IAEA Safety Standards

for protecting people and the environment

Licensing Process for Nuclear Installations

Specific Safety Guide

No. SSG-12

IAEA
International Atomic Energy Agency

IAEA SAFETY RELATED PUBLICATIONS

IAEA SAFETY STANDARDS

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

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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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LICENSING PROCESS FOR NUCLEAR INSTALLATIONS

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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-12

LICENSING PROCESS FOR NUCLEAR INSTALLATIONS

SPECIFIC SAFETY GUIDE

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FOREWORD

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

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

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

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

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

THE IAEA SAFETY STANDARDS

BACKGROUND

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

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

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

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

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

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

THE IAEA SAFETY STANDARDS

The status of the IAEA safety standards derives from the IAEA's Statute, which authorizes the IAEA to establish or adopt, in consultation and, where appropriate, in collaboration with the competent organs of the United Nations and with the specialized agencies concerned, standards of safety for protection

of health and minimization of danger to life and property, and to provide for their application.

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

Safety measures and security measures[1] have in common the aim of protecting human life and health and the environment. Safety measures and security measures must be designed and implemented in an integrated manner so that security measures do not compromise safety and safety measures do not compromise security.

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

Safety Fundamentals

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

Safety Requirements

An integrated and consistent set of Safety Requirements establishes the requirements that must be met to ensure the protection of people and the environment, both now and in the future. The requirements are governed by the objective and principles of the Safety Fundamentals. If the requirements are not met, measures must be taken to reach or restore the required level of safety. The format and style of the requirements facilitate their use for the establishment, in a harmonized manner, of a national regulatory framework. Requirements, including numbered 'overarching' requirements, are expressed

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

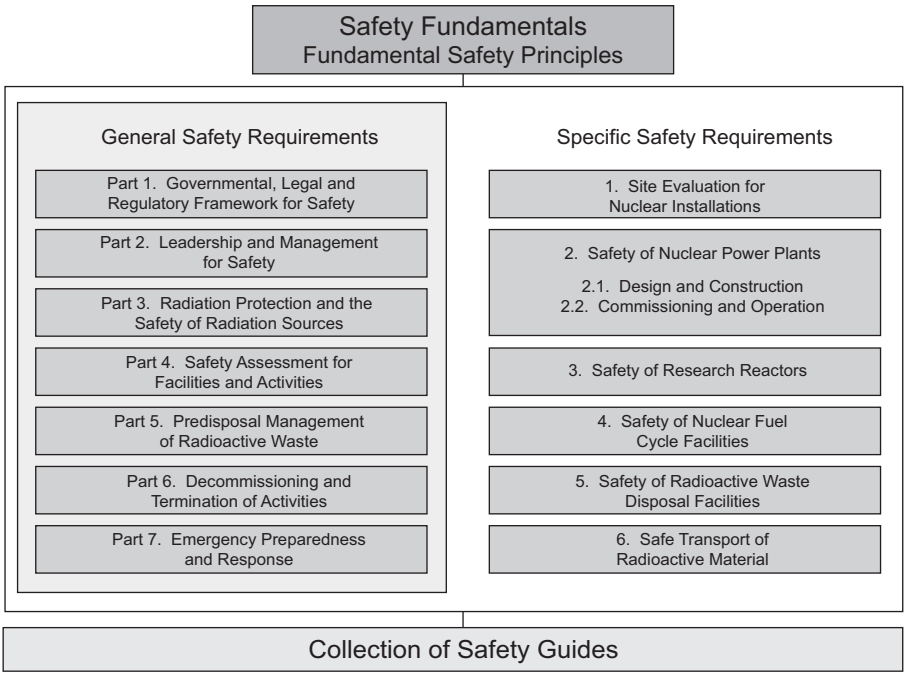

FIG. 1. The long term structure of the IAEA Safety Standards Series.

