and the follow-up measures taken.
- (c) Methods for selecting and recording safety related operational data, including data for maintenance, testing and inspection.
- (d) Trend analyses of safety related operational data.
- (e) Feedback of safety related operational data, including records and reports of incidents including accidents.
- (f) Records of radiation doses to persons on the site.
- (g) Records of off-site contamination and data from radiation monitoring on the site.
- (h) Records of quantities and relevant characteristics of radioactive waste generated and stored at the facility.
- (i) Records of the quantities of radioactive effluents discharged.
- (j) Analyses of safety performance indicators, such as:
 - Frequency of unplanned shutdowns of operation;
 - Frequency of selected safety system actuations and demands;
 - Frequency of safety system failures;
 - Unavailability of safety systems;
 - Annual individual and collective occupational radiation doses;
 - Trends in causes of failures (operator errors, equipment failures, administrative matters, control matters);
 - Backlog of outstanding maintenance tasks;
 - Extent of repeat maintenance;
 - Extent of corrective maintenance, including repair and replacement;

- Frequency of unplanned operator actions in relation to safety and their success rate;
- Amounts of radioactive waste generated;
- Quantities of radioactive waste in storage.

EXPERIENCE FROM OTHER FACILITIES AND RESEARCH FINDINGS

III.17. The authorized party should be required to provide information to the regulatory body on its arrangements for:

- (a) Obtaining and assessing feedback of experience relevant to safety from similar facilities and activities and from other nuclear and non-nuclear facilities and activities, and taking action on the basis of this feedback;
- (b) Determining the need for research and development;
- (c) Obtaining and assessing the findings of relevant research programmes, and taking action on the basis of these findings.

Appendix IV

REGULATORY INSPECTION AREAS FOR NUCLEAR FACILITIES

IV.1. This appendix sets out the areas of nuclear facilities that may be of particular interest for regulatory inspection at different steps of the authorization process. Depending on the facility or activity and on the particular stage of the lifetime, some topics will be more important than others, and the degree of their applicability may differ.

SITE EVALUATION

IV.2. Before the construction of a nuclear facility is to begin, the regulatory body should monitor, as appropriate, by means of its inspection programme, site preparation activities undertaken by the applicant or authorized party, including verification of site characteristics and authorized excavations and earthworks.

IV.3. The specific objectives of regulatory inspection in these areas include verification that the authorized party is undertaking siting activities in full compliance with existing regulatory requirements, and assurance that the site preparation work does not proceed beyond that permitted by any authorization in force. During site preparation, the regulatory body should also confirm that the site characteristics remain consistent with the description presented by the authorized party in its authorization application and in the subsequent supporting documentation submitted to the regulatory body. This is vital for disposal sites, for which the action of a major barrier to the movement of radionuclides is dependent on the characteristics of the site. In addition, inspectors should be alert to any new conditions or information revealed as a result of activities for site preparation, which should then be considered by the regulatory body in making subsequent decisions on authorization.

DESIGN AND CONSTRUCTION

IV.4. The chief objectives of the regulatory inspection programme in the design and construction of the facility should be to verify that:

- (a) Materials and structures, systems and components important to safety meet the requirements established by the regulatory body and conform to good practices;

- (b) Construction activities associated with manufacturing and installing structures, systems and components are conducted in accordance with regulatory requirements and in conformity with general safety objectives;
- (c) The as-built configuration of structures, systems and components is in conformity with the assumptions made in the regulatory review and assessment, any deviation is analysed and justified and the documentation is updated accordingly;
- (d) The authorized party's system and procedures for quality assurance and inspection are adequate to ensure the conformance of equipment to the technical specifications.

IV.5. The regulatory body should inspect design and construction activities in a number of areas in order to meet these objectives. In particular, the following areas should receive close attention in the construction stage, primarily because of the difficulty of detecting and correcting deficiencies in these areas once fissile material or other radioactive material has been brought to the site and the facility enters the active commissioning stage:

- (a) Mixing and placement of concrete and its reinforcement, especially in:
 - Foundations;
 - Structures important to safety, particularly containment structures.
- (b) Construction of cooling intakes and discharge systems.
- (c) Installation of components important to safety, particularly:
 - Containment and shielding boundaries;
 - Internals of vessels that will contain fissile material and other radioactive material;
 - Equipment to be used in radiation areas.
- (d) Installation of control, protection and power systems important to safety.
- (e) Areas of the facility that are inaccessible after construction is completed, particularly systems and components embedded in the foundations or the building structure.
- (f) Housekeeping in respect of structures, systems and components important to safety.
- (g) The management systems of the designer, manufacturer and constructor.

