

IAEA SAFETY STANDARDS SERIES

Legal and
Governmental
Infrastructure for
Nuclear, Radiation,
Radioactive Waste and
Transport Safety

REQUIREMENTS

No. GS-R-1



INTERNATIONAL
ATOMIC ENERGY AGENCY
VIENNA

IAEA SAFETY RELATED PUBLICATIONS

IAEA SAFETY STANDARDS

Under the terms of Article III of its Statute, the IAEA is authorized to establish standards of safety for protection against ionizing radiation and to provide for the application of these standards to peaceful nuclear activities.

The regulatory related publications by means of which the IAEA establishes safety standards and measures are issued in the **IAEA Safety Standards Series**. This series covers nuclear safety, radiation safety, transport safety and waste safety, and also general safety (that is, of relevance in two or more of the four areas), and the categories within it are **Safety Fundamentals**, **Safety Requirements** and **Safety Guides**.

Safety Fundamentals (blue lettering) present basic objectives, concepts and principles of safety and protection in the development and application of nuclear energy for peaceful purposes.

Safety Requirements (red lettering) establish the requirements that must be met to ensure safety. These requirements, which are expressed as 'shall' statements, are governed by the objectives and principles presented in the Safety Fundamentals.

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Information on the IAEA's safety standards programme (including editions in languages other than English) is available at the IAEA Internet site

www.iaea.org/ns/coordinet

or on request to the Safety Co-ordination Section, IAEA, P.O. Box 100, A-1400 Vienna, Austria.

OTHER SAFETY RELATED PUBLICATIONS

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LEGAL AND GOVERNMENTAL
INFRASTRUCTURE FOR NUCLEAR,
RADIATION, RADIOACTIVE WASTE
AND TRANSPORT 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".

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AND TRANSPORT SAFETY

SAFETY REQUIREMENTS

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FOREWORD

by **Mohamed ElBaradei**
Director General

One of the statutory functions of the IAEA is to establish or adopt standards of safety for the protection of health, life and property in the development and application of nuclear energy for peaceful purposes, and to provide for the application of these standards to its own operations as well as to assisted operations and, at the request of the parties, to operations under any bilateral or multilateral arrangement, or, at the request of a State, to any of that State's activities in the field of nuclear energy.

The following advisory bodies oversee the development of safety standards: the Advisory Commission for Safety Standards (ACSS); the Nuclear Safety Standards Advisory Committee (NUSSAC); the Radiation Safety Standards Advisory Committee (RASSAC); the Transport Safety Standards Advisory Committee (TRANSSAC); and the Waste Safety Standards Advisory Committee (WASSAC). Member States are widely represented on these committees.

In order to ensure the broadest international consensus, safety standards are also submitted to all Member States for comment before approval by the IAEA Board of Governors (for Safety Fundamentals and Safety Requirements) or, on behalf of the Director General, by the Publications Committee (for Safety Guides).

The IAEA's safety standards are not legally binding on Member States but may be adopted by them, at their own discretion, for use in national regulations in respect of their own activities. The standards are binding on the IAEA in relation to its own operations and on States in relation to operations assisted by the IAEA. Any State wishing to enter into an agreement with the IAEA for its assistance in connection with the siting, design, construction, commissioning, operation or decommissioning of a nuclear facility or any other activities will be required to follow those parts of the safety standards that pertain to the activities to be covered by the agreement. However, it should be recalled that the final decisions and legal responsibilities in any licensing procedures rest with the States.

Although the safety standards establish an essential basis for safety, the incorporation of more detailed requirements, in accordance with national practice, may also be necessary. Moreover, there will generally be special aspects that need to be assessed by experts on a case by case basis.

The physical protection of fissile and radioactive materials and of nuclear power plants as a whole is mentioned where appropriate but is not treated in detail; obligations of States in this respect should be addressed on the basis of the relevant instruments and publications developed under the auspices of the IAEA.

Non-radiological aspects of industrial safety and environmental protection are also not explicitly considered; it is recognized that States should fulfil their international undertakings and obligations in relation to these.

The requirements and recommendations set forth in the IAEA safety standards might not be fully satisfied by some facilities built to earlier standards. Decisions on the way in which the safety standards are applied to such facilities will be taken by individual States.

The attention of States is drawn to the fact that the safety standards of the IAEA, while not legally binding, are developed with the aim of ensuring that the peaceful uses of nuclear energy and of radioactive materials are undertaken in a manner that enables States to meet their obligations under generally accepted principles of international law and rules such as those relating to environmental protection. According to one such general principle, the territory of a State must not be used in such a way as to cause damage in another State. States thus have an obligation of diligence and standard of care.

Civil nuclear activities conducted within the jurisdiction of States are, as any other activities, subject to obligations to which States may subscribe under international conventions, in addition to generally accepted principles of international law. States are expected to adopt within their national legal systems such legislation (including regulations) and other standards and measures as may be necessary to fulfil all of their international obligations effectively.

EDITORIAL NOTE

An appendix, when included, is considered to form an integral part of the standard and to have the same status as the main text. Annexes, footnotes and bibliographies, if included, are used to provide additional information or practical examples that might be helpful to the user.

The safety standards use the form 'shall' in making statements about requirements, responsibilities and obligations. Use of the form 'should' denotes recommendations of a desired option.