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

Safety Guides

Safety Guides provide recommendations and guidance on how to comply with the safety requirements, indicating an international consensus that it is necessary to take the measures recommended (or equivalent alternative measures). The Safety Guides present international good practices, and increasingly they reflect best practices, to help users striving to achieve high levels of safety. The recommendations provided in Safety Guides are expressed as 'should' statements.

APPLICATION OF THE IAEA SAFETY STANDARDS

The principal users of safety standards in IAEA Member States are regulatory bodies and other relevant national authorities. The IAEA safety

standards are also used by co-sponsoring organizations and by many organizations that design, construct and operate nuclear facilities, as well as organizations involved in the use of radiation and radioactive sources.

The IAEA safety standards are applicable, as relevant, throughout the entire lifetime of all facilities and activities — existing and new — utilized for peaceful purposes and to protective actions to reduce existing radiation risks. They can be used by States as a reference for their national regulations in respect of facilities and activities.

The IAEA's Statute makes the safety standards binding on the IAEA in relation to its own operations and also on States in relation to IAEA assisted operations.

The IAEA safety standards also form the basis for the IAEA's safety review services, and they are used by the IAEA in support of competence building, including the development of educational curricula and training courses.

International conventions contain requirements similar to those in the IAEA safety standards and make them binding on contracting parties. The IAEA safety standards, supplemented by international conventions, industry standards and detailed national requirements, establish a consistent basis for protecting people and the environment. There will also be some special aspects of safety that need to be assessed at the national level. For example, many of the IAEA safety standards, in particular those addressing aspects of safety in planning or design, are intended to apply primarily to new facilities and activities. The requirements established in the IAEA safety standards might not be fully met at some existing facilities that were built to earlier standards. The way in which IAEA safety standards are to be applied to such facilities is a decision for individual States.

The scientific considerations underlying the IAEA safety standards provide an objective basis for decisions concerning safety; however, decision makers must also make informed judgements and must determine how best to balance the benefits of an action or an activity against the associated radiation risks and any other detrimental impacts to which it gives rise.

DEVELOPMENT PROCESS FOR THE IAEA SAFETY STANDARDS

The preparation and review of the safety standards involves the IAEA Secretariat and four safety standards committees, for nuclear safety (NUSSC), radiation safety (RASSC), the safety of radioactive waste (WASSC) and the safe transport of radioactive material (TRANSSC), and a Commission on Safety Standards (CSS) which oversees the IAEA safety standards programme (see Fig. 2).

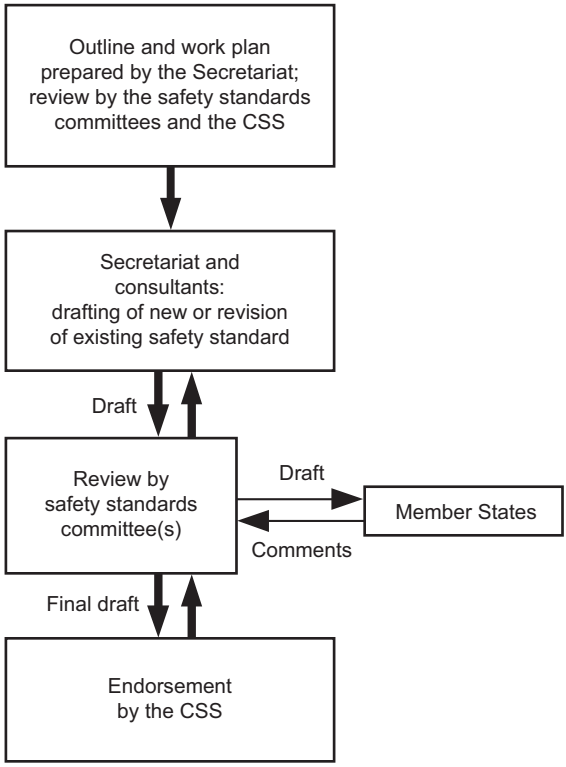

FIG. 2. The process for developing a new safety standard or revising an existing standard.