COMMISSIONING

IV.6. Activities associated with commissioning will normally begin before construction is completed. Accordingly, the regulatory body should be prepared to inspect areas of commissioning activity in parallel with activities of the

construction stage. In some States the commissioning programme is subject to approval by the regulatory body and the agreement of the regulatory body should be obtained before advancing beyond certain hold points.

IV.7. Inspection by the regulatory body during the commissioning stage should focus on four broad areas of the authorized party's activity:

- (a) Testing before the introduction of fissile material and other radioactive material;
- (b) Initial introduction of fissile material and other radioactive material;
- (c) Testing of operations involving fissile material and other radioactive material;
- (d) Other commissioning activities.

Testing before the introduction of fissile material and other radioactive material

IV.8. The inspection area of testing before the introduction of fissile material and other radioactive material encompasses those activities and tests performed before the introduction of such material by the authorized party in order to demonstrate that structures, systems and components function properly and conform to design requirements. It also covers the inspection and acceptance criteria for the receipt at the facility of fissile material and other radioactive material. The regulatory inspection programme should include:

- (a) Examination of documented procedures to verify that they are in accordance with the conclusions of the regulatory review and assessment;
- (b) Review of the implementation of these procedures;
- (c) Direct observation of the performance of certain key pre-operational tests;
- (d) Examination of the results of selected tests;
- (e) Confirmation of the integrity of any engineered barriers.

IV.9. The number of tests and the key tests that are to be examined and directly witnessed by the regulatory body will differ depending on factors such as the importance of the test for safety and whether the facility to be commissioned is the first of its kind or one of several similar facilities. The regulatory body should, however, place particular emphasis on inspection by the examination of documentation and by the direct observation of some of the tests performed on:

- (a) Structures, systems and components that prevent unsafe conditions or that mitigate the consequences of anticipated operational occurrences and accident conditions;
- (b) Structures, systems and components whose failure to operate properly will require action from one or more safety related structures, systems and components.

IV.10. As such, the regulatory body may inspect the following tests:

- (a) Tests of safety systems (such as instrumentation and control systems, shutdown systems and standby systems);
- (b) Tests of the integrity of the containment and shielding boundaries (such as hydraulic tests of pressurized structures), as appropriate;
- (c) Tests of the susceptibility of structures, systems and components to vibration or to other design loads;
- (d) Tests for secondary containment integrity (such as overpressure and leak rate tests), as appropriate;
- (e) Tests of emergency power systems, as appropriate;
- (f) Tests of communication capabilities;
- (g) Tests of ventilation systems;
- (h) Integrated cold and hot functional tests.

Initial introduction of fissile material and other radioactive material

IV.11. In the regulatory inspection programme, close attention should be paid to authorized party activities relating to the preparation for and actual introduction of fissile material and other radioactive material. Inspectors should be present at the facility site to observe some of these activities directly.

IV.12. Although some of these tests may be performed at times other than the time when fissile material and other radioactive material is first introduced, the regulatory body should inspect the following:

- (a) Tests of the main control room;
- (b) Access control and implementation of the radiation protection programme;
- (c) Arrangements for emergency preparedness and response and demonstration of the emergency plan;
- (d) Systems for monitoring radioactive releases and meteorological monitoring systems;

- (e) The distribution of fissile material and other radioactive material (such as the fuel loading pattern in a reactor) and process calculations and/or criticality calculations, as appropriate;
- (f) Systems involved in the handling or movement of radioactive or fissile material.

Testing of operations involving fissile material and other radioactive material

IV.13. Tests during this stage, which should be subject to regulatory review and inspection, will depend on the type of facility being commissioned. They include tests to demonstrate as far as possible that:

- (a) The facility is being operated in accordance with the descriptions given in the safety analysis report;
- (b) Systems respond to malfunctions in accordance with the claims made in the safety analysis report.