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1. INTRODUCTION

BACKGROUND

1.1. The safety of nuclear facilities and sources of ionizing radiation, radiation protection, the safe management of radioactive waste and the safe transport of radioactive material are of great importance to individuals and society and to the environment in the State of use and in other States.

1.2. This Safety Requirements publication establishes the basic requirements for legal and governmental infrastructures for nuclear, radiation, radioactive waste and transport safety. It should be used in conjunction with the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources [1] and the Regulations for the Safe Transport of Radioactive Material [2]. It supersedes both the Code on the Safety of Nuclear Power Plants: Governmental Organization (Safety Series No. 50-C-G (Rev. 1) (1988) and the safety standard on Establishing a National System for Radioactive Waste Management (Safety Series No. 111-S-1 (1995)).

OBJECTIVE

1.3. The objective of this Safety Requirements publication is to specify requirements related to the legal and governmental infrastructure for the safety of nuclear facilities and sources of ionizing radiation, radiation protection, the safe management of radioactive waste and the safe transport of radioactive material, which must be satisfied in order to achieve the objectives and apply the principles that are presented in the Safety Fundamentals publications [3–5].

SCOPE

1.4. This publication establishes requirements for legal and governmental responsibilities in respect of the safety of nuclear facilities, the safe use of sources of ionizing radiation, radiation protection, the safe management of radioactive waste and the safe transport of radioactive material. Thus, it covers development of the legal framework for establishing a regulatory body and other actions to achieve effective regulatory control of facilities and activities. Other responsibilities are also covered, such as those for developing the necessary support for safety, involvement in securing third party liability and emergency preparedness.

1.5. This publication establishes legal and governmental responsibilities which are common to a broad range of facilities and activities including the following:

Activities

- (1) Sources of ionizing radiation; their production, use (e.g. in industrial, research and medical applications), import and export;
- (2) transport of radioactive materials;
- (3) mining and processing of radioactive ores (e.g. uranium and thorium ores), and close-out of associated facilities;
- (4) site rehabilitation; and
- (5) activities in radioactive waste management (such as discharge and clearance).

Facilities

- (1) Enrichment and fuel manufacturing plants;
- (2) nuclear power plants;
- (3) other reactors (such as research reactors and critical assemblies);
- (4) spent fuel reprocessing plants;
- (5) radioactive waste management facilities (such as treatment, storage and disposal facilities);
- (6) nuclear and irradiation facilities for medical, industrial and research purposes; and
- (7) decommissioning or closure of nuclear facilities and site rehabilitation.

1.6. This publication establishes all the legal and governmental requirements for the entire range of facilities and activities, from the use of a limited number of radiation sources to a major nuclear power programme. Not all the safety requirements will apply for all States. Each State shall identify the requirements to apply as appropriate, taking into account the State's particular circumstances, the potential magnitude and nature of the hazard presented by the facilities and activities concerned, and the guidance provided in related Safety Standards Series publications.

1.7. This publication addresses all phases of the life cycle of facilities or the duration of activities, and any subsequent period of institutional control until there is no significant residual radiation hazard. For a facility, these phases usually include siting, design, construction, commissioning, operation and decommissioning (or close-out or closure).

1.8. This publication concentrates on legal and governmental aspects, with due emphasis on regulatory control. Other Safety Standards Series publications cover in more detail requirements for the operator responsible for facilities and activities.

STRUCTURE

1.9. Section 2 establishes requirements for legislative and governmental responsibilities. The responsibilities and functions of the regulatory body are established in Section 3, its organization is outlined in Section 4, and its activities are set forth in Section 5. The supporting infrastructure is addressed in more detail in Section 6. Additional requirements specific to nuclear power plants are given in the Appendix. A Glossary gives definitions of terms used in the text which apply for the purposes of the present publication.

2. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES

GENERAL

2.1. Facilities and activities cover a broad and diverse range, from the use of a single low energy radiation source to the operation of complex facilities such as nuclear power plants or spent fuel reprocessing plants. The regulatory regime shall be structured and resourced in a manner commensurate with the potential magnitude and nature of the hazard to be controlled.

2.2. There are certain prerequisites for the safety of facilities and activities. These give rise to the following requirements for the legislative and governmental mechanisms of States:

- (1) A legislative and statutory framework shall be established to regulate the safety of facilities and activities.
- (2) A regulatory body shall be established and maintained which shall be effectively independent of organizations or bodies charged with the promotion of nuclear technologies or responsible for facilities or activities. This is so that regulatory judgements can be made, and enforcement actions taken, without pressure from interests that may conflict with safety.
- (3) Responsibility shall be assigned to the regulatory body for authorization, regulatory review and assessment, inspection and enforcement, and for establishing safety principles, criteria, regulations and guides.
- (4) The regulatory body shall be provided with adequate authority and power, and it shall be ensured that it has adequate staffing and financial resources to discharge its assigned responsibilities.