All IAEA Member States may nominate experts for the safety standards committees and may provide comments on draft standards. The membership of the Commission on Safety Standards is appointed by the Director General and includes senior governmental officials having responsibility for establishing national standards.

A management system has been established for the processes of planning, developing, reviewing, revising and establishing the IAEA safety standards. It articulates the mandate of the IAEA, the vision for the future application of the safety standards, policies and strategies, and corresponding functions and responsibilities.

INTERACTION WITH OTHER INTERNATIONAL ORGANIZATIONS

The findings of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the recommendations of international

expert bodies, notably the International Commission on Radiological Protection (ICRP), are taken into account in developing the IAEA safety standards. Some safety standards are developed in cooperation with other bodies in the United Nations system or other specialized agencies, including the Food and Agriculture Organization of the United Nations, the United Nations Environment Programme, the International Labour Organization, the OECD Nuclear Energy Agency, the Pan American Health Organization and the World Health Organization.

INTERPRETATION OF THE TEXT

Safety related terms are to be understood as defined in the IAEA Safety Glossary (see http://www-ns.iaea.org/standards/safety-glossary.htm). Otherwise, words are used with the spellings and meanings assigned to them in the latest edition of The Concise Oxford Dictionary. For Safety Guides, the English version of the text is the authoritative version.

The background and context of each standard in the IAEA Safety Standards Series and its objective, scope and structure are explained in Section 1, Introduction, of each publication.

Material for which there is no appropriate place in the body text (e.g. material that is subsidiary to or separate from the body text, is included in support of statements in the body text, or describes methods of calculation, procedures or limits and conditions) may be presented in appendices or annexes.

An appendix, if included, is considered to form an integral part of the safety standard. Material in an appendix has the same status as the body text, and the IAEA assumes authorship of it. Annexes and footnotes to the main text, if included, are used to provide practical examples or additional information or explanation. Annexes and footnotes are not integral parts of the main text. Annex material published by the IAEA is not necessarily issued under its authorship; material under other authorship may be presented in annexes to the safety standards. Extraneous material presented in annexes is excerpted and adapted as necessary to be generally useful.

CONTENTS

1. INTRODUCTION

BACKGROUND

1.1. Achievement of the highest level of safety that can reasonably be achieved in site evaluation, design, construction, commissioning, operation, modification, decommissioning and release from regulatory control of nuclear installations and related activities requires: a sound legal basis; qualified vendors, manufacturers and operating organizations; and an appropriate governmental infrastructure, including a regulatory body with well defined responsibilities and functions. Authorization of specific activities and nuclear installations, or parts of them, through a process of licensing is one of the principal functions of a regulatory body. This licensing process may result in the granting of one or more licences during the lifetime of a nuclear installation, depending on national regulations and laws.

1.2. This Safety Guide supplements and provides recommendations on meeting the requirements relating to authorization by the regulatory body (Requirements 7, 23 and 24) established in Ref. [1].

1.3. Figure 1 shows the main stages dealt with in this Safety Guide regarding the licensing process. Past experience has shown that there is some overlapping of these stages; that is, one stage may start before the previous one is fully completed. Moreover, in a given stage, there may be one or more 'hold points', set by national legislation and regulatory requirements. These hold points give the regulatory body the power to ensure that risks to the health and safety of people and to the environment from nuclear installations and their activities are properly controlled by the persons or organizations responsible for the nuclear installations and their activities.

OBJECTIVE

1.4. The purpose of this Safety Guide is to provide:

(a) Recommendations on developing the basis of a licensing process to be applied by regulatory bodies for granting licences for nuclear installations and their activities, including some aspects of regulatory control;