IV.14. The inspection area of testing of operations involving fissile material and other radioactive material encompasses activities of the authorized party performed in conditions gradually progressing towards nominal operating conditions. At this point, structures, systems and components are tested in an operational environment to ensure that they have been constructed and installed properly and are capable of functioning in compliance with the design requirements. Consideration should be given to the performance of radiation surveys of facility shielding (such as concrete walls) during startup of the facility. This will help to identify any voids or faulty joints in the shielding or any radiation penetrating through joints. In the event of such an occurrence, alterations should be made prior to further operation. During this period, the authorized party carries out tests at increasing operational levels. This testing includes the recording and analysis of data relating to temperatures, pressures, radiation levels, flows and variations in process parameters as well as other relevant parameters.

IV.15. Inspectors should examine and assess the safety aspects of a sample of the authorized party's procedures for conducting operational tests. In addition, as the tests are completed, a sample of the test documentation and the results of the inspection should be examined by regulatory personnel to verify that the tests have been completed in accordance with the test instructions and that the results are acceptable. Regulatory inspection should also include the monitoring and direct observation of several tests.

Other commissioning activities

IV.16. In addition to the examination of documentation and the surveillance of tests, there are a number of other areas necessitating inspection by the regulatory body at the commissioning stage. The ability of the authorized party's management to progress from supervising construction to supervising operation and its arrangements for doing so should also be inspected. This inspection should cover the management's provisions for putting the emergency plan into effect and for the training and qualification of operating personnel. Hold points during the pre-operational tests, fuel loading and subcritical tests, initial criticality and low power tests, power ascension tests stage and into the full operational stage should be closely monitored. These areas overlap, necessitating continuing attention in inspections during the operation stage.

OPERATION

IV.17. Once the facility has reached the authorized operation stage, the regulatory body shall implement an inspection programme to systematically verify the authorized party's compliance with regulatory requirements and achievement of general safety objectives, and to detect potential safety problems. This verification should consist of: a balanced approach to monitoring and direct observation of activities; interviews with personnel, including managers; a review of the qualifications of the authorized party's personnel; and sampling of documentation. For waste management facilities and particularly for waste disposal facilities, the structure of the inspection programme and the tests to be carried out will primarily relate to conformance to the relevant design criteria and waste acceptance criteria for the facility and will constitute an element in providing confidence in the long term safety of the facility. For all facilities, these inspections should cover the aspects detailed in paras IV.18–IV.41.

Operations

IV.18. Inspections in the area of operations should focus on the control and execution of activities directly relating to operating a facility to the operational limits and conditions established by regulatory requirements and authorizations or by procedures or specifications. Inspectors should perform safety verification of: operating procedures; the operating configuration of systems important to safety; control room activities; and the abilities of the operations staff to perform their duties. Simulator training and the responses of operating staff to abnormal events and emergency conditions, as well as the adequacy of the management's

actions, should also be assessed. In performing this safety verification, the reviews described in paras IV.19–IV.22 should be carried out.

Operating procedures

IV.19. A sampling review of operating procedures should be performed, including all the procedures for normal operations, anticipated operational occurrences and accident conditions. Inspections should be focused on the operating personnel's adherence to procedures, including operational limits and conditions. The usability and adequacy of the procedures should also be evaluated. The inspection programme in this area may necessitate sustained observations (e.g. in the control room) to cover 24 hour operation as necessary, and in particular shift turnovers. The inspectors should check the availability of safety systems and the presence of alarm systems, and the way in which they are handled by the operations staff.

Authorized party's training programme

IV.20. The adequacy of the authorized party's training programme for staff should be assessed routinely to ensure that the training reflects actual conditions in the facility.

Safety systems

IV.21. A sampling review of safety systems should be performed to evaluate the following:

- (a) Any identified degraded equipment;
- (b) Discrepancies between installed components and/or system hardware and the facility drawings;
- (c) Controls for performing maintenance on equipment;
- (d) The quality of performance of the operations staff in log keeping and record keeping and in routine monitoring of equipment.