- (5) No other responsibility shall be assigned to the regulatory body which may jeopardize, or conflict with, its responsibility for regulating safety.
- (6) Adequate infrastructural arrangements shall be made for decommissioning, close-out or closure, site rehabilitation, and the safe management of spent fuel and radioactive waste.
- (7) Adequate infrastructural arrangements shall be made for the safe transport of radioactive material.
- (8) An effective system of governmental emergency response and intervention capabilities shall be established and emergency preparedness shall be ensured.
- (9) Adequate infrastructural arrangements shall be made for physical protection, where these influence safety.
- (10) Adequate financial indemnification arrangements shall be made for third parties in the event of a nuclear or radiation accident in view of the damage and injury which may arise from an accident.
- (11) The technological infrastructure necessary for ensuring the safety of facilities and activities shall be provided, where this is not provided by other organizations.

2.3. The prime responsibility for safety shall be assigned to the operator. The operator shall have the responsibility for ensuring safety in the siting, design, construction, commissioning, operation, decommissioning, close-out or closure of its facilities, including, as appropriate, rehabilitation of contaminated areas; and for activities in which radioactive materials are used, transported or handled. Organizations which generate radioactive waste shall have responsibility for the safe management of the radioactive waste that they produce. Since during the transport of radioactive material, primary reliance for safety is put on the use of approved packaging, it is the responsibility of the consignor to ensure appropriate selection and use of packaging. Compliance with the requirements imposed by the regulatory body shall not relieve the operator of its prime responsibility for safety. The operator shall demonstrate to the satisfaction of the regulatory body that this responsibility has been and will continue to be discharged.

LEGISLATIVE

2.4. Legislation shall be promulgated to provide for the effective control of nuclear, radiation, radioactive waste and transport safety. This legislation:

- (1) shall set out objectives for protecting individuals, society and the environment from radiation hazards, both for the present and in the future;

- (2) shall specify facilities, activities and materials that are included in the scope of the legislation and what is excluded from the requirements of any particular part of the legislation;
- (3) shall establish authorization and other processes (such as notification and exemption), with account taken of the potential magnitude and nature of the hazard associated with the facility or activity, and shall specify the steps of the processes;
- (4) shall establish a regulatory body with the authority outlined in para. 2.6;
- (5) shall arrange for adequate funding of the regulatory body;
- (6) shall specify the process for removal of a facility or activity from regulatory control;
- (7) shall establish a procedure for review of, and appeal against, regulatory decisions (without compromising safety);
- (8) shall provide for continuity of responsibility when activities are carried out by several operators successively and for the recording of the transfers of responsibility;
- (9) shall allow for the creation of independent advisory bodies to provide expert opinion to, and for consultation by, the government and regulatory body;
- (10) shall set up a means whereby research and development work is undertaken in important areas of safety;
- (11) shall define liabilities in respect of nuclear damage¹;
- (12) shall set out the arrangements for provision of financial security in respect of any liabilities;
- (13) shall set out the responsibilities and obligations in respect of financial provision for radioactive waste management and decommissioning;
- (14) shall define what is an offence and the corresponding penalties;
- (15) shall implement any obligations under international treaties, conventions or agreements;
- (16) shall define how the public and other bodies are involved in the regulatory process; and
- (17) shall specify the nature and extent of the application of newly established requirements to existing facilities and current activities.

2.5. If other authorities, which may fail to meet the requirement of independence set out in item (2) of para. 2.2, are involved in the granting of authorizations, it shall be ensured that the safety requirements of the regulatory body remain in force and are not modified in the regulatory process.

¹ Nuclear damage is as defined in the Protocol amending the Vienna Convention on Civil Liability for Nuclear Damage of 1997.

2.6. The regulatory body shall have the authority:

- (1) to develop safety principles and criteria;
- (2) to establish regulations and issue guidance;
- (3) to require any operator to conduct a safety assessment;
- (4) to require that any operator provide it with any necessary information, including information from its suppliers, even if this information is proprietary;
- (5) to issue, amend, suspend or revoke authorizations and to set conditions;
- (6) to require an operator to perform a systematic safety reassessment or a periodic safety review over the lifetime of facilities;
- (7) to enter a site or facility at any time to carry out an inspection;
- (8) to enforce regulatory requirements;
- (9) to communicate directly with governmental authorities at higher levels when such communication is considered to be necessary for exercising effectively the functions of the body;
- (10) to obtain such documents and opinions from private or public organizations or persons as may be necessary and appropriate;
- (11) to communicate independently its regulatory requirements, decisions and opinions and their basis to the public;
- (12) to make available, to other governmental bodies, national and international organizations, and to the public, information on incidents and abnormal occurrences, and other information, as appropriate;
- (13) to liaise and co-ordinate with other governmental or non-governmental bodies having competence in such areas as health and safety, environmental protection, security, and transport of dangerous goods; and
- (14) to liaise with regulatory bodies of other countries and with international organizations to promote co-operation and the exchange of regulatory information.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

3.1. In order to fulfil its statutory obligations, the regulatory body shall define policies, safety principles and associated criteria as a basis for its regulatory actions.

