

IAEA Safety Standards

for protecting people and the environment

Governmental, Legal and Regulatory Framework for Safety

General Safety Requirements Part 1

No. GSR Part 1



IAEA

International Atomic Energy Agency

IAEA SAFETY RELATED PUBLICATIONS

IAEA SAFETY STANDARDS

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

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

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

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

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

OTHER SAFETY RELATED PUBLICATIONS

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

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

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

GOVERNMENTAL, LEGAL
AND REGULATORY FRAMEWORK
FOR SAFETY

Safety standards survey

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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. GSR Part 1

GOVERNMENTAL, LEGAL AND REGULATORY FRAMEWORK FOR SAFETY

GENERAL SAFETY REQUIREMENTS

This publication includes a CD-ROM containing the IAEA Safety Glossary: 2007 Edition (2007) and the Fundamental Safety Principles (2006), each in Arabic, Chinese, English, French, Russian and Spanish versions.

The CD-ROM is also available for purchase separately.

See: <http://www-pub.iaea.org/MTCD/publications/publications.asp>

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2010

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email: sales.publications@iaea.org
<http://www.iaea.org/books>

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Printed by the IAEA in Austria
September 2010
STI/PUB/1465

IAEA Library Cataloguing in Publication Data

Governmental, legal and regulatory framework for safety. — Vienna : International Atomic Energy Agency, 2010.
p. ; 24 cm. — (IAEA safety standards series, ISSN 1020-525X ; no. GSR Part 1)
STI/PUB/1465
ISBN 978-92-0-106410-3
Includes bibliographical references.

1. Radioactive substances — Safety measures. 2. Nuclear facilities — Safety measures. 3. Radiation protection — Government policy. 4. Radiation protection — Law and legislation. 5. Radioactive waste management — Safety measures. I. International Atomic Energy Agency. II. Series.

IAEAL

10-00639

FOREWORD

The IAEA's Statute authorizes the Agency to establish safety standards to protect health and minimize danger to life and property — standards which the IAEA must use in its own operations, and which a State can apply by means of its regulatory provisions for nuclear and radiation safety. A comprehensive body of safety standards under regular review, together with the IAEA's assistance in their application, has become a key element in a global safety regime.

In the mid-1990s, a major overhaul of the IAEA's safety standards programme was initiated, with a revised oversight committee structure and a systematic approach to updating the entire corpus of standards. The new standards that have resulted are of a high calibre and reflect best practices in Member States. With the assistance of the Commission on Safety Standards, the IAEA is working to promote the global acceptance and use of its safety standards.

Safety standards are only effective, however, if they are properly applied in practice. The IAEA's safety services — which range in scope from engineering safety, operational safety, and radiation, transport and waste safety to regulatory matters and safety culture in organizations — assist Member States in applying the standards and appraise their effectiveness. These safety services enable valuable insights to be shared and all Member States are urged to make use of them.

Regulating nuclear and radiation safety is a national responsibility, and many Member States have decided to adopt the IAEA's safety standards for use in their national regulations. For the contracting 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 designers, manufacturers and operators around the world to enhance nuclear and radiation safety in power generation, medicine, industry, agriculture, research and education.

The IAEA takes seriously the enduring challenge for users and regulators everywhere: that of ensuring a high level of safety in the use of nuclear materials and radiation sources around the world. Their continuing utilization for the benefit of humankind must be managed in a safe manner, and the IAEA safety standards are designed to facilitate the achievement of that goal.

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

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

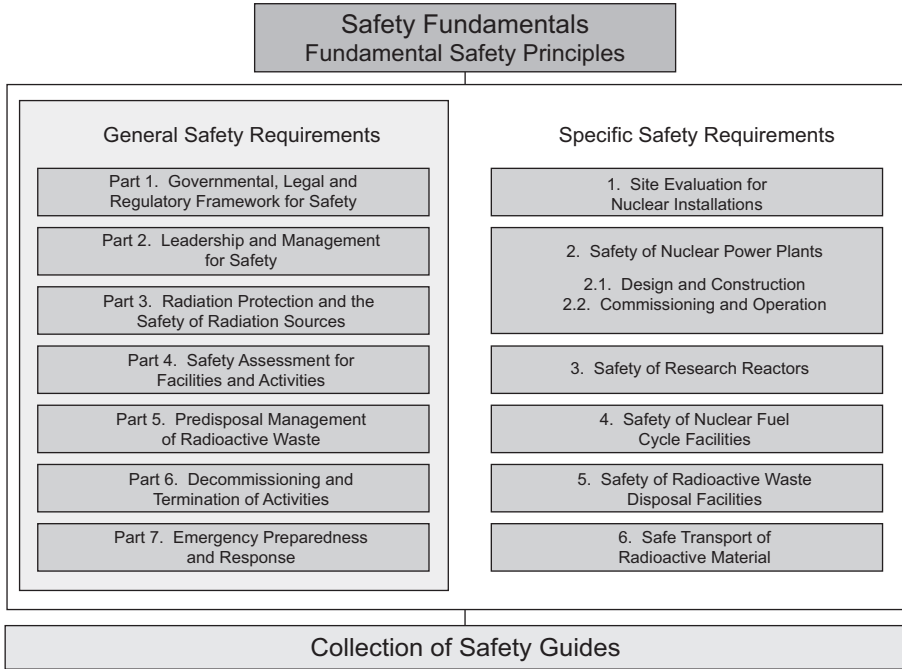


FIG. 1. The long term structure of the IAEA Safety Standards Series.

as ‘shall’ statements. Many requirements are not addressed to a specific party, the implication being that the appropriate parties are responsible for fulfilling them.

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 four safety standards committees, for 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).

