

IAEA Safety Standards

for protecting people and the environment

Use of a Graded Approach in the Application of the Safety Requirements for Research Reactors

Specific Safety Guide

No. SSG-22



IAEA

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IAEA SAFETY STANDARDS

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

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

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USE OF A GRADED APPROACH
IN THE APPLICATION OF
THE SAFETY REQUIREMENTS FOR
RESEARCH REACTORS



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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. SSG-22

USE OF A GRADED APPROACH IN THE APPLICATION OF THE SAFETY REQUIREMENTS FOR RESEARCH REACTORS

SPECIFIC SAFETY GUIDE

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2012

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FOREWORD

by Yukiya Amano
Director General

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

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

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

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

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

NOTE BY THE SECRETARIAT

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. The process of developing, reviewing and establishing the IAEA standards involves the IAEA Secretariat and all Member States, many of which are represented on the four IAEA safety standards committees and the IAEA Commission on Safety Standards.

The IAEA standards, as a key element of the global safety regime, are kept under regular review by the Secretariat, the safety standards committees and the Commission on Safety Standards. The Secretariat gathers information on experience in the application of the IAEA standards and information gained from the follow-up of events for the purpose of ensuring that the standards continue to meet users' needs. The present publication reflects feedback and experience accumulated until 2010 and it has been subject to the rigorous review process for standards.

Lessons that may be learned from studying the accident at the Fukushima Daiichi nuclear power plant in Japan following the disastrous earthquake and tsunami of 11 March 2011 will be reflected in this IAEA safety standard as revised and issued in the future.



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THE IAEA SAFETY STANDARDS

BACKGROUND

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

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

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

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

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

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

THE IAEA SAFETY STANDARDS

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

With a view to ensuring the protection of people and the environment from harmful effects of ionizing radiation, the IAEA safety standards establish

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

Safety measures and security measures¹ have in common the aim of protecting human life and health and the environment. Safety measures and security measures must be designed and implemented in an integrated manner so that security measures do not compromise safety and safety measures do not compromise security.

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

Safety Fundamentals

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

Safety Requirements

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

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

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

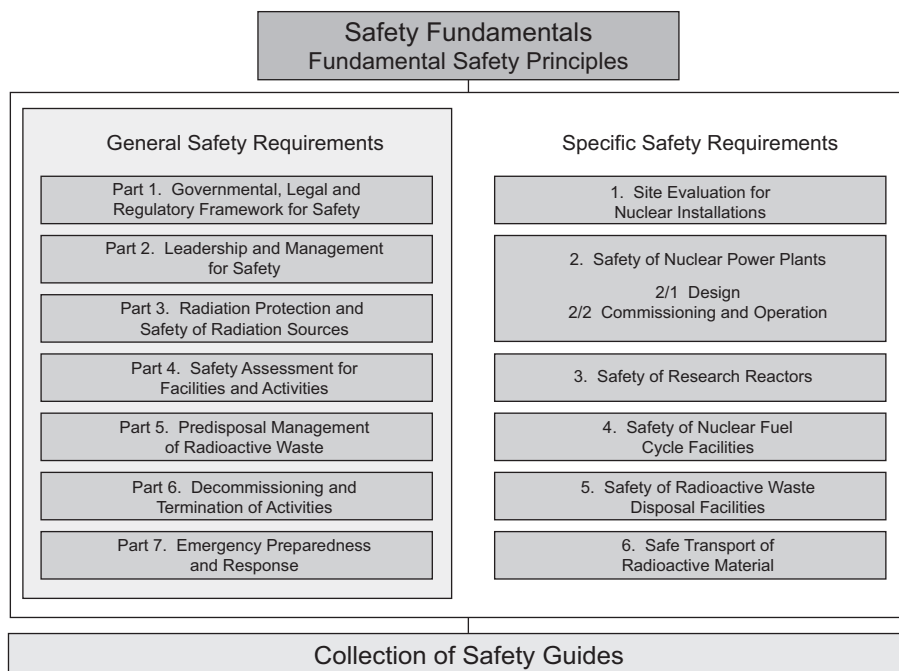


FIG. 1. The long term structure of the IAEA Safety Standards Series.