3.2. In fulfilling its statutory obligations, the regulatory body:

- (1) shall establish, promote or adopt regulations and guides upon which its regulatory actions are based;

- (2) shall review and assess submissions on safety from the operators both prior to authorization and periodically during operation as required;
- (3) shall provide for issuing, amending, suspending or revoking authorizations, subject to any necessary conditions, that are clear and unambiguous and which shall specify (unless elsewhere specified):
 - (i) the facilities, activities or inventories of sources covered by the authorization;
 - (ii) the requirements for notifying the regulatory body of any modifications to safety related aspects;
 - (iii) the obligations of the operator in respect of its facility, equipment, radiation source(s) and personnel;
 - (iv) any limits on operation and use (such as dose or discharge limits, action levels or limits on the duration of the authorization);
 - (v) conditioning criteria for radioactive waste processing for existing or foreseen waste management facilities;
 - (vi) any additional separate authorizations that the operator is required to obtain from the regulatory body;
 - (vii) the requirements for incident reporting;
 - (viii) the reports that the operator is required to make to the regulatory body;
 - (ix) the records that the operator is required to retain and the time periods for which they must be retained; and
 - (x) the emergency preparedness arrangements.
- (4) shall carry out regulatory inspections;
- (5) shall ensure that corrective actions are taken if unsafe or potentially unsafe conditions are detected; and
- (6) shall take the necessary enforcement action in the event of violations of safety requirements.

3.3. In order to discharge its main responsibilities, as outlined in para. 3.2, the regulatory body:

- (1) shall establish a process for dealing with applications, such as applications for the issuing of an authorization, accepting a notification or the granting of an exemption, or for removal from regulatory control;
- (2) shall establish a process for changing conditions of authorization;
- (3) shall provide guidance to the operator on developing and presenting safety assessments or any other required safety related information;
- (4) shall ensure that proprietary information is protected;
- (5) shall provide an explanation of the reasons for the rejection of a submission;
- (6) shall communicate with, and provide information to, other competent governmental bodies, international organizations and the public;

- (7) shall ensure that operating experience is appropriately analysed and that lessons to be learned are disseminated;
- (8) shall ensure that appropriate records relating to the safety of facilities and activities are retained and retrievable;
- (9) shall ensure that its regulatory principles and criteria are adequate and valid, and shall take into consideration internationally endorsed standards and recommendations;
- (10) shall establish and inform the operator of any requirements for systematic safety reassessment or periodic safety review;
- (11) shall advise the government on matters related to the safety of facilities and activities;
- (12) shall confirm the competence of personnel responsible for the safe operation of the facility or activity; and
- (13) shall confirm that safety is managed adequately by the operator.

3.4. The regulatory body shall co-operate with other relevant authorities, advise them and provide them with information on safety matters in the following areas, as necessary:

- (1) environmental protection;
- (2) public and occupational health;
- (3) emergency planning and preparedness;
- (4) radioactive waste management (including determination of national policy);
- (5) public liability (including implementation of national regulations and international conventions concerning third party liability);
- (6) physical protection and safeguards;
- (7) water use and consumption of food;
- (8) land use and planning; and
- (9) safety in the transport of dangerous goods.

3.5. The regulatory body may also have additional functions. Such functions may include:

- (1) independent radiological monitoring in and around nuclear facilities;
- (2) independent testing and quality control measurements;
- (3) initiating, co-ordinating and monitoring safety related research and development work in support of its regulatory functions;
- (4) providing personnel monitoring services and conducting medical examinations;
- (5) monitoring of nuclear non-proliferation; and
- (6) regulatory control of industrial safety.

When such functions are undertaken, care shall be taken by the regulatory body to ensure that any conflict with its main regulatory functions is avoided and that the prime responsibility of the operator for safety is not diminished.

4. ORGANIZATION OF THE REGULATORY BODY

GENERAL

4.1. The regulatory body shall be structured so as to ensure that it is capable of discharging its responsibilities and fulfilling its functions effectively and efficiently. The regulatory body shall have an organizational structure and size commensurate with the extent and nature of the facilities and activities it must regulate, and it shall be provided with adequate resources and the necessary authority to discharge its responsibilities. The structure and size of the regulatory body are influenced by many factors, and it is not appropriate to require a single organizational model. The regulatory body's reporting line in the governmental infrastructure shall ensure effective independence from organizations or bodies charged with the promotion of nuclear or radiation related technologies, or those responsible for facilities or activities.

4.2. If the regulatory body consists of more than one authority, effective arrangements shall be made to ensure that regulatory responsibilities and functions are clearly defined and co-ordinated, in order to avoid any omissions or unnecessary duplication and to prevent conflicting requirements being placed on the operator. The main functions of review and assessment and inspection and enforcement shall be organized in such a way as to achieve consistency and to enable the necessary feedback and exchange of information. In addition, the authorities responsible for the different disciplines concerned in the regulatory process, such as those responsible for nuclear, radiation, radioactive waste and transport safety, shall be effectively co-ordinated.

4.3. If the regulatory body is not entirely self-sufficient in all the technical or functional areas necessary to discharge its responsibilities for review and assessment or inspection, it shall seek advice or assistance, as appropriate, from consultants. Whoever may provide such advice or assistance (such as a dedicated support organization, universities or private consultants), arrangements shall be made to ensure that the consultants are effectively independent of the operator. If this is not possible, then advice or assistance may be sought from other States or from international organizations whose expertise in the field concerned is well established and recognized.

4.4. The use of consultants shall not relieve the regulatory body of any of its responsibilities. In particular, the regulatory body's responsibility for making decisions and recommendations shall not be delegated.

4.5. The regulatory body shall establish and implement appropriate arrangements for a systematic approach to quality management which extend throughout the range of responsibilities and functions undertaken.