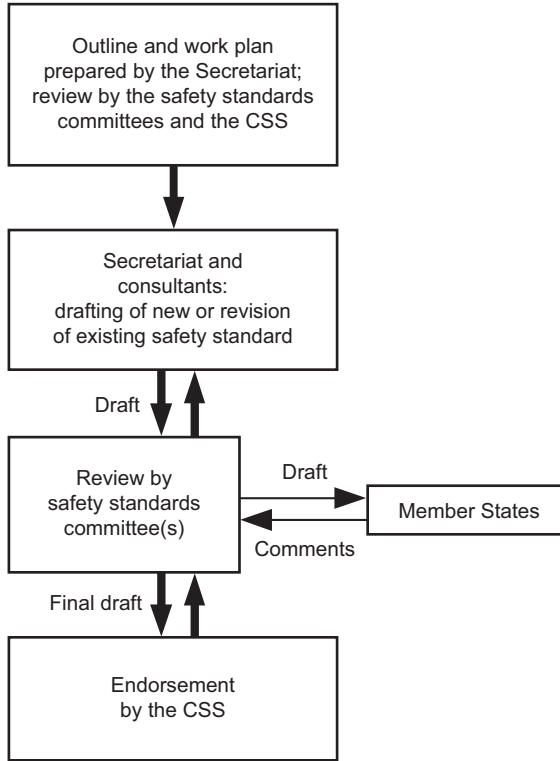


FIG. 2. The process for developing a new safety standard or revising an existing standard.

All IAEA Member States may nominate experts for the safety standards committees and may provide comments on draft standards. The membership of 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. Safety in the operation of facilities and the use of radiation sources is of great importance for the protection of people — individually and collectively — society and the environment in those States authorizing their operation or use, and also in other States, in particular in neighbouring States.

1.2. IAEA Safety Requirements publications establish international consensus requirements that apply the fundamental safety objective and fundamental safety principles established in the Safety Fundamentals [1].

1.3. The terms used in this publication have the meanings ascribed to them in the IAEA Safety Glossary, 2007 Edition [2], where applicable.

OBJECTIVE

1.4. The objective of this Safety Requirements publication is to establish requirements in respect of the governmental, legal and regulatory framework for safety. The framework for safety is to be established for the entire range of facilities and activities, from the use of a limited number of radiation¹ sources to a nuclear power programme. Not all the safety requirements are relevant for all States; account has to be taken of the circumstances pertaining in the State and of the radiation risks² associated with its facilities and activities.

¹ The term ‘radiation’ in this context means ionizing radiation.

² The term ‘radiation risks’ is used in a general sense to refer to:

- Detrimental health effects of radiation exposure (including the likelihood of such effects occurring);
- Any other safety related risks (including those to the environment) that might arise as a direct consequence of:
 - Exposure to radiation;
 - The presence of radioactive material (including radioactive waste) or its release to the environment;
 - A loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source or any other source of radiation.

SCOPE

1.5. This Safety Requirements publication covers the essential aspects of the governmental and legal framework for establishing a regulatory body and for taking other actions necessary to ensure the effective regulatory control of facilities and activities — existing and new — utilized for peaceful purposes³. Other responsibilities and functions are also covered, such as liaison within the global safety regime and liaison for providing the necessary support services for the purposes of safety (including radiation protection), emergency preparedness and response, nuclear security⁴, and the State system of accounting for, and control of, nuclear material.

1.6. For the purposes of this publication, and as in the Fundamental Safety Principles [1], ‘safety’ means the protection of people and the environment against radiation risks, and the safety of facilities and activities that give rise to radiation risks. The term ‘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.

1.7. This Safety Requirements publication covers all stages in the lifetime of facilities and the duration of activities until their release from regulatory control, and any subsequent period of institutional control.

³ The term ‘facilities and activities — existing and new — utilized for peaceful purposes’ is hereafter abbreviated for convenience to ‘facilities and activities’ as a general term encompassing any human activity that may cause people to be exposed to radiation risks arising from naturally occurring or artificial sources. The term ‘facilities’ includes: nuclear facilities; irradiation installations; some mining and raw material processing facilities, such as uranium mines; radioactive waste management facilities; and any other places where radioactive materials are produced, processed, used, handled, stored or disposed of — or where radiation generators are installed — on such a scale that consideration of protection and safety is required. The term ‘activities’ includes the production, use, import and export of radiation sources for industrial, research and medical purposes; the transport of radioactive material; the decommissioning of facilities; radioactive waste management activities such as the discharge of effluents; and some aspects of the remediation of sites affected by residues from past activities.

⁴ The IAEA issues guidance on nuclear security in the separate IAEA Nuclear Security Series of publications.

1.8. Although the scope of this publication is limited to safety and does not extend to nuclear security, it is recognized that measures taken to ensure safety are often consistent with the promotion of nuclear security, and that measures taken to ensure nuclear security are often consistent with the promotion of safety.

1.9. This Safety Requirements publication does not apply to military activities or to defence related activities unless so decided by the State.

STRUCTURE

1.10. Section 2 establishes requirements for governmental responsibilities and functions for safety. Section 3 establishes requirements for liaison within the global safety regime. Section 4 establishes requirements for the regulatory body.

2. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

2.1. States have different legal structures, and therefore the term ‘government’ as used in the IAEA safety standards is to be understood in a broad sense, and is accordingly interchangeable here with the term ‘State’.

2.2. The government establishes national policy for safety by means of different instruments, statutes and laws. Typically, the regulatory body, as designated by the government, is charged with the implementation of policies by means of a regulatory programme and a strategy set forth in its regulations or in national standards. The government determines the specific functions of the regulatory body and the allocation of responsibilities. For example, the government establishes laws and adopts policies pertaining to safety, whereas the regulatory body develops strategies and promulgates regulations in implementation of such laws and policies. In addition, the government establishes laws and adopts policies specifying the responsibilities and functions of different governmental entities in respect of safety and emergency preparedness and response, whereas the regulatory body establishes a system to provide effective coordination. The requirements established in Section 2 are to be understood in the context of these respective functions, although some flexibility may be necessary, depending on the particular national circumstances.

Requirement 1: National policy and strategy for safety

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, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals.