Note should be taken of the effectiveness of the operations staff in getting degraded equipment repaired by maintenance staff or its prompt evaluation to ensure operability. Inspection of the facility should also include observations of non-safety-related areas to ensure that they have no adverse effects on the safety related areas of the facility. The adequacy of the fire protection and prevention programme, including the management's attention to this area, should be noted in these inspections.

Management

IV.22. The management's involvement in the facility and its effectiveness in paying appropriate attention to operational issues, including abnormal events, should be evaluated. In inspections it should be considered: whether the organizational structure is suitable; whether there are adequate numbers of staff; how well management and staff communicate; and how the management emphasizes the importance of safety and fosters a strong safety culture.

Outages

IV.23. Inspections should cover outage activities. In addition to providing opportunities to observe modifications being made to the facility, outages provide opportunities to observe activities in areas that are not always accessible during normal operation. Certain activities, such as inspections in highly radioactive areas or the maintenance and repair of highly contaminated systems, present a challenge to the authorized party's organization. Outages can provide valuable insights into the management's ability to perform tasks outside the normal operational mode. Furthermore, movements of fissile and other radioactive material need to be well controlled and special checks may be necessary before returning the facility to normal operation to ensure that it is still within its safety justification. Before returning the facility to normal operation, it is usual for the regulatory body to perform a special inspection.

Radiation protection and radioactive waste management

IV.24. The area of radiation protection should cover all related activities at the facility, including radiation protection of staff and contractor personnel and of the public [49, 50]. The area of radioactive waste management should cover processing (i.e. pretreatment, treatment and conditioning), storage and transport of waste, the release of effluents and the environmental monitoring programme [42].

Organizational structure for radiation protection

IV.25. The structure of the organization responsible for the implementation of the radiation protection programme, the procedures necessary for implementation of the programme, the effectiveness of the management and its commitment with respect to radiation protection, including application of the optimization principle, should all be assessed during inspections. Indicators of the effectiveness of the management are the levels of exposure of personnel, levels of contamination in

working areas, levels of releases of effluents, and the level of understanding on the part of management and workers of their responsibilities in the implementation of the radiation protection programme. Any self-assessments performed by the authorized party under this programme should be reviewed.

Records of occupational radiation doses

IV.26. Inspectors should selectively review records of individual occupational doses, including internal and external doses. Activities should be observed to ensure that procedural and management controls are effective. This includes controls for radiation areas and contamination areas as well as inspection of activities for internal and external dosimetry. Exposures of personnel that result in the authorized party's reference levels for effective doses or intakes being exceeded should be noted. Records of radiation protection training and retraining should be assessed.

Effluents

IV.27. The inspection programme should include verification that any releases of effluents are within the authorized discharge limits. This should include the review of systems for the treatment of radioactive waste and for the monitoring of effluents. Training and qualifications for technicians and workers employed in the areas concerned should also be reviewed.

Environmental monitoring

IV.28. The environmental monitoring programme should be reviewed to ensure that all environmental monitoring is performed in accordance with established procedures. Independent measurements may be performed to verify the accuracy of the authorized party's monitoring equipment and the results of measurements.

Radioactive waste management

IV.29. The implementation of arrangements for on-site waste treatment, conditioning and storage should be reviewed and records should be inspected. In particular, the waste characterization process, the compliance with any requirements for waste storage or disposal, and the records for these processes should be subject to inspection.

IV.30. Whenever unpackaged waste is stored or waste packages are stored, or have been placed in a waste disposal facility pending a decision on closure of the

facility, degradation of the waste may occur over time. The storage conditions for the waste and the waste packages should be inspected at appropriate intervals to provide confidence that the waste remains suitable for treatment and/or conditioning or that the waste packages will be suitable for retrieval, transport and further steps in radioactive waste management, as necessary.

IV.31. Transport arrangements for radioactive material on the site should be examined. Receipt and dispatch arrangements should be inspected and attention should be paid to the integrity of packages, residual levels of contamination and associated records.

Maintenance and testing

IV.32. Inspection in the area of maintenance and testing should comprise assessments of the implementation of the maintenance and testing programme. These should cover:

- (a) All types of maintenance performed on structures, systems and components and maintenance of the physical condition of the facility;
- (b) Testing, including the conduct of all surveillance testing activities, all in-service inspection and testing, calibration of instruments, equipment operability tests and other special tests.