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).

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

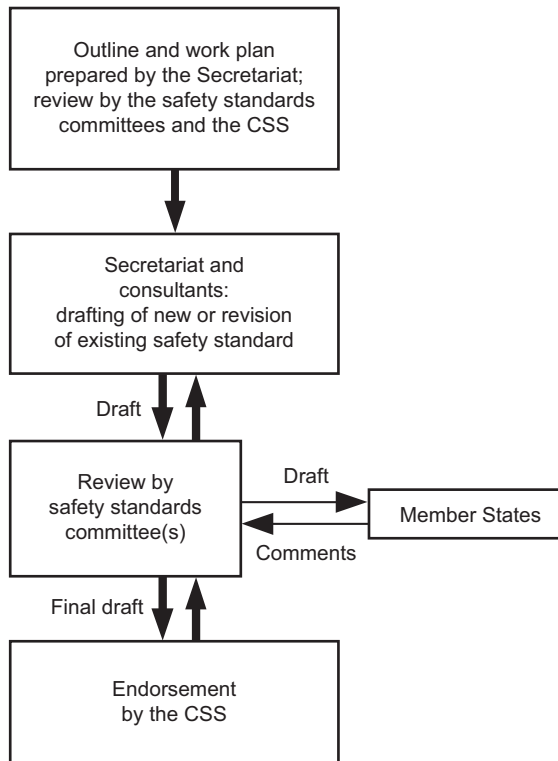


FIG. 2. The process for developing a new safety standard or revising an existing standard.

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. This Safety Guide presents recommendations on the graded approach to application of the safety requirements for research reactors established in the Safety Requirements publication on Safety of Research Reactors¹ [1].

1.2. Research reactors in Member States employ a variety of designs. Operating power levels vary significantly, ranging from a few watts to over a hundred megawatts in a few cases. The inventory of radioactive material may also have a broad range, including not only the radioactive material of the core inventory, but also radioactive material contained in stored spent fuel elements, radioactive waste from radioisotope production and various types of active experimental facility. Utilization of research reactors covers a wide range of activities such as: core physics experiments, training, target material irradiation for materials science, transmutation studies, commercial production of radioisotopes, neutron activation analysis, experiments involving high pressure and temperature loops for fuel and material testing, cold and hot neutron sources, neutron scattering research, and neutron and gamma radiography. These uses call for a variety of different design features and operational regimes. Therefore, site evaluation, design and operating characteristics of research reactors vary significantly.

1.3. Owing to the wide range of utilization activities, the safety requirements for research reactors may not be required to be applied to every research reactor in the same way. For example, the way in which requirements are demonstrated to be met for a multipurpose, high power level research reactor might be very different from the way in which the requirements are demonstrated to be met for a research reactor with very low power and very low associated radiological hazard to facility staff, the public and the environment. Reference [1], which applies to a wide range of research reactors, includes information on the application of the safety requirements in accordance with a graded approach (see paras 1.11–1.14 of Ref. [1]).

¹ “A research reactor is a nuclear reactor used mainly for the generation and utilization of the neutron flux and ionizing radiation for research and other purposes” (footnote 4 of Ref. [1]). In the context of this Safety Guide, the term ‘research reactor’ also includes associated experimental devices and critical assemblies, but excludes reactors used for the production of electricity, naval propulsion, desalination or district heating (see para. 1.7 and footnote 4 of Ref. [1]).

1.4. The general definition and purpose of the graded approach is set out in Ref. [2]. Both parts of the definition are applicable to the safety requirements of Ref. [1]:

- (i) “For a system of control, such as a regulatory system or a safety system, a process or method in which the stringency of the control measures and conditions to be applied is commensurate, to the extent practicable, with the likelihood and possible consequences of, and the level of risk associated with, a loss of control” [2].
- (ii) “An application of safety requirements that is commensurate with the characteristics of the practice or source and with the magnitude and likelihood of the exposures” [2].