2.3. National policy and strategy for safety shall express a long term commitment to safety. The national policy shall be promulgated as a statement of the government's intent. The strategy shall set out the mechanisms for implementing the national policy. In the national policy and strategy, account shall be taken of the following:

- (a) The fundamental safety objective and the fundamental safety principles established in the Fundamental Safety Principles [1];
- (b) Binding international legal instruments, such as conventions and other relevant international instruments;
- (c) The specification of the scope of the governmental, legal and regulatory framework for safety;
- (d) The need and provision for human and financial resources;
- (e) The provision and framework for research and development;
- (f) Adequate mechanisms for taking account of social and economic developments;
- (g) The promotion of leadership and management for safety, including safety culture.

2.4. 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.

Requirement 2: Establishment of a framework for safety

The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated.

2.5. The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following:

- (1) The safety principles for protecting people — individually and collectively — society and the environment from radiation risks, both at present and in the future;
- (2) The types of facilities and activities that are included within the scope of the framework for safety;
- (3) The type of authorization⁵ that is required for the operation of facilities and for the conduct of activities, in accordance with a graded approach;
- (4) The rationale for the authorization of new facilities and activities, as well as the applicable decision making process;
- (5) Provision for the involvement of interested parties and for their input to decision making;
- (6) Provision for assigning legal responsibility for safety to the persons or organizations responsible for the facilities and activities, and for ensuring the continuity of responsibility where activities are carried out by several persons or organizations successively;
- (7) The establishment of a regulatory body, as addressed in Requirements 3 and 4;
- (8) Provision for the review and assessment of facilities and activities, in accordance with a graded approach;
- (9) The authority and responsibility of the regulatory body for promulgating (or preparing for the enactment of) regulations and preparing guidance for their implementation;
- (10) Provision for the inspection of facilities and activities, and for the enforcement of regulations, in accordance with a graded approach;
- (11) Provision for appeals against decisions of the regulatory body;
- (12) Provision for preparedness for, and response to, a nuclear or radiological emergency;
- (13) Provision for an interface with nuclear security;
- (14) Provision for an interface with the system of accounting for, and control of, nuclear material;

⁵ Authorization to operate a facility or to conduct an activity may be granted by the regulatory body or by another governmental body to an operating organization or to a person. ‘Authorization’ includes approval, written permission, licensing, certification or registration. See Ref. [2].

- (15) Provision for acquiring and maintaining the necessary competence nationally for ensuring safety;
- (16) Responsibilities and obligations in respect of financial provision for the management of radioactive waste and of spent fuel, and for decommissioning of facilities and termination of activities;
- (17) The criteria for release from regulatory control;
- (18) The specification of offences and the corresponding penalties;
- (19) Provision for controls on the import and export of nuclear material and radioactive material, as well as for their tracking within, and to the extent possible outside, national boundaries, such as tracking of the authorized export of radioactive sources.

2.6. Where several authorities are involved, the government shall specify clearly the responsibilities and functions of each authority within the governmental, legal and regulatory framework for safety.

Requirement 3: Establishment of a regulatory body

The government, through the legal system, shall establish and maintain a regulatory body, and shall confer on it the legal authority and provide it with the competence and the resources necessary to fulfil its statutory obligation for the regulatory control of facilities and activities.

Requirement 4: Independence of the regulatory body

The government shall ensure that the regulatory body is effectively independent in its safety related decision making and that it has functional separation from entities having responsibilities or interests that could unduly influence its decision making.

2.7. An independent regulatory body will not be entirely separate from other governmental bodies. The government has the ultimate responsibility for involving those with legitimate and recognized interests in its decision making. However, the government shall ensure that the regulatory body is able to make decisions under its statutory obligation for the regulatory control of facilities and activities, and that it is able to perform its functions without undue pressure or constraint.

2.8. To be effectively independent, the regulatory body shall have sufficient authority and sufficient staffing and shall have access to sufficient financial resources for the proper discharge of its assigned responsibilities. The regulatory body shall be able to make independent regulatory judgements and decisions, free

from any undue influences that might compromise safety, such as pressures associated with changing political circumstances or economic conditions, or pressures from government departments or from other organizations. Furthermore, the regulatory body shall be able to give independent advice to government departments and governmental bodies on matters relating to the safety of facilities and activities.

2.9. No responsibilities shall be assigned to the regulatory body that might compromise or conflict with its discharging of its responsibility for regulating the safety of facilities and activities.

2.10. The staff of the regulatory body shall have no direct or indirect interest in facilities and activities or authorized parties⁶ beyond the interest necessary for regulatory purposes.

2.11. In the event that a department or agency of government is itself an authorized party operating an authorized facility or facilities, or conducting authorized activities, the regulatory body shall be separate from, and effectively independent of, the authorized party.

2.12. Where several authorities are involved in the authorization process, the regulatory requirements shall apply, and they shall be applied consistently and without undue modification.

2.13. The regulatory body shall be conferred with the legal authority to require an authorized party or an applicant, whether a person or an organization, to make arrangements to provide:

- (a) All necessary safety related information, including information from suppliers, even if this information is proprietary;
- (b) Access, solely or together with the authorized party or applicant, for making inspections on the premises of any designer, supplier, manufacturer, constructor, contractor or operating organization associated with the authorized party.

⁶ An 'authorized party' is 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 the regulatory body or another governmental body to perform specified activities. The 'authorized party' for an authorized facility or activity is usually the operating organization or the registrant or licensee (although forms of authorization other than registration or licensing may apply).

Requirement 5: Prime responsibility for safety

The government shall expressly assign the prime responsibility for safety to the person or organization responsible for a facility or an activity, and shall confer on the regulatory body the authority to require such persons or organizations to comply with stipulated regulatory requirements, as well as to demonstrate such compliance.