STAFFING AND TRAINING OF THE REGULATORY BODY

4.6. The regulatory body shall employ a sufficient number of personnel with the necessary qualifications, experience and expertise to undertake its functions and responsibilities. It is likely that there will be positions of a specialist nature and positions needing more general skills and expertise. The regulatory body shall acquire and maintain the competence to judge, on an overall basis, the safety of facilities and activities and to make the necessary regulatory decisions.

4.7. In order to ensure that the proper skills are acquired and that adequate levels of competence are achieved and maintained, the regulatory body shall ensure that its staff members participate in well defined training programmes. This training should ensure that staff are aware of technological developments and new safety principles and concepts.

4.8. In undertaking its own review and assessment of a safety submission presented by the operator, the regulatory body shall not rely solely on any safety assessment performed for it by consultants or on that conducted by the operator. Accordingly, the regulatory body shall have a full time staff capable of either performing regulatory reviews and assessments, or evaluating any assessments performed for it by consultants.

ADVISORY BODIES TO THE REGULATORY BODY

4.9. The government or the regulatory body may choose to give formal structure to the processes by which expert opinion and advice are provided to the regulatory body; the need or otherwise for such formal advisory bodies is determined by many factors. When the establishment of advisory bodies is considered necessary, on a temporary or permanent basis, such bodies shall give independent advice. The advice given may

be technical or non-technical (in advising, for example, on ethical issues in the use of radiation in medicine). Any advice offered shall not relieve the regulatory body of its responsibilities for making decisions and recommendations.

RELATIONS BETWEEN THE REGULATORY BODY AND THE OPERATOR

4.10. Mutual understanding and respect between the regulatory body and the operator, and a frank, open and yet formal relationship, shall be fostered.

INTERNATIONAL CO-OPERATION

4.11. The safety of facilities and activities is of international concern. Several international conventions relating to various aspects of safety are in force. National authorities, with the assistance of the regulatory body, as appropriate, shall establish arrangements for the exchange of safety related information, bilaterally or regionally, with neighbouring States and other interested States, and with relevant intergovernmental organizations, both to fulfil safety obligations and to promote co-operation.

5. ACTIVITIES OF THE REGULATORY BODY

GENERAL

5.1. The main functions of the regulatory body, as described in para. 3.2, are carried out within, and are dependent upon, the national legal framework. The regulatory process continues throughout the life cycle of a facility or the duration of an activity. The day to day activities of an established regulatory body in discharging its functional responsibilities will be those relating to authorization, review and assessment, and inspection and enforcement. Other functions, such as establishing, updating or adopting safety principles, regulations and guides, will be undertaken less frequently.

5.2. For all facilities and activities, a prior authorization, a notification or an exemption shall be in force. Alternatively, activities of a particular type may be authorized in general to be performed in strict accordance with detailed technical regulations (such as the routine shipment of radioactive materials in packages approved under detailed transport safety regulations).

AUTHORIZATION

5.3. Prior to the granting of an authorization, the applicant shall be required to submit a detailed demonstration of safety, which shall be reviewed and assessed by the regulatory body in accordance with clearly defined procedures. The extent of the control applied shall be commensurate with the potential magnitude and nature of the hazard presented. Thus, for example, a dental X ray machine may require only registration with the regulatory body, whereas for a radioactive waste repository a multistage authorization process may be required.

5.4. The regulatory body shall issue guidance on the format and content of documents to be submitted by the operator in support of applications for authorization. The operator shall be required to submit or make available to the regulatory body, in accordance with agreed time-scales, all information that is specified or requested. For complex facilities (such as a nuclear power plant) authorization may be carried out in several stages, each requiring hold points, separate permits or licences. In such cases, each stage of the process shall be subject to review and assessment, with account taken of feedback from the previous stages.

5.5. The regulatory review and assessment will lead to a series of regulatory decisions. At a certain stage in the authorization process, the regulatory body shall take formal actions which will result in either:

- (1) the granting of an authorization which, if appropriate, imposes conditions or limitations on the operator's subsequent activities; or
- (2) the refusal of such an authorization.

The regulatory body shall formally record the basis for these decisions.

5.6. Any subsequent amendment, renewal, suspension or revocation of the authorization shall be undertaken in accordance with a clearly defined and established procedure. The procedure shall include requirements for the timely submission of applications for renewal or amendment of authorizations. For amendment and

renewal, the associated regulatory review and assessment shall be consistent with the requirements of para. 5.3.

REVIEW AND ASSESSMENT

5.7. Review and assessment shall be performed in accordance with the stage in the regulatory process and the potential magnitude and nature of the hazard associated with the particular facility or activity.

5.8. In connection with its review and assessment activities, the regulatory body shall define and make available to the operator the principles and associated criteria on which its judgements and decisions are based.

5.9. A primary basis for review and assessment is the information submitted by the operator. A thorough review and assessment of the operator's technical submission shall be performed by the regulatory body in order to determine whether the facility or activity complies with the relevant safety objectives, principles and criteria. In doing this, the regulatory body shall acquire an understanding of the design of the facility or equipment, the safety concepts on which the design is based and the operating principles proposed by the operator, to satisfy itself that:

- (1) the available information demonstrates the safety of the facility or proposed activity;
- (2) the information contained in the operator's submissions is accurate and sufficient to enable confirmation of compliance with regulatory requirements; and
- (3) the technical solutions, and in particular any novel ones, have been proven or qualified by experience or testing or both, and are capable of achieving the required level of safety.