1.5. The graded approach in general is a structured method by means of which the stringency of application of requirements is varied in accordance with the circumstances and the regulatory and management systems used. For example, a method in which:

- (i) “The significance and complexity of a product or service are determined” [2];
- (ii) “The potential impacts of a product or service on health, safety, security, the environment, and the achieving of quality and the organization’s objectives are determined” [2];
- (iii) “The consequences if a product fails or if a service is carried out incorrectly are taken into account” [2].

1.6. Guidance has been provided in the past on grading the application of safety requirements. There are a number of historical publications, which are now superseded, relating to grading² and several current IAEA safety standards refer to a graded approach:

— Principle 3 of the Fundamental Safety Principles states that “Safety has to be assessed for all facilities and activities, consistent with a graded approach” (para. 3.15 of Ref. [3]).

² INTERNATIONAL ATOMIC ENERGY AGENCY, Safety Functions and Component Classification for BWR, PWR and PTR, IAEA Safety Series No. 50-SG-D1, IAEA, Vienna (1979); INTERNATIONAL ATOMIC ENERGY AGENCY, Grading of Quality Assurance Requirements, Technical Reports Series No. 328, IAEA, Vienna (1991).

- Principle 5 of the Fundamental Safety Principles states that “The resources devoted to safety by the licensee, and the scope...have to be commensurate with the magnitude of the radiation risks” (para. 3.24 of Ref. [3]).
- Requirement 1 of Ref. [4] states that:

“The government shall establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities.”
- Paragraphs 2.6 and 2.7 of Ref. [5] establish requirements for grading the application of management system requirements, and paras 2.37–2.44, 5.6 and 6.68 of Ref. [6] provide related recommendations.
- Requirement 1 of Ref. [7] states that:

“A graded approach shall be used in determining the scope and level of detail of the safety assessment carried out in a particular State for any particular facility or activity, consistent with the magnitude of the possible radiation risks arising from the facility or activity.”
- Paragraph 3.10 of Ref. [8] states that “in implementing the inspection programme, the regulatory body should establish a graded approach in responding to unforeseen circumstances.”³

OBJECTIVE

1.7. The objective of this Safety Guide is to provide support for the application of the safety requirements for research reactors throughout the various stages of the lifetime of a research reactor (site selection and site evaluation, design, construction, commissioning, operation and decommissioning). The relevant safety requirements are established in Ref. [1], and also in Refs [4, 5, 7]. This Safety Guide is intended for use by regulatory bodies, operating organizations and other organizations involved in the design, construction and operation of research reactors.

³ In some Member States, a graded approach is referred to as ‘proportionality’.

SCOPE

1.8. This Safety Guide presents recommendations on applying a graded approach without compromising safety.

1.9. The application of a graded approach to all of the important activities⁴ throughout the lifetime of a research reactor is discussed. These activities are identified in sections 3–8 of Ref. [1]. A major aspect of the design activity, as described in Section 6 of this Safety Guide, involves the grading of specific requirements for design of structures, systems and components (SSCs) for particular reactor types, so that the safety objectives set out in para. 2.2 of Ref. [1] are achieved. Recommendations on the application of grading to reactor hardware and equipment (SSCs), as opposed to activities in general, are also provided in Section 6.

1.10. In this Safety Guide, it is considered that all relevant safety requirements have to be complied with in applications of a graded approach. The graded approach should be used to determine the appropriate manner to comply with a requirement; it is not used to provide relief from meeting the requirement. To eliminate a requirement for the purposes of identifying all relevant safety requirements, a waiving⁵ process, as suggested in para 1.10 of Ref. [1], can be used.