Requirement 6: Compliance with regulations and responsibility for safety

The government shall stipulate that compliance with regulations and requirements established or adopted by the regulatory body does not relieve the person or organization responsible for a facility or an activity of its prime responsibility for safety.⁷

2.14. The legal framework for safety shall be established in such a way that the authorized party retains the prime responsibility for safety throughout the lifetime of facilities and the duration of activities, and shall not delegate this prime responsibility. Responsibility for safety may be transferred to a different authorized party when there has been a declared change, approved by the regulatory body, of general responsibility for a facility or activity. In addition, responsibility for safety may extend to other groups associated with the authorized party, such as designers, suppliers, manufacturers and constructors, employers, contractors, and consignors and carriers, in so far as their activities or products may be of significance for safety. However, in no case may this extension of responsibility relieve the authorized party of the prime responsibility for safety. The authorized party has the responsibility for verifying that products and services meet its expectations (e.g. in terms of completeness, validity or robustness) and that they comply with regulatory requirements.

2.15. The prime responsibility for safety shall extend to all stages in the lifetime of facilities and the duration of activities, until their release from regulatory control; i.e. to site evaluation, design, construction, commissioning, operation, shutdown and decommissioning (or closure in the case of disposal facilities for radioactive waste) of facilities. This prime responsibility for safety includes, as appropriate, responsibility for the management of radioactive waste and the management of spent fuel, and responsibility for the remediation of contaminated

⁷ Not having an authorization would not exonerate the person or organization responsible for the facility or activity from the responsibility for safety [1].

areas. It also includes responsibility for activities in which radioactive material and radioactive sources are produced, used, stored, transported or handled.

2.16. Persons or organizations who are responsible for facilities or activities in which radioactive waste is generated shall have responsibility for safety in the management of the radioactive waste, including waste characterization and storage of the waste [3].

2.17. For ensuring safety in the transport of radioactive material, reliance is placed primarily on the performance of packages [4]. It is the responsibility of the consignor to ensure the appropriate selection of the package and packaging and the mode of transport.

Requirement 7: Coordination of different authorities with responsibilities for safety within the regulatory framework for safety

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.

2.18. Where several authorities have responsibilities for safety within the regulatory framework for safety, the responsibilities and functions of each authority shall be clearly specified in the relevant legislation. The government shall ensure that there is appropriate coordination of and liaison between the various authorities concerned in areas such as:

- (1) Safety of workers and the public;
- (2) Protection of the environment;
- (3) Applications of radiation in medicine, industry and research;
- (4) Emergency preparedness and response;
- (5) Management of radioactive waste (including government policy making and the strategy for the implementation of policy);
- (6) Liability for nuclear damage (including relevant conventions);
- (7) Nuclear security;
- (8) The State system of accounting for, and control of, nuclear material;
- (9) Safety in relation to water use and the consumption of food;
- (10) Land use, planning and construction;
- (11) Safety in the transport of dangerous goods, including nuclear material and radioactive material;

- (12) Mining and processing of radioactive ores;
- (13) Controls on the import and export of nuclear material and radioactive material.

This coordination and liaison can be achieved by means of memoranda of understanding, appropriate communication and regular meetings. Such coordination assists in achieving consistency and in enabling authorities to benefit from each other's experience.

2.19. If responsibilities and functions do overlap, this could create conflicts between different authorities and lead to conflicting requirements being placed on authorized parties or on applicants. This, in turn, could undermine the authority of the regulatory body and cause confusion on the part of the authorized party or the applicant.

Requirement 8: Emergency preparedness and response

The government shall make provision for emergency preparedness to enable a timely and effective response in a nuclear or radiological emergency.

2.20. The government shall make each authorized party responsible for preparing an emergency response plan and for making arrangements for emergency preparedness and response [5]. Emergency response arrangements shall include a clear assignment of responsibility for immediate notification of an emergency to the competent authorities. The regulatory body shall take account of the fact that, in an emergency, routine regulatory administration such as the issue of prior authorizations may need to be suspended in favour of a timely emergency response.

2.21. In addition to assigning the responsibilities of authorized parties, the government shall establish a nationwide system, including emergency response arrangements, to protect the public in a nuclear or radiological emergency declared as a consequence of an incident within or outside the territories and jurisdiction of the State.

2.22. The government shall designate competent authorities that will have the responsibilities and resources necessary to make preparations and arrangements for dealing with the consequences of incidents in facilities and activities that affect, or that might affect, the public and the environment. Such preparations shall include planning the actions to be taken both in an emergency and in its aftermath.

2.23. The government shall specify and shall assign clear responsibilities for decision making in an emergency, and shall make provision for effective liaison between authorized parties and competent authorities and for an effective means of communication.

2.24. In preparing an emergency response plan and in the event of an emergency, the regulatory body shall advise the government and competent authorities, and shall 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 [5].

Requirement 9: System for protective actions to reduce existing or unregulated radiation risks

The government shall establish an effective system for protective actions to reduce undue radiation risks associated with unregulated sources (of natural or artificial origin) and contamination from past activities or events, consistent with the principles of justification and optimization.

2.25. Radiation risks may arise in situations other than in facilities and activities that are in compliance with regulatory control. In such situations, if the radiation risks are relatively high, consideration shall be given to whether protective actions can reasonably be taken to reduce radiation exposures and to remediate adverse conditions [1]. Where unacceptable radiation risks arise as a consequence of an accident, a discontinued practice, or inadequate control over a radioactive source or a natural source, the government shall designate the organizations to be responsible for making the necessary arrangements for the protection of workers, the public and the environment [6]. The organization taking the protective action shall have access to the resources necessary to fulfil its function.

2.26. The regulatory body shall provide any necessary inputs for the protective action, including advising the government or exercising regulatory control over protective actions. It shall establish the regulatory requirements and criteria for protective actions in cooperation with the other authorities involved, and in consultation with interested parties, as appropriate.

2.27. International assistance may have to be requested if there are insufficient resources available nationally to take protective actions.

Requirement 10: Provision for the decommissioning of facilities and the management of radioactive waste and of spent fuel

The government shall make provision for the safe decommissioning of facilities, the safe management and disposal of radioactive waste arising from facilities and activities, and the safe management of spent fuel.