IV.33. Direct observation by the regulatory body should include a sampling of the authorized party's inspection and testing activities, including such tests as:

- (a) Calibration of nuclear instrumentation systems;
- (b) Verification of containment integrity;
- (c) Testing of local leak rates for the containment;
- (d) Testing of piping support and restraint systems;
- (e) Tests for safety pumps, valve capacity and stroke timing;
- (f) Surveillance tests for breakers and transformers.

Inspectors should note the capability of the individuals performing the tests and, for complex surveillance activities, should assess the interface between the surveillance personnel and the operations staff involved in the performance of the test. The adequacy and usability of the procedures should be assessed and the control and calibration of the test equipment should be observed. The inspectors should observe the involvement of management in these programmes to ensure that the programmes are effective and that safety equipment is properly maintained, with few recurring problems. Maintenance backlogs, the

intervals at which repetitive equipment repairs are carried out and the amount of maintenance work actually being performed should be noted, as these may be early indicators of declining performance in the maintenance programme. A large backlog of repairs, a high number of equipment failures and a low level of maintenance activity may also be indicative of a maintenance programme that is difficult to manage and requires a disproportionate amount of documentation. Self-assessment activities in these programmes should be observed and their findings should be routinely reviewed.

IV.34. As part of the inspection area, a sample of maintenance activities should be observed to assess the adequacy of programmes and procedures and the capability of the maintenance technicians to perform their assigned tasks. The planning and scheduling of maintenance should be assessed to ensure that maintenance activities are performed by competent staff and are properly coordinated, and that repairs to equipment are handled in accordance with appropriate priorities. All types of maintenance activities should be observed. Before initiating maintenance work, special attention should be paid to the isolation and tagging of safety systems that are out of service. Inspectors should observe compliance with procedures for such isolation and tagging controls in order to evaluate their adequacy and should evaluate the procedures for ensuring that systems are returned correctly to their operational state. The in-service inspection programme and the in-service testing programme should be reviewed to ensure that their purpose, which is to ensure the early detection of degradation of equipment and components, is being served. Programmes, procedures and data should be reviewed and evaluated, particularly for those maintenance tasks that can be performed only during outages. Data that may indicate that a high number of component systems need repair may necessitate an in-depth review of the maintenance programmes. Repairs to piping systems, pumps, valves, electrical systems and instrumentation and control systems should all be selectively sampled for review. Welding on systems of safety significance should be observed, including examination by non-destructive means.

Engineering support

IV.35. The engineering support group usually provides necessary support to the operations or maintenance staff anywhere in the facility at any time. The engineering support group usually assists operations staff with the evaluation of non-conforming or degraded conditions and assists maintenance staff in the performance of activities in the course of which problems may arise. Inspectors should review a sample of the evaluations for non-conforming or degraded

conditions for both adequacy and quality, and should observe the interface between the maintenance groups and engineering support groups.

IV.36. Inspectors should walk down part of a system to assess how well systems are being maintained and should note any non-conformance. Any problems identified by inspectors but not known to the facility's management would call into question the adequacy of the support programme for system engineering.

Modifications

IV.37. Modifications may be simple or complex and may involve changes to engineering, operating procedures and/or the organizational structure. For major modifications to the structures, systems and components of a facility, most of the planning, design and manufacture will be performed prior to outages. The regulatory body should inspect the authorized party's record to determine whether its modification process has been effective in controlling modifications in a manner that is appropriate for their safety significance. Where required, the regulatory body should also inspect submissions by the authorized party to the regulatory body concerning a modification. The details of the process should be checked in the inspections by sampling specific modifications and reviewing their execution and their implications for documentation, such as the need for changes to safety related documentation, for updating of maintenance schedules and engineering drawings, and for changes to operational procedures and training modules. These checks may involve other parts of the regulatory body in addition to the inspection unit. The regulatory body should also determine whether the qualifications of the authorized party's staff who perform the modifications are suitable for the function they are performing.