STRUCTURE

1.11. Section 2 provides the description of the basic elements of a graded approach and its application. The remaining sections provide recommendations on the application of a graded approach to regulatory supervision (Section 3); management and verification of safety (Section 4); site evaluation (Section 5); design (Section 6); operation (Section 7); and decommissioning (Section 8). Sections 3–8 have titles identical to the corresponding sections of Ref. [1].

⁴ ‘Activities’, in the context of this Safety Guide, include all of the stages needed to achieve the purpose for which the nuclear research reactor was designed and constructed or modified (see footnote 2 of Ref. [1]). Reference [5] uses a more general definition of activities that encompasses “any...practices or circumstances in which people may be exposed to radiation”.

⁵ ‘Waiving’ is sometimes called ‘grading to zero’, implying complete elimination of a requirement.

1.12. Each section of this Safety Guide begins with a brief description of the relevant safety requirements established in Ref. [1] and, in some areas, a summary of additional requirements established in other IAEA Safety Requirements publications. The descriptions are followed by a discussion of grading in the application of the requirements.

2. BASIC ELEMENTS OF THE APPROACH TO GRADING

GENERAL CONSIDERATIONS REGARDING THE CONCEPT OF GRADING

2.1. A graded approach is applicable in all stages of the lifetime of a research reactor (see para. 1.7).

2.2. During the lifetime of a research reactor, any grading that is performed should be such that safety functions and operational limits and conditions are preserved, and such that there are no undue radiological hazards to workers, the public or the environment.

2.3. The grading of activities should be based on safety analyses, regulatory requirements and engineering judgement. Engineering judgement implies that account is taken of the safety functions of SSCs and the consequences of failure to perform these functions, and implies that the judgement is documented. Other elements to be considered in grading are the complexity and the maturity of the technology, operating experience associated with the activities and the stage in the lifetime of the facility.

DESCRIPTION OF THE APPLICATION OF A GRADED APPROACH

2.4. This Safety Guide does not recommend the use of a quantitative ranking procedure in grading the safety requirements. The application of the graded approach will determine the appropriate effort to be expended and appropriate manner of complying with a requirement, in accordance with the attributes of the facility.

2.5. The application of grading presented in this Safety Guide begins with categorization of the facility in accordance with its potential hazard (Step 1). In this step, a facility can initially be categorized into a range from facilities posing the highest risk to those posing the lowest risk. This categorization serves to provide an initial grading of the facility. The next step (Step 2) is analysis and grading of activities and/or SSCs important to safety. This second step provides more detailed grading to be applied to the particular characteristics of the facility.

Step 1: Categorization of the facility in accordance with potential hazards

2.6. Qualitative categorization of the facility should be performed on the basis of the potential radiological hazard, using a multi-category system similar to that set out in para. 1.11 of Ref. [9]:

- (a) Facilities with off-site radiological hazard potential;
- (b) Facilities with on-site radiological hazard potential only;
- (c) Facilities with no radiological hazard potential beyond the research reactor hall and associated beam tubes or connected experimental facility areas.

2.7. The individual characteristics, or attributes, to be considered in deriving the category of the facility in accordance with its hazard are typically as follows (see para 1.14 of Ref. [1]):

- (a) The reactor power (for pulsed reactors, energy deposition is typically used, while for accelerator driven subcritical systems, thermal power is typically used);
- (b) The radiological source term;
- (c) The amount and enrichment of fissile material and fissionable material;
- (d) Spent fuel storage areas, high pressure systems, heating systems and the storage of flammables, which may affect the safety of the reactor;
- (e) The type of fuel and its chemical composition;
- (f) The type and mass of moderator, reflector and coolant;
- (g) The amount of reactivity that can be introduced and its rate of introduction, reactivity control, and inherent and engineered safety features;
- (h) The quality of the containment structure or other means of confinement;
- (i) The utilization of the reactor (experimental devices, tests, radioisotope production, reactor physics experiments);
- (j) The location of the site, including the potential for external hazards (including those due to the proximity of other nuclear facilities) and the characteristics of airborne and liquid releases of radioactive material;

- (k) Proximity to population groups and the feasibility of implementing emergency plans.