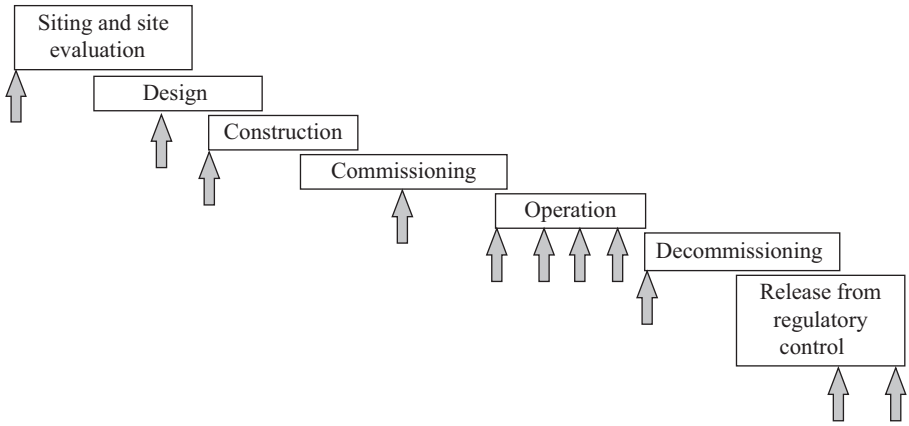

FIG. 1. Stages in the lifetime of a nuclear installation; the arrows indicate where hold points may be imposed.

(b) As much information as is practicable on the topics and documents that should be considered in the licensing process throughout the lifetime of the nuclear installation, irrespective of the number of licensing steps or hold points imposed on the licensee.

SCOPE

1.5. This Safety Guide describes how the licensing process should be applied at the various stages of the lifetime of a nuclear installation, with discussion of the topics and required documents to be considered at each stage (siting and site evaluation, design, construction, commissioning, operation, decommissioning and release from regulatory control). Some of these stages may be grouped together, depending on national regulations. Complementary detailed information can be found in other IAEA publications, including those referenced in this Safety Guide. Recommendations on the application by a regulatory body of a graded approach to the licensing process are also provided in this Safety Guide.

1.6. This Safety Guide describes the processes that should be undertaken to meet the regulatory and legal requirements in a Member State to authorize the establishment of a nuclear installation and initiation of its activities. Throughout the nuclear installation's lifetime, interactions between the regulatory body and the licensee may lead to changes or modifications to improve safety. Both in establishing the requirements for the licensing process and in developing the

process itself, account should be taken of the graded approach described in Section 2.

1.7. While this Safety Guide focuses on safety at nuclear installations, integration of safety and security aspects should be considered and evaluated by the regulatory body during the licensing process. The IAEA Nuclear Security Series covers security issues at authorized installations.

STRUCTURE

1.8. General recommendations on the licensing process, including basic licensing principles, the content of a licence, public participation, and the roles and responsibilities of the regulatory body, applicant and licensee, are provided in Section 2. Recommendations specific to the various steps of the licensing process are provided in Section 3.

2. GENERAL RECOMMENDATIONS ON THE LICENSING PROCESS

DEFINITIONS

2.1. A licence is a legal document issued by the regulatory body granting authorization to create a nuclear installation and to perform specified activities. The regulatory body, whose status may vary from one State to another, is an authority or a system of authorities designated by the government of a State as having legal authority to conduct the regulatory process, including issuing authorizations [2].

2.2. A licence is a product of the authorization process, generally covering a particular stage of the lifetime of a nuclear installation. The term ‘licensing process’ is often used for nuclear installations; it includes all licensing and authorization processes for a nuclear installation and its activities. In this Safety Guide, the terms ‘licence’, ‘authorization’ and ‘permit’ are considered to be synonymous; authorization may take different forms, such as certification, granting of a permit, agreement, consent, regulatory approval or granting of

another similar regulatory instrument, depending on the governmental and regulatory framework of the particular State.

2.3. The holder of a current and valid licence is termed a licensee. The licensee is the person or organization having overall responsibility for a nuclear installation and its activities and possessing all necessary licences for the installation and its activities. The person or organization having overall responsibility for a nuclear installation needs to apply to the regulatory body for permission to begin or continue to carry out certain activities, as specified by the regulatory body. A licensee may lose its licence for operation, for instance, but should not be released from its prime responsibility for safety and security unless so specified by the regulatory body.