2.28. Decommissioning of facilities and the safe management and disposal of radioactive waste shall constitute essential elements of the governmental policy and the corresponding strategy over the lifetime of facilities and the duration of activities [3, 7]. The strategy shall include appropriate interim targets and end states. Radioactive waste generated in facilities and activities necessitates special consideration because of the various organizations concerned and the long timescales that may be involved. The government shall enforce continuity of responsibility between successive authorized parties.

2.29. In strategies for radioactive waste management, account shall be taken of the diversity between types of radioactive waste and the radiological characteristics of radioactive waste.

2.30. Radioactive waste generated in facilities and activities shall be managed in an integrated, systematic manner up to its disposal. The interdependences of the steps in the entire management process for radioactive waste, and likewise for spent fuel, shall be recognized [3].

2.31. If institutional control after the closure of a disposal facility for radioactive waste is deemed to be necessary, the responsibility for maintaining institutional control shall be clearly assigned.

2.32. The government shall make provision for appropriate research and development programmes in relation to the disposal of radioactive waste, in particular programmes for verifying safety in the long term.

2.33. Appropriate financial provision shall be made for:

- (a) Decommissioning of facilities;
- (b) Management of radioactive waste, including its storage and disposal;
- (c) Management of disused radioactive sources and radiation generators;
- (d) Management of spent fuel.

Requirement 11: Competence for safety

The government shall make provision for building and maintaining the competence of all parties having responsibilities in relation to the safety of facilities and activities.

2.34. As an essential element of the national policy and strategy for safety, the necessary professional training for maintaining the competence of a sufficient number of suitably qualified and experienced staff shall be made available.

2.35. The building of competence shall be required for all parties with responsibilities for the safety of facilities and activities, including authorized parties, the regulatory body and organizations providing services or expert advice on matters relating to safety. Competence shall be built, in the context of the regulatory framework for safety, by such means as:

- Technical training;
- Learning through academic institutions and other learning centres;
- Research and development work.

2.36. The government:

- (a) Shall stipulate a necessary level of competence for persons with responsibilities in relation to the safety of facilities and activities;
- (b) Shall make provision for adequate arrangements for the regulatory body and its support organizations to build and maintain expertise in the disciplines necessary for discharge of the regulatory body's responsibilities in relation to safety;
- (c) Shall make provision for adequate arrangements for increasing, maintaining and regularly verifying the technical competence of persons working for authorized parties.

2.37. In cases where the training programmes available in the State are insufficient, arrangements for training shall be made with other States or with international organizations.

2.38. Development of the necessary competence for the operation and regulatory control of facilities and activities shall be facilitated by the establishment of, or participation in, centres where research and development work and practical applications are carried out in key areas for safety.

Requirement 12: Interfaces of safety with nuclear security and with the State system of accounting for, and control of, nuclear material

The government shall ensure that, within the governmental and legal framework, adequate infrastructural arrangements are established for interfaces of safety with arrangements for nuclear security and with the State system of accounting for, and control of, nuclear material.

2.39. Specific responsibilities within the governmental and legal framework shall include:

- (a) Assessment of the configuration of facilities and activities for the optimization of safety, with factors relating to nuclear security and to the system of accounting for, and control of, nuclear material being taken into account;
- (b) Oversight and enforcement to maintain arrangements for safety, nuclear security and the system of accounting for, and control of, nuclear material;
- (c) Liaison with law enforcement agencies, as appropriate;
- (d) Integration of emergency response arrangements for safety related and nuclear security related incidents.

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

Requirement 13: Provision of technical services

The government shall make provision, where necessary, for technical services in relation to safety, such as services for personal dosimetry, environmental monitoring and the calibration of equipment.

2.41. Technical services do not necessarily have to be provided by the government. However, if no suitable commercial or non-governmental provider of the necessary technical services is available, the government may have to make provision for the availability of such services. The regulatory body shall authorize technical services that may have significance for safety, as appropriate.

3. THE GLOBAL SAFETY REGIME

3.1. International cooperation in relation to safety, including the safety of nuclear installations, radiation safety, the safety of radioactive waste management and safety in the transport of radioactive material, has contributed to the development of a global safety regime. The organizations and persons involved in the utilization of nuclear energy and radiation sources for peaceful purposes are interdependent in that the performance of one may have implications for all, and a serious nuclear accident would be of major significance around the world. Recognition of this mutual dependence has led to a number of international arrangements that are intended to enhance safety in all States.

Requirement 14: International obligations and arrangements for international cooperation

The government shall fulfil its respective international obligations, participate in the relevant international arrangements, including international peer reviews, and promote international cooperation to enhance safety globally.

3.2. The features of the global safety regime include:

- (a) International conventions that establish common obligations and mechanisms for ensuring protection and safety;
- (b) Codes of conduct that promote the adoption of good practices in the relevant facilities and activities;
- (c) Internationally agreed IAEA safety standards that promote the development and application of internationally harmonized safety requirements, guides and practices;
- (d) International peer reviews of the regulatory control and safety of facilities and activities, and mutual learning by participating States;
- (e) Multilateral and bilateral cooperation that enhances safety by means of harmonized approaches as well as increased quality and effectiveness of safety reviews and inspections.

Requirement 15: Sharing of operating experience and regulatory experience

The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities.

3.3. The reporting of operating experience and regulatory experience has led to significant corrective actions in relation to equipment, human performance and the management system for safety, as well as changes to regulatory requirements and modifications to regulatory practices.

3.4. The regulatory body shall establish and maintain a means for receiving information from other States and from authorized parties, as well as a means for making available to others lessons learned from operating experience and regulatory experience. The regulatory body shall require appropriate corrective actions to be carried out to prevent the recurrence of safety significant events. This process involves acquisition of the necessary information and its analysis to facilitate the effective utilization of international networks for learning from operating experience and regulatory experience.

3.5. To enhance the safety of facilities and activities globally, feedback shall be provided on measures that have been taken in response to information received via national and international knowledge and reporting networks. Such measures could comprise promulgating new regulatory requirements or making safety enhancing modifications to operating practices or to equipment in authorized facilities and activities. Such feedback provided in response to information received via international networks also covers descriptions of good practices that have been adopted to reduce radiation risks.

4. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

4.1. The requirements established here in Section 4 relate to the organization of the regulatory body: its structure, allocation of resources, coordination with other authorities, management system, staffing, and relationship with advisory bodies

and support organizations. This section also establishes general requirements for performing the functions of the regulatory body — in an effectively independent manner — to preserve the consistency and stability of operations and constructive liaison with authorized parties.

4.2. The responsibilities of the regulatory body shall be discharged within, and are dependent upon, the governmental and legal framework for safety. The regulatory process shall be continued throughout the lifetime of a facility or the duration of an activity.

4.3. The objective of regulatory functions is the verification and assessment of safety in compliance with regulatory requirements. The performance of regulatory functions shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach. The regulatory process shall provide a high degree of confidence, until the release of facilities and activities from regulatory control, that:

- (a) Safety is optimized, the balance between operational benefits and potential consequences for people and the environment being taken into account.
- (b) Safety assessments carried out for facilities and activities demonstrate that an adequate level of safety has been achieved, and that the objectives and criteria for safety established by the designer, the authorized party and the regulatory body have been met [8].
- (c) Site evaluation confirms the consistency of the site conditions with the design requirements, and the adequacy of the local civil infrastructure to support safe operation of facilities and conduct of activities.
- (d) Facilities are designed and constructed to meet the relevant regulatory requirements.
- (e) Facilities are operated and activities are conducted within the limits and conditions specified in the safety assessment and established in the authorization, and operations are carried out safely under a proper management system [8, 9].
- (f) Authorized parties have the human, organizational, financial and technical capabilities to operate facilities safely or to conduct activities safely under all circumstances until their release from regulatory control.
- (g) The shutdown and decommissioning (or closure with the continuation of institutional control) of facilities and termination of activities comply with the regulatory requirements.

Requirement 16: Organizational structure of the regulatory body and allocation of resources

The regulatory body shall structure its organization and manage its resources so as to discharge its responsibilities and perform its functions effectively; this shall be accomplished in a manner commensurate with the radiation risks associated with facilities and activities.

4.4. Requirement 3 establishes that the government shall be responsible for ensuring that the regulatory body has sufficient resources to fulfil its statutory obligations.

4.5. The regulatory body has the responsibility for structuring its organization and managing its available resources so as to fulfil its statutory obligations effectively. The regulatory body shall allocate resources commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach. Thus, for the lowest associated radiation risks, it may be appropriate for the regulatory body to exempt a particular activity from some or all aspects of regulatory control; for the highest associated radiation risks, it may be appropriate for the regulatory body to carry out a detailed scrutiny in relation to any proposed facility or activity before it is authorized, and also subsequent to its authorization.

Requirement 17: Effective independence in the performance of regulatory functions

The regulatory body shall perform its functions in a manner that does not compromise its effective independence.

4.6. Requirements 3 and 4 in Section 2 stipulate that the government establish and maintain a regulatory body that is effectively independent in its decision making and that has functional separation from entities having responsibilities or interests that could unduly influence its decision making. This imposes an obligation on the regulatory body to discharge its responsibilities in such a way as to preserve its effective independence. The staff of the regulatory body shall remain focused on performing their functions in relation to safety, irrespective of any personal views. The competence of staff is a necessary element in achieving effective independence in decision making by the regulatory body.

4.7. The regulatory body shall prevent or duly resolve any conflicts of interests or, where this is not possible, shall seek a resolution of conflicts within the governmental and legal framework.

4.8. To maintain the effective independence of the regulatory body, special consideration shall be given when new staff members are recruited from authorized parties, and the independence of the regulatory body, regulatory aspects and safety considerations shall be emphasized in their training. The regulatory body shall ensure that its staff operate professionally and within its remit in relation to safety.

4.9. To maintain its effective independence, the regulatory body shall ensure that, in its liaison with interested parties, it has a clear separation from organizations or bodies that have been assigned responsibilities for facilities or activities or for their promotion.

4.10. The regulatory body, consistent with its effective independence, shall exercise its authority to intervene in connection with any facilities or activities that present significant radiation risks, irrespective of the possible costs to the authorized party.

Requirement 18: Staffing and competence of the regulatory body

The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities.

4.11. The regulatory body has to have appropriately qualified and competent staff. A human resources plan shall be developed that states the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the necessary regulatory functions.

4.12. The human resources plan for the regulatory body shall cover recruitment and, where relevant, rotation of staff in order to obtain staff with appropriate competence and skills, and shall include a strategy to compensate for the departure of qualified staff.

4.13. A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include the development of a specific training

programme on the basis of an analysis of the necessary competence and skills. The training programme shall cover principles, concepts and technological aspects, as well as the procedures followed by the regulatory body for assessing applications for authorization, for inspecting facilities and activities, and for enforcing regulatory requirements.

Requirement 19: The management system of the regulatory body

The regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement.

4.14. The regulatory body shall establish and implement a management system whose processes are open and transparent [9]. The management system of the regulatory body shall be continuously assessed and improved.

4.15. The management system of the regulatory body has three purposes:

- (1) The first purpose is to ensure that the responsibilities assigned to the regulatory body are properly discharged.
- (2) The second purpose is to maintain and improve the performance of the regulatory body by means of the planning, control and supervision of its safety related activities.
- (3) The third purpose is to foster and support a safety culture in the regulatory body through the development and reinforcement of leadership, as well as good attitudes and behaviour in relation to safety on the part of individuals and teams.

4.16. The management system shall maintain the efficiency and effectiveness of the regulatory body in discharging its responsibilities and performing its functions. This includes the promotion of enhancements in safety, and the fulfilment of its obligations in an appropriate, timely and cost effective manner so as to build confidence.

4.17. The management system shall specify, in a coherent manner, the planned and systematic actions necessary to provide confidence that the statutory obligations placed on the regulatory body are being fulfilled. Furthermore, regulatory requirements shall be considered in conjunction with the more general requirements under the management system of the regulatory body; this helps to prevent safety from being compromised.