Step 2: Analysis and grading

2.8. In this step, the level of detail at which requirements are applied to activities and/or SSCs is determined, in accordance with the importance to safety of the activity or SSC. The level of detail covers, for example, the rigour of the analysis to be conducted, the frequency of activities such as testing and preventive maintenance, the stringency of required approvals and the degree of oversight of activities.

2.9. The appropriateness of applying a graded approach should be determined through analysis for each of the major activities and SSCs set out in sections 3–8 of Ref. [1]. The application of grading should be commensurate with the importance to safety of the activities and SSCs, and with the magnitude of the associated radiological risks.

2.10. The safety functions⁶ performed by each item important to safety⁷ should be identified (see para. 2.11(b) of Ref. [10]). A starting point for assessing the importance to safety of activities and SSCs is conducting a safety assessment⁸.

2.11. Paragraphs 6.12 and 6.13 of Ref. [1] state that all SSCs (including software for instrumentation and control) that are important to safety are required first to be identified and then to be classified according to their function and significance for safety. The classification of SSCs, including software, in a research reactor

⁶ See annex I of Ref. [1].

⁷ An item important to safety is an “item that is part of a safety group and/or whose malfunction or failure could lead to radiation exposure of the site personnel or members of the public...Items important to safety include:

- Those structures, systems and components whose malfunction or failure could lead to undue radiation exposure of site personnel or members of the public;
- Those structures, systems and components that prevent anticipated operational occurrences from leading to accident conditions;
- Those features that are provided to mitigate the consequences of malfunction or failure of structures, systems and components” [2].

⁸ Guidance on this subject is provided in Ref. [11].

facility should be based on the safety function(s)⁹ performed by the SSC and on the consequences of the SSC's failure to perform its function. Analytical techniques together with engineering judgement (see para. 2.3) should be used to evaluate these consequences. The basis for the safety classification of SSCs, including software, should be stated and the engineering design rules applied should be commensurate with their safety class.

2.12. "The application of management system requirements shall be graded so as to deploy appropriate resources, on the basis of the consideration of:

- The significance and complexity of each product or activity;
- The hazards and the magnitude of the potential impact (risks) associated with the safety, health, environmental, security, quality and economic elements of each product or activity;
- The possible consequences if a product fails or an activity is carried out incorrectly" (para. 2.6 of Ref. [5]).

2.13. "Grading of the application of management system requirements shall be applied to the products and activities of each process" (para. 2.7 of Ref. [5]). Where these activities involve modifications or experiments, further categorization should be carried out (see para. 7.49 of this Safety Guide).

3. REGULATORY SUPERVISION

3.1. The requirements for the legal and regulatory infrastructure for a broad range of facilities and activities are established in Ref. [4]. Additional guidance is provided in the associated Safety Guides (Refs [12–15]). Owing to the broad applicability of the requirements and recommendations in these publications, not all will apply to the nuclear activities in all States. In each State, the requirements and recommendations that are applicable for the regulatory supervision of its nuclear programme should be identified. For the purpose of this Safety Guide, the

⁹ The safety functions are essential, characteristic functions associated with SSCs for ensuring the safety of the reactor and are one of the key elements in grading the application of requirements to SSCs. Some safety functions may not be relevant for some types of research reactors.

applicable safety requirements are those for the regulatory supervision of research reactors that are established in section 3 of Ref. [1], and include the following:

- Legal infrastructure;
- The regulatory body;
- The licensing process;
- The programme for inspection and enforcement.

APPLICATION OF GRADING TO LEGAL INFRASTRUCTURE

3.2. The requirements for the legal infrastructure are established in para. 3.2 of Ref. [1], and in Requirement 3 on establishment of a regulatory body and Requirement 4 on independence of the regulatory body in Ref. [4]. The application of these requirements cannot be graded.