2.4. An applicant is a person or organization who applies to a regulatory body for authorization to establish a nuclear installation, or parts of a nuclear installation, or to undertake specified activities.

2.5. Licences and authorizations, as defined in para. 2.2, should be granted or denied in accordance with the national legal and governmental framework and should cover all stages of the lifetime of the nuclear installation, namely, site evaluation, design, construction, commissioning, operation, decommissioning and subsequent release of the site from regulatory control.

BASIC LICENSING PRINCIPLES

2.6. The licensing process should be understood by the parties concerned and should be predictable (i.e. well defined, clear, transparent and traceable). The licensing process should be established in a systemic way to facilitate efficient progression of regulatory activities. The steps of the licensing process should be discrete and should follow a logical order. In developing a licensing process, consideration might be given to adoption or adaptation of 'pre-licensing' processes, for example, steps that provide for early approval of sites and advance certification of standardized plant designs for authorization for construction and operation of a nuclear installation. Such a licensing process may help to minimize duplication of effort through the different steps and may allow for some steps to be conducted in parallel. It also provides for a clear division of responsibilities, at the various steps, between regulators, vendors and operators; gives the public opportunities for early participation; and ensures that the most important safety issues are dealt with properly in the pre-licensing phase. Further

recommendations on such alternative approaches to licensing are provided in para. 3.2 of this Safety Guide.

2.7. Licences may be granted:

(a) For a specific time period (e.g. 10 years, 40 years), or for a specific stage in the lifetime of the nuclear installation (e.g. construction, operation). In such a case, a mechanism should be put in place to ensure that the person or organization responsible for the nuclear installation and its activities remains responsible for safety and security at the installation, even if the licence has expired, unless the site has been removed from regulatory control.
(b) For an indefinite period of time (a permanent licence), under certain conditions and until the licence is officially terminated by the regulatory body.
(c) For a specific activity or a specific condition of the nuclear installation (e.g. temporary storage of spent fuel).

2.8. The licensing process involves fulfilment of a set of regulatory requirements applicable to a nuclear installation and formal submissions by an applicant. The licensing process may also include agreements and commitments made between the regulatory body and the applicant (e.g. in the form of letters exchanged or statements made in technical meetings).

2.9. The legal framework of the State should set out the responsibilities for issuing a licence or authorization and, in particular, determine who is empowered to issue licences or other authorizations. Depending on the system used in the particular State, different authorizations may be issued by different authorities.

2.10. Once an application has been accepted and the initial licence has been issued, subsequent licensing process activities and arrangements should be undertaken between the licensee and the regulatory body. These will include requests for carrying out further activities, including, in some States, the construction of additional facilities on the site.

2.11. Reference [1] states that:

> "Authorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all those facilities and activities that are not either explicitly exempted or approved by means of a notification process" (Requirement 23).

> "The applicant shall be required to submit an adequate demonstration of safety in support of an application for the authorization of a facility or an activity" (Requirement 24).

Furthermore, Ref. [1] states that:

> "Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties" (Requirement 7).

2.12. The objective of granting authorizations in the licensing process is for the regulatory body to establish regulatory control over all activities and facilities where safety is concerned. Laws and practices relating to licensing aspects vary among States. Licences, authorizations, permits and other regulatory instruments are the principal documents issued by the regulatory body that, at each step of the licensing process, relate the legal and regulatory framework to the duties of the person or organization responsible for the nuclear installation and its activities. Authorizations enable effective regulatory control of facilities and activities.

2.13. Procedures for issuing authorizations for each stage of the lifetime of the installation and for each type of installation should be prepared by the regulatory body, to ensure that all necessary steps have been taken prior to the granting of a licence.

2.14. Licence conditions are additional specific obligations with the force of law. Licence conditions should be incorporated into the licence, to supplement general requirements or to make them more precise, if necessary. Licences should state explicitly, or should include by reference or attachment, all conditions imposed by the regulatory body.