5.10. The regulatory body shall prepare its own programme of review and assessment of the facilities and activities under scrutiny. The regulatory body shall follow the development of a facility or activity, as applicable, from initial selection of the site, through design, construction, commissioning and operation, to decommissioning, closure or closeout. Additional requirements for the review and assessment of a nuclear power plant are given in the Appendix.

5.11. Any modification to safety related aspects of a facility or activity (or having an indirect but significant influence on safety related aspects) shall be subject to review and assessment, with the potential magnitude and nature of the associated hazard being taken into account.

INSPECTION AND ENFORCEMENT

5.12. Regulatory inspection and enforcement activities shall cover all areas of regulatory responsibility. The regulatory body shall conduct inspections to satisfy itself that the operator is in compliance with the conditions set out, for example, in the authorization or regulations. In addition, the regulatory body shall take into account, as necessary, the activities of suppliers of services and products to the operator. Enforcement actions shall be applied as necessary by the regulatory body in the event of deviations from, or non-compliance with, conditions and requirements.

5.13. The main purposes of regulatory inspection and enforcement are to ensure that:

- (1) facilities, equipment and work performance meet all necessary requirements;
- (2) relevant documents and instructions are valid and are being complied with;
- (3) persons employed by the operator (including contractors) possess the necessary competence for the effective performance of their functions;
- (4) deficiencies and deviations are identified and are corrected or justified without undue delay;
- (5) any lessons learned are identified and propagated to other operators and suppliers and to the regulatory body as appropriate; and
- (6) the operator is managing safety in a proper manner.

Regulatory inspections shall not diminish the operator's prime responsibility for safety or substitute for the control, supervision and verification activities that the operator must carry out.

Inspection

5.14. The regulatory body shall establish a planned and systematic inspection programme. The extent to which inspection is performed in the regulatory process will depend on the potential magnitude and nature of the hazard associated with the facility or activity.

5.15. Inspection by the regulatory body, both announced and unannounced, shall be a continuing activity. If the regulatory body uses the services of consultants for the inspections, then it shall have the responsibility for taking any actions on the basis of these inspections.

5.16. In addition to routine inspection activities, the regulatory body shall carry out inspections at short notice if an abnormal occurrence warrants immediate

investigation. Such regulatory inspection shall not diminish the responsibility of the operator to investigate any such occurrence immediately.

5.17. Regulatory inspectors shall be required to prepare reports of their inspection activities and findings, which shall be fed back into the regulatory process.

Enforcement

5.18. Enforcement actions are designed to respond to non-compliance with specified conditions and requirements. The action shall be commensurate with the seriousness of the non-compliance. Thus there are different enforcement actions, from written warnings to penalties and, ultimately, withdrawal of an authorization. In all cases the operator shall be required to remedy the non-compliance, to perform a thorough investigation in accordance with an agreed time-scale, and to take all necessary measures to prevent recurrence. The regulatory body shall ensure that the operator has effectively implemented any remedial actions.

5.19. Deviations from, or violations of, requirements, or unsatisfactory situations which have minor safety significance, may be identified at facilities or in the conduct of activities. In such circumstances, the regulatory body shall issue a written warning or directive to the operator which shall identify the nature and regulatory basis of each violation and the period of time permitted for taking remedial action.

5.20. If there is evidence of a deterioration in the level of safety, or in the event of serious violations which in the judgement of the regulatory body pose an imminent radiological hazard to workers, public or environment, the regulatory body shall require the operator to curtail activities and to take any further action necessary to restore an adequate level of safety.

5.21. In the event of continual, persistent or extremely serious non-compliance, or a significant release of radioactive material to the environment due to serious malfunctioning at or damage to a facility, the regulatory body shall direct the operator to curtail activities and may suspend or revoke the authorization. The operator shall be directed to eliminate any unsafe conditions.

5.22. All enforcement decisions shall be confirmed to the operator in writing.

5.23. The extent of the authority of the regulatory inspectors to take on the spot enforcement actions shall be determined by the regulatory body.

5.24. Where on the spot enforcement authority is not granted to individual inspectors, the transmission of information to the regulatory body shall be suited to the urgency of the situation so that necessary actions are taken in a timely manner; information shall be transmitted immediately if the inspectors judge that the health and safety of workers or the public are at risk, or the environment is endangered.

DEVELOPMENT OF REGULATIONS AND GUIDES

5.25. The system of regulations and guides shall be chosen so as to suit the legal system of the State, and the nature and extent of the facilities and activities to be regulated. Where regulations are not issued by the regulatory body, the legislative and governmental mechanisms shall ensure that such regulations are developed and approved in accordance with appropriate time-scales.

5.26. The main purpose of regulations is to establish requirements with which all operators must comply. Such regulations shall provide a framework for more detailed conditions and requirements to be incorporated into individual authorizations.

5.27. Guides, of a non-mandatory nature, on how to comply with the regulations shall be prepared, as necessary. These guides may also provide information on data and methods to be used in assessing the adequacy of the design and on analyses and documentation to be submitted to the regulatory body by the operator.