Requirement 20: Liaison with advisory bodies and support organizations

The regulatory body shall obtain technical or other expert professional advice or services as necessary in support of its regulatory functions, but this shall not relieve the regulatory body of its assigned responsibilities.

4.18. The regulatory body may decide to give formal status to the processes by which it is provided with expert opinion and advice. If the establishment of advisory bodies, whether on a temporary or a permanent basis, is considered necessary, it is essential that such bodies provide independent advice, whether technical or non-technical in nature.

4.19. Technical and other expert professional advice or services may be provided in several ways by experts external to the regulatory body. The regulatory body may decide to establish a dedicated support organization, in which case clear limits shall be set for the degree of control and direction by the regulatory body over the work of the support organization. Other forms of external support would require a formal contract between the regulatory body and the provider of advice or services.

4.20. Arrangements shall be made to ensure that there is no conflict of interest for those organizations that provide the regulatory body with advice or services.⁸ If this is not possible domestically, then the necessary advice or assistance shall be sought from organizations in other States or, as and where appropriate, from international organizations which have no such conflicts of interest.

4.21. If the necessary advice or assistance can be obtained only from organizations whose interests potentially conflict with those of the regulatory body, the seeking of this advice or assistance shall be monitored, and the advice given shall be carefully assessed for conflicts of interest.

4.22. The obtaining of advice and assistance does not relieve the regulatory body of its assigned responsibilities. The regulatory body shall have an adequate core competence to make informed decisions. In making decisions, the regulatory body shall have the necessary means to assess advice provided by advisory bodies and information submitted by authorized parties and applicants.

⁸ If an organization that provides the regulatory body with advice or services were also to advise an authorized party on the same subject, the potential conflict of interest could compromise its reliability.

Requirement 21: Liaison between the regulatory body and authorized parties

The regulatory body shall establish formal and informal mechanisms of communication with authorized parties on all safety related issues, conducting a professional and constructive liaison.

4.23. As its primary purpose, the regulatory body shall carry out oversight of facilities and activities. The regulatory body, while maintaining its independence, shall liaise with authorized parties to achieve their common objectives in ensuring safety. Meetings shall be held as necessary to fully understand and discuss the arguments of each party on safety related issues.

4.24. The regulatory body shall foster mutual understanding and respect on the part of authorized parties through frank, open and yet formal relationships, providing constructive liaison on safety related issues.

4.25. The decisions of the regulatory body shall be justified as appropriate, and the basis for the decisions shall be explained.

Requirement 22: Stability and consistency of regulatory control

The regulatory body shall ensure that regulatory control is stable and consistent.

4.26. The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system. The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by the individual staff members of the regulatory body. The regulatory body shall be able to justify its decisions if they are challenged. In connection with its reviews and assessments and its inspections, the regulatory body shall inform applicants of the objectives, principles and associated criteria for safety on which its requirements, judgements and decisions are based.

4.27. The regulatory body shall emphasize the continuous enhancement of safety as a general objective. However, it shall also 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.

4.28. There shall be consistency in the decision making process of the regulatory body and in the regulatory requirements themselves, to build confidence among interested parties.

Requirement 23: Authorization of facilities and activities by the regulatory body

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.

Requirement 24: Demonstration of safety for the authorization of facilities and activities

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.

4.29. Different types of authorization shall be obtained for the different stages in the lifetime of a facility or the duration of an activity. The regulatory body shall be able to modify authorizations for safety related purposes. For a facility, the stages in the lifetime usually include: site evaluation, design, construction, commissioning, operation, shutdown and decommissioning (or closure). This includes, as appropriate, the management of radioactive waste and the management of spent fuel, and the remediation of contaminated areas. For radioactive sources and radiation generators, the regulatory process shall continue over their entire lifetime.

4.30. Authorization for a facility shall include authorization of the activities taking place at the facility (e.g. operation, maintenance and engineering activities). The regulatory body shall verify, by appropriate means, the competence of individuals having responsibilities for the safety of authorized facilities and activities.

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

4.32. The regulatory body shall establish a process that allows the authorized party to appeal against a regulatory decision relating to an authorization for a facility or an activity or a condition attached to an authorization.

4.33. Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment [8], which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures. The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach.

4.34. The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization. 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.

4.35. Some of the stages in the lifetime of a facility or the duration of an activity (see para. 4.29) may require specific hold points at which separate authorizations are required. In such cases, the completed stages have to be subject to review and assessment, with account taken of feedback from the previous stages.

4.36. An authorization may have to be reconsidered and/or renewed in the different stages in the lifetime of the facility or the duration of the activity concerned (e.g. as a result of a change in the conditions under which the authorization was granted). This would have to lead to a new regulatory decision which may require the amendment, renewal, suspension or revocation of the authorization.

4.37. 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.

4.38. The safety assessment may need to be repeated or reaffirmed by the regulatory body in support of its decision. The results of regulatory actions such as inspections, reviews and assessments, and feedback from operational performance (e.g. feedback on the exceeding of limits and conditions or on incidents), shall be taken into account in making decisions on the amendment, renewal, suspension or revocation of authorizations.

4.39. The regulatory body shall record formally the basis for its decision on the authorization of a facility or an activity, or on its amendment, renewal, suspension or revocation, and shall inform the applicant, in a timely manner, of its decision, and provide the applicant with reasons and a justification for the decision.

Requirement 25: Review and assessment of information relevant to safety

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.

Requirement 26: Graded approach to review and assessment of a facility or an activity

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.

4.40. The regulatory body shall review and assess the particular facility or activity in accordance with the stage in the regulatory process (initial review, subsequent reviews, reviews of changes to safety related aspects of the facility or activity, reviews of operating experience, or reviews of long term operation, life extension, decommissioning or release from regulatory control). The depth and scope of the review and assessment of the facility or activity by the regulatory body shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.

4.41. Technical and other documents submitted by the applicant shall be reviewed and assessed by the regulatory body to determine whether the facility or activity complies with the relevant objectives, principles and associated criteria for safety.