APPLICATION OF GRADING TO THE REGULATORY BODY

3.3. A graded approach should be applied in establishing the regulatory body and determining aspects of its organizational framework, based on the potential hazards of all of the facilities and activities under its supervision or oversight.

3.4. The regulatory body is required to be provided with sufficient authority and power, and a sufficient number of experienced staff and financial resources to discharge its assigned responsibilities (para 2.8 of Ref. [4]). The responsibilities of the regulatory body include establishing regulations, review and assessment of safety related information (e.g. from the safety analysis report), issuing licences, performing compliance inspections, taking enforcement actions and providing information to other competent authorities and the public. External experts, technical support organizations or advisory committees may assist the regulatory body in these activities¹⁰.

3.5. Examples of the regulatory organization, associated activities and requirements that can be graded are: requirements for staffing, resources for in-house technical support, compliance inspections, the content and detail of

¹⁰ The IAEA provides safety review services to governments of Member States, regulatory bodies and operating organizations.

licences, regulations and guides, and the detail required of the licensee for submissions of documentation on safety of the facility, including the safety analysis report.

APPLICATION OF GRADING TO THE LICENSING PROCESS

3.6. The licensing process is often performed in steps for the various stages of the lifetime of a research reactor, as described in paras 3.4 and 3.5 of Ref. [1], and in Ref. [15]. For a research reactor, these stages are site approval, authorization of construction¹¹, authorization of commissioning, authorization of initial and routine operation, and all proposed modifications, and authorization of decommissioning.

3.7. At each of these stages, regulatory evaluations are usually made and authorizations or approvals are issued. In some cases, the stages may be combined, depending on the nature of the facility and relevant laws and regulations. This practice is consistent with the concept of the graded approach.

3.8. The licensing process should be used by the regulatory body to exercise control during all stages of the lifetime of the research reactor [15]. This control is accomplished by means of the following:

- Clearly defined lines of authority for authorizations to proceed;
- Review and assessment of all safety relevant documents, particularly the safety analysis report;
- Issue of permits and licences, for the various stages;
- Hold points for inspections, review and assessment;
- Review, assessment and approval of operational limits and conditions;
- Commissioning authorization;
- Operating licence;
- Licensing of operating personnel;
- Decommissioning licence.

3.9. The steps in the licensing process apply to all research reactors, including all proposed experiments and design modifications, at all stages of the reactor lifetime. However, at each step in the licensing process, a graded approach should

¹¹ In some States, design and manufacturing activities are included in the licensing process.

be taken by the regulatory body in determining the scope, extent, level of detail and effort that should be used, depending on the magnitude of the potential risks (see paras 2.19(h) and 2.46–2.50 of Ref. [15]). For example, in general, there will be fewer inspections and hold points for a research reactor with a power level less than 100 kW, compared to those for a research reactor with a power level greater than 5 MW.

3.10. Detailed recommendations on the application of a graded approach to the regulatory review of the safety assessment in support of the licence for decommissioning of a research reactor are provided in paras 5.6–5.8 of Ref. [16].

APPLICATION OF GRADING TO INSPECTION AND ENFORCEMENT

3.11. The requirements for inspection and enforcement are established in paras 3.14–3.16 of Ref. [1]. For inspections, Ref. [1] states that “The regulatory body shall establish a planned and systematic inspection programme. The scope of this programme and frequency of inspections shall be commensurate with the potential hazard posed by the research reactor” and particular situations such as organizational changes or personnel turnover. Reference [8] recommends in para. 3.14 that “Inspections by the regulatory body should be concentrated on areas of safety significance” and in para 3.10 that “the regulatory body should establish a graded approach in responding to unforeseen circumstances.”

3.12. Enforcement actions should also be graded, since the severity and impact on safety of non-compliance with the requirements of an authorization may vary. Regulatory bodies should allocate resources and apply enforcement actions or methods in a manner commensurate with the seriousness of the non-compliance, increasing them as necessary to bring about compliance with requirements. A graded approach should be applied with respect to the corrective action process for non-conformances, to ensure that problems of the highest significance are afforded the most critical evaluation (see para. 6.68 of Ref. [6]).