5.28. In developing regulations and guides, the regulatory body shall take into consideration comments from interested parties and the feedback of experience. Due account shall also be taken of internationally recognized standards and recommendations, such as IAEA safety standards.

6. SPECIFIC INFRASTRUCTURE

GENERAL

6.1. In order to safely derive the benefits of the exploitation of nuclear and radiation related technologies, governments must provide for both an effective regulatory regime and an appropriate supporting infrastructure. The regulatory regime has been considered in the preceding sections of this Safety Requirements publication. Requirements in respect of the supporting infrastructure are presented in this section.

INFRASTRUCTURE FOR EMERGENCY PREPAREDNESS

6.2. Despite all the precautions that are taken in the design and operation of nuclear facilities and the conduct of nuclear activities, there remains a possibility that a failure or an accident may give rise to an emergency. In some cases, this may give rise to the release of radioactive materials within facilities and/or into the public domain, which may necessitate emergency response actions. Such emergencies may include transport accidents. Adequate preparations shall be established and maintained at local and national levels and, where agreed between States, at the international level to respond to emergencies.

6.3. The arrangements for emergency response actions both within and outside facilities, if applicable, or elsewhere under the control of the operator, are dealt with through the regulatory process. Government shall ensure that competent authorities have the necessary resources and that they make preparations and arrangements to deal with any consequences of accidents in the public domain, whether the accident occurs within or beyond national boundaries. These preparations shall include the actions to be taken both in and after an emergency.

6.4. The nature and extent of emergency arrangements shall be commensurate with the potential magnitude and nature of the hazard associated with the facility or activity.

6.5. The emergency arrangements shall include a clear allocation of responsibility for notification and decision making. They shall ensure an effective interface between the operator and the competent authorities and shall provide for effective means of communication. The arrangements of all parties shall be exercised on a periodic basis and shall, where appropriate, be witnessed by the regulatory body.

6.6. In planning for, and in the event of, emergencies, the regulatory body shall act as an adviser to the government and competent authorities in respect of nuclear safety and radiation protection.

INFRASTRUCTURE FOR RADIOACTIVE WASTE MANAGEMENT

6.7. Radioactive waste generated in nuclear facilities and activities may necessitate special considerations, particularly in view of the long time-scales and different organizations which may be involved from its generation through to its final disposal and the closure of a repository. Continuity of responsibility between the organizations involved shall be ensured. Consequently, national policies and implementation

strategies for the safe management of radioactive waste shall be developed, in accordance with the objectives and principles set out in the IAEA Safety Fundamentals publication on The Principles of Radioactive Waste Management [4]. These strategies shall take into account the diversity between types of radioactive waste and shall be commensurate with the radiological characteristics of the waste. The regulatory body shall ensure that an appropriate waste classification scheme is established accordingly.

6.8. Prior to the granting of an authorization for activities that generate radioactive waste or for radioactive waste management facilities, the regulatory body shall ensure that interdependences among all steps in the generation and management of radioactive waste are appropriately taken into account. In planning the management of radioactive waste, account shall be taken of all safety aspects and needs at all the various steps, and of the fact that decisions made concerning one step may foreclose alternatives or may have other significant consequences for other steps. No step shall be considered in isolation.

6.9. Prior to the authorization of activities that generate radioactive waste, the regulatory body shall ensure that:

- (1) appropriate consideration is given to making provision for the necessary capacity for processing and storage of the anticipated radioactive waste;
- (2) the processed waste and waste packages are compatible with the anticipated nature and duration of storage, with account taken of the strategy for regular surveillance of waste and the need for retrievability of waste from storage for further processing or disposal.

6.10. Government shall ensure that adequate arrangements are made for the safe storage and disposal of radioactive waste. Responsibilities shall be delineated and assigned to ensure that any transfer of responsibility for waste is adequately managed.

6.11. Government shall ensure that the regulations provide for establishing an inventory of existing and anticipated radioactive waste, including its location and radionuclide content and other physical and chemical characteristics significant to the safety of its management; and for preventing and reducing the generation of radioactive waste and promoting the reuse and recycle of equipment and materials and the reuse of buildings.

6.12. If institutional control after closure of a repository is deemed necessary, responsibility for carrying out institutional control shall be clearly assigned.

6.13. Government shall ensure that appropriate research and development programmes for radioactive waste disposal are implemented, in particular for long term safety.

INFRASTRUCTURE FOR INTERVENTION

6.14. Nuclear and radiation facilities and activities will give rise to some radiation exposure. This can be safely controlled by design and operational measures. However, circumstances may arise in which intervention is needed to reduce or avert exposure or potential exposure to radiation arising from an accident or from a discontinued or inadequately controlled practice, or to radiation occurring naturally at unusually high levels. In such situations the government shall appoint organizations to be responsible for making the necessary arrangements for intervention to ensure that remedial action is taken to protect the public, workers and the environment. The intervening organization shall have the necessary resources and authority to fulfil its function.

6.15. The regulatory body shall provide any necessary input to the intervention process. Such input may be advice to the government or regulatory control of intervention activities.

6.16. Principles and criteria for intervention actions shall be established and the regulatory body shall provide any necessary advice in this regard.