4.42. 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 [1, 6].
- (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.

4.43. The regulatory body shall assess all radiation risks associated with normal operation, anticipated operational occurrences and accident conditions, prior to operation of the facility or conduct of the activity, and periodically throughout the lifetime of the facility or the duration of the activity, to determine whether radiation risks are as low as reasonably achievable.

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.

4.45. 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) [6];
- (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. for the long term disposal of 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.

4.46. For an integrated safety assessment, the regulatory body shall first organize the results obtained in a systematic manner. It shall then identify trends and conclusions drawn from inspections, from reviews and assessments for operating facilities, and from the conduct of activities where relevant. Feedback information shall be provided to the authorized party. This integrated safety assessment shall be repeated periodically, with account taken of the radiation risks associated with the facility or activity, in accordance with a graded approach.

4.47. Risks that are not related to radiation may arise in the operation of facilities or the conduct of activities, and these risks shall also be taken into account in the decision making process of the regulatory body.

4.48. The regulatory body shall record the results and decisions deriving from reviews and assessments, and shall take appropriate action (including enforcement action) as necessary. The results of reviews and assessments shall be used as feedback information for the regulatory process.

Requirement 27: Inspection of facilities and activities

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.

Requirement 28: Types of inspection of facilities and activities

Inspections of facilities and activities shall include programmed inspections and reactive inspections; both announced and unannounced.

Requirement 29: Graded approach to inspections of facilities and activities

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

4.49. 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.

4.50. 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.

4.51. 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.

4.52. 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. The manner, extent and frequency of inspections shall be in accordance with a graded approach.

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

- Structures, systems, 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.

Requirement 30: Establishment of an enforcement policy

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.

Requirement 31: Requiring of corrective action by authorized parties

In the event that risks are identified, including risks unforeseen in the authorization process, the regulatory body shall require corrective actions to be taken by authorized parties.

4.54. The 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.

4.55. 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.

4.56. 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.

4.57. The authorized party shall be held accountable for remedying non-compliances, for performing a thorough investigation in accordance with an agreed timetable and for taking all the measures that are necessary to prevent recurrence of the non-compliances.

4.58. The regulatory body shall establish criteria for corrective actions, including enforcing the cessation of activities or the shutting down of a facility where

necessary. On-site inspectors, if any, shall be authorized to take corrective action if there is an imminent likelihood of safety significant events.

4.59. In the event that unforeseen radiation risks are identified, whether or not they are due to non-compliances with regulatory requirements or authorization conditions, the regulatory body shall require the authorized party to take appropriate corrective actions to reduce the risks.

4.60. Finally, the regulatory body shall confirm that the authorized party has effectively implemented any necessary corrective actions.

Requirement 32: Regulations and guides

The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based.

Requirement 33: Review of regulations and guides

Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical standards and of relevant experience gained.

Requirement 34: Promotion of regulations and guides to interested parties

The regulatory body shall notify interested parties and the public of the principles and associated criteria for safety established in its regulations and guides, and shall make its regulations and guides available.

4.61. 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.

4.62. The regulations and guides shall provide the framework for the regulatory requirements and conditions to be incorporated into individual authorizations or applications for authorization. They shall also establish the criteria to be used for

assessing compliance. The regulations and guides shall be kept consistent and comprehensive, and shall provide adequate coverage commensurate with the radiation risks associated with the facilities and activities, in accordance with a graded approach.

Requirement 35: Safety related records

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

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

- Registers of sealed radioactive sources and radiation generators;⁹
- Records of occupational doses;
- 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.

4.64. The regulatory body may or may not be the sole entity responsible for the maintenance of these registers and inventories, but it shall be involved in their proper retention and use. The authorized party shall be responsible for maintaining its own records. The authorized party shall maintain all the records necessary for the safe operation of facilities and the safe conduct of activities, as specified in the authorization. This includes maintaining an inventory of radioactive sources and inventories of radioactive waste and of spent fuel, as well as records of occupational doses. The requirement for the regulatory body to maintain records cannot diminish the responsibility of authorized parties to keep their own records.

4.65. Applicants shall be responsible for ensuring the recording of information relating to facilities and activities in registers and inventories, and analysing it, where relevant, for the purposes of demonstrating safety. Moreover, the

⁹ The regulatory body specifies which sources are to be included in the registers and inventories, with due consideration given to the associated risks.

regulatory body shall use such records in support of its regulatory functions and to support the enforcement of regulatory requirements.

Requirement 36: Communication and consultation with interested parties

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.

4.66. The regulatory body shall establish, either directly or through authorized parties, provision for effective mechanisms of communication, and it shall hold meetings to inform interested parties and the public and for informing the decision making process. This communication shall include constructive liaison such as:

- (a) Communication with interested parties and the public on regulatory judgements and decisions;
- (b) Direct communication with governmental authorities at a high level when such communication is considered necessary for effectively performing the functions of the regulatory body;
- (c) Communication of such documents and opinions from private or public organizations or persons to the regulatory body as may be considered necessary and appropriate;
- (d) Communication on the requirements, judgements and decisions of the regulatory body, and on the bases for them, to the public;
- (e) Making information on incidents in facilities and activities, including accidents and abnormal occurrences, and other information, as appropriate, available to authorized parties, governmental bodies, national and international organizations, and the public.

4.67. The regulatory body, in its public informational activities and consultation, shall set up appropriate means of informing interested parties, the public and the news media about the radiation risks associated with facilities and activities, the requirements for protection of people and the environment, and the processes of the regulatory body. In particular, there shall be consultation by means of an open and inclusive process with interested parties residing in the vicinity of authorized facilities and activities.

4.68. The authorized party has an obligation to inform the public about the possible radiation risks associated with the operation of a facility or the conduct

of an activity, and this obligation shall be specified in the regulations promulgated by the regulatory body, in the authorization or by other legal means.

4.69. Public information activities shall reflect the radiation risks associated with facilities and activities, in accordance with a graded approach.

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ISBN 978-92-0-106410-3
ISSN 1020-525X**