3.13. Some of the factors to consider in the grading of enforcement actions are:

- The safety significance or seriousness of the deficiency or violation;
- The need for timeliness of corrective actions to restore compliance;
- The frequency of this or other violations, or the degree of recidivism;

- Who identified and reported the non-compliance, i.e. whether the non-compliance was reported by an operator or identified by an inspector;
- The need for consistency and transparency in the treatment of operators and licences;
- The complexity of the remedial, corrective or preventive action needed.

3.14. In contrast to the factors in para 3.13, enforcement actions for violation of a regulatory requirement should not be graded. This is necessary to hold regulatory compliance in the highest regard.

4. MANAGEMENT AND VERIFICATION OF SAFETY

4.1. Section 4 of Ref. [1] establishes the requirements on the elements of the management and verification of safety to be considered, the responsibilities of the operating organization and the interaction with the regulatory body. Requirements are also established in Ref. [5], and recommendations and guidance for the management system and verification of safety are also provided in Refs [6, 17, 18]. For management of safety, at a minimum:

“the operating organization shall:

- (a) Establish and implement safety policies and ensure that safety matters are given the highest priority;
- (b) Clearly define responsibilities and accountabilities with corresponding lines of authority and communication;
- (c) Ensure that it has sufficient staff with appropriate education and training at all levels;
- (d) Develop and strictly adhere to sound procedures for all activities that may affect safety, ensuring that managers and supervisors promote and support good safety practices while correcting poor safety practices;
- (e) Review, monitor and audit all safety related matters on a regular basis, implementing appropriate corrective actions where necessary;
- (f) Be committed to safety culture on the basis of a statement of safety policy and safety objectives which is prepared and disseminated and is understood by all staff.” (para. 4.1 of Ref. [1]).

4.2. The management system should provide for a process for assessment and verification of safety, including periodic safety review at an interval specified by the regulatory body. The basis for the assessment should include, inter alia, data derived from the safety analysis report and other information (e.g. the operational limits and conditions, the radiation protection programme, the emergency plan, operating procedures and training documentation).

4.3. Such assessments should include consideration of modifications to SSCs and their cumulative effects. Additional safety related aspects that should be included in the assessment are changes to procedures, radiation protection measures, regulations and standards; ageing effects; operating experience; lessons learned from similar reactors; technological developments; site re-evaluation; physical protection; and emergency planning. Requirements on assessment and verification of safety for research reactors are established in paras 4.14–4.16 (for general purpose and scope) and in paras 7.108–7.110 (for operational issues) of Ref. [1].

APPLICATION OF GRADING TO THE MANAGEMENT OF SAFETY

4.4. Grading of the scope and content of activities making up the elements of management of safety¹², such as items (a)–(f) in para. 4.1, is possible while still meeting the requirement that they be comprehensive. For example, in item (c) of para. 4.1, grading is clearly essential in specifying the staffing levels required for operations and maintenance. Requirements for staff education and training should be based on the operating schedule and the complexity of the facility. The latter is determined, in particular, on the basis of the research reactor power level, the extent of isotope production and the scope of experimental facilities. In addition, grading can be applied to determine the depth, frequency and type of safety assessments, in-service inspections and auditing of all safety related matters.

¹² In Ref. [1], the term ‘quality assurance’ was used. References [5, 6] were issued later, and adopted the term ‘management system’ instead. The term ‘management system’ reflects and includes the initial concept of ‘quality control’ (controlling the quality of products) and its evolution through ‘quality assurance’ (the system to ensure the quality of products) and ‘quality management’ (the system to manage quality). The management system is a set of interrelated or interacting elements that establishes policies and objectives, and which enables those objectives to be achieved in a safe, efficient and effective manner.