INFRASTRUCTURE FOR SERVICES

6.17. The achievement of a high level of nuclear, radiation, radioactive waste and transport safety in States depends on operators discharging their prime responsibility for the safety of their facilities and activities, and on the regulatory body being competent, efficient and adequately resourced. Achievement of a high level of safety will be greatly facilitated by an adequate supporting infrastructure for nuclear, radiation, radioactive waste and transport related activities. Government and, as appropriate, concerned organizations shall therefore pay attention to, and provide for, among other things, the following:

- (1) training and education;
- (2) dosimetry services;
- (3) calibration and radioanalytical services;
- (4) special emergency equipment;
- (5) appropriate medical resources; and
- (6) international co-operation.

Appendix

REVIEW AND ASSESSMENT DURING THE LIFE CYCLE OF A NUCLEAR POWER PLANT

A.1. Before authorizing or licensing the construction of a nuclear power plant, the regulatory body shall review and assess:

- (1) the competence and capability of the applicant or licensee to meet the authorization or licence requirements;
- (2) the site characteristics, in order to confirm the acceptability of the site and the related data used in the design of the proposed plant;
- (3) the basic design of the proposed plant, in order to confirm that it can meet the safety requirements;
- (4) the quality assurance organization and programmes of the applicant/licensee and vendors;
- (5) the design features related to physical protection which are important for safety;
- (6) research and development plans or programmes related to demonstration of the design, where applicable; and
- (7) arrangements for decommissioning and for management of radioactive waste.

A.2. During construction, the regulatory body shall review and assess:

- (1) on a systematic basis, the development of the design of the plant as demonstrated in the safety documentation submitted by the applicant or licensee in accordance with an agreed programme; and
- (2) the progress of research and development programmes relating to demonstration of the design, if applicable.

A.3. Before the beginning of commissioning, the regulatory body shall review and assess the commissioning programme and, if appropriate, establish hold points for review and assessment.

A.4. Before authorizing the loading of nuclear fuel or initial criticality, as appropriate, the regulatory body shall complete the review and assessment of:

- (1) the as-built design of the plant;
- (2) the results of non-nuclear commissioning tests;
- (3) the limits and conditions for operation during commissioning;
- (4) the provisions for radiological protection;

- (5) the adequacy of operating instructions and procedures, especially the main administrative procedures, general operating procedures and emergency operating procedures;
- (6) the recording and reporting systems;
- (7) the arrangements for ensuring training and qualification of plant personnel, including staffing levels and fitness for duty;
- (8) the quality assurance organization and programme for operation;
- (9) on-site and off-site emergency preparedness;
- (10) the accounting measures for nuclear and radioactive materials;
- (11) the adequacy of the physical protection arrangements important for safety; and
- (12) the arrangements for periodic testing, maintenance, inspection, control of modifications and surveillance.

A.5. Before authorizing or licensing routine operation at full power, the regulatory body shall complete the review and assessment of:

- (1) the results of commissioning tests; and
- (2) the limits and conditions for operation.

A.6. In the operation of the plant, changes in operational limits and conditions or significant safety related modifications may be necessary because of operating experience feedback, advances in reactor technology, plant modifications proposed by the operator or new regulatory requirements. The regulatory body shall review and assess such proposed changes or modifications prior to their authorization.

A.7. In the operation of a nuclear power plant, the regulatory body may require a periodic safety review. In such cases, the regulatory body shall first review and assess the operators' strategy and the safety factors to be evaluated. The regulatory body shall subsequently review and assess the completed periodic safety review.

A.8. Before authorizing the decommissioning of the nuclear power plant, the regulatory body shall review and assess the proposed procedures for demonstrating nuclear and radiation safety and the safe management of radioactive waste.

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GLOSSARY

authorization. The granting by a regulatory or other governmental body of written permission for an operator to perform specified activities. Authorization could include, for example, licensing, certification, registration, etc.

facilities and activities. A general term encompassing nuclear facilities, uses of all sources of ionizing radiation, all radioactive waste management activities, transport of radioactive material and any other practice or circumstances in which people may be exposed to radiation from naturally occurring or artificial sources.

institutional control. Control of a radioactive waste site by an authority or institution designated under the laws of a country. This control may be active (monitoring, surveillance, remedial work) or passive (land use control) and may be a factor in the design of a nuclear facility (e.g. near surface repository).

operator. Any organization or person applying for authorization or authorized and/or responsible for nuclear, radiation, radioactive waste or transport safety when undertaking activities or in relation to any nuclear facilities or sources of ionizing radiation. This includes, inter alia, private individuals, governmental bodies, consignors or carriers, licensees, hospitals, self-employed persons, etc.

regulatory body. An authority or a system of authorities designated by the government of a State as having legal authority for conducting the regulatory process, including issuing authorizations, and thereby regulating nuclear, radiation, radioactive waste and transport safety. The national competent authority for the regulation of radioactive material transport safety is included in this description.

regulatory inspection. An examination, observation, measurement or test undertaken by or on behalf of the regulatory body to assess structures, systems, components and materials, as well as operational activities, processes, procedures and personnel competence.

safety. The achievement of proper operating conditions, prevention of accidents or mitigation of accident consequences, resulting in protection of workers, the public and the environment from undue radiation hazards.

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