Emergency preparedness and response

IV.38. Inspection in the area of emergency preparedness and response should include a review of emergency response plans and procedures in order to verify that the arrangements for dealing with an emergency are adequate. Procedures for the detection and classification of an emergency and for decision making in an emergency should be assessed. Procedures for notification of a nuclear or radiological emergency, communication, shift staffing, shift augmentation, dose calculation and dose assessment should also be evaluated. Emergency exercises should be witnessed to ensure that the emergency planning is adequate and that its implementation is effective.

Management system

IV.39. Inspection of the effectiveness of the management system should include inspection of those indicators that demonstrate that the management system is focused on safe operation and on the identification and remediation of problems and weaknesses within the programme. This includes the management's involvement in day to day operations and its routine presence in the facility. What is most important is whether the management demonstrates a willingness to listen to problems and then to ensure that problems are promptly evaluated and solved. The management's ability to create an environment in which problems are openly identified and discussed and self-assessment programmes are effectively supported helps to foster a strong safety culture.

IV.40. The authorized party's quality assurance programme should be reviewed to ensure that it is comprehensive and adequately implemented. The review should cover, in addition to the activities described earlier, activities such as: procurement, receipt, storage and handling of equipment; document control; and operating experience. In particular, the adequacy and effectiveness of the authorized party's performance of corrective actions should be assessed.

DECOMMISSIONING

IV.41. During the decommissioning stage of a nuclear facility, inspection activities should concentrate on:

- (a) The adequacy of the authorized party's procedure for the control of each stage of decommissioning;
- (b) The removal of radioactive material;
- (c) The strategy for management of radioactive material;
- (d) The drainage of any residual fluids;
- (e) Decontamination and dismantling activities;
- (f) The waste management strategy for the treatment, conditioning, storage and disposal of all radioactive waste;
- (g) The physical condition of the facility, especially surveillance of the integrity and/or the availability of relevant structures, systems and components, including protective barriers, and the appropriateness of the procedures at each stage of decommissioning;
- (h) Characterization of the residual radioactivity;

- (i) Accounting for and control of nuclear material and access control; environmental monitoring, radiological monitoring and surveillance, including plans for radiation protection of workers and the public;
- (j) The adequacy and maintenance of instrumentation and control systems for long term safety;
- (k) Decommissioning records.

IV.42. After a long period of safe enclosure, some of these regulatory inspection activities may be reduced in thoroughness and frequency.

Closure of waste disposal facilities

IV.43. Before the regulatory body considers the release of any waste disposal facility from further regulatory control, inspection activities should concentrate on:

- (a) Conformance with the overall radioactive waste inventory;
- (b) Sealing arrangements for the facility including any measures to prevent human intrusion;
- (c) Arrangements for any environmental monitoring after closure.

The release of a facility and/or site from regulatory control

IV.44. Before releasing a site from any further control, the regulatory body should carry out an inspection to confirm that any residual radioactivity has been reduced to acceptable levels. This will include review of the remediation and monitoring procedures, review of the management system, independent monitoring and analysis of compliance with the release criteria for the site or review of the implementation of restrictions at the site. For waste disposal facilities, the release from control will be related to the long term safety of the facility as set out in the post-closure safety case.

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CONTRIBUTORS TO DRAFTING AND REVIEW

Asfaw, K.	International Atomic Energy Agency
Bosnjak, J.	International Atomic Energy Agency
Jones, G.	International Atomic Energy Agency
Kamenopoulou, V.	Greek Atomic Energy Commission, Greece
Lungu, S.	International Atomic Energy Agency
Mansoor, F.	Pakistan Nuclear Regulatory Authority, Pakistan
Mansoux, H.	International Atomic Energy Agency
Nicic, A.	International Atomic Energy Agency
Pacheco Jimenez, R.	International Atomic Energy Agency
Parlange, J.	International Atomic Energy Agency
Shaw, P.	International Atomic Energy Agency
Suman, H.	International Atomic Energy Agency
Trivelloni, S.	National Institute for Environmental Protection and Research, Italy
Vaughan, G.	Consultant, United Kingdom
Westermeier, E.	Federal Office for Radiation Protection (BfS), Germany
Wrona, D.	United States Nuclear Regulatory Commission, United States of America



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