2.15. Licence conditions should cover, as appropriate, safety related aspects affecting the site evaluation, design, construction, commissioning, operation and decommissioning of the nuclear installation and its subsequent release from regulatory control, so as to enable effective regulatory control at all stages. These requirements should cover, among other things, important aspects such as design, radiation protection, maintenance programmes, emergency planning and procedures, modifications, the management system, operational limits and conditions, procedures and authorization of personnel. Furthermore, licence

conditions may refer to, but should not duplicate, regulations, to avoid discrepancies or inconsistencies when the regulations are amended.

2.16. While licence conditions may vary in format, there are certain basic qualities and definitions that should characterize the set of conditions, to make them understandable and effective. Each licence condition should be consistent with all other licence conditions in that the fulfilment of one should not conflict with the fulfilment of another or with any other legal requirement. In the event that it is necessary to specify several licence conditions addressing various technical and administrative aspects, it may be useful to group the conditions into categories, such as:

— Licence conditions that set technical limits and thresholds;
— Licence conditions that specify procedures and modes of operation;
— Licence conditions pertaining to administrative matters;
— Licence conditions relating to inspection and enforcement;
— Licence conditions pertaining to the response to abnormal circumstances.

2.17. On a particular site, there may be different nuclear installations at different stages of their lifetimes with different licensees and with authorizations or licences having different licensing bases, depending on the type of regulatory control established in the State. However, when different authorizations and licences are granted for different installations on a particular site, a process for keeping all of them consistent should be put in place. In cases where several licensees share common safety related features, arrangements should be made to ensure that overall safety is not compromised.

2.18. The documents submitted to the regulatory body in the framework of the licensing process should be updated, as appropriate, during the lifetime of the nuclear installation. These documents should be incorporated as part of the licence, if necessary; the content of such submissions to the regulatory body may be divided or combined into different documents, as appropriate, depending on national regulations, regulatory regimes and practices. A generic list of such documents is included in the Appendix to this Safety Guide; the content and names of these documents may vary from one State to another. The safety analysis report is an important document for the entire licensing process; however, this Safety Guide aims to focus on the content of licences, acceptance criteria and the topics to be dealt with in the licensing process rather than on the format of documents.

2.19. Licensing principles should be established in the regulatory and legal framework. Examples of licensing principles are the following:

(a) A facility and/or activity should be authorized only when the regulatory body has confirmed that the facility or activity is going to be used or conducted in a manner that does not pose an undue risk to workers, the public or the environment. This should include confirmation that the applicant has the organizational capability, organizational structures, adequacy of resources, competence of managers and staff, and appropriateness of management arrangements to fulfil its safety obligations as a nuclear operator.
(b) The regulatory framework for dealing with authorization requests should be clear, especially the process for applying for a licence or authorization.
(c) The regulatory regime (prescriptive, non-prescriptive or goal setting) for the licensing process should be explicitly established by regulation and by the regulatory body.
(d) The licensing of a nuclear installation should be based on predefined documents that are submitted to the regulatory body by the person or organization responsible for the nuclear installation and its activities. These documents should be reviewed by the regulatory body and, where required, should be updated regularly by the licensee, as indicated in licence conditions or regulations.
(e) Expenses associated with the licensing process and the person or organization that will be charged these expenses should be clearly specified.
(f) A clear and explicit set of requirements, criteria and standards forming the licensing basis should be defined by regulation and by the regulatory body.
(g) Physical protection and security requirements should be predefined and should be considered in the licensing process.
(h) A graded approach should be taken by the regulatory body when performing reviews, assessments or inspections throughout the authorization or licensing process. Such an approach should be reflected in regulations and guides, and the extent of reviews, assessments or inspections should be appropriate to the magnitude and the nature of the hazard and the risk posed by the nuclear installation.
(i) The licensing process should be transparent to the public, and any licence or authorization should be published or made available to the public by other means, except for security sensitive and commercial proprietary information.

(j) The scope of the licence (the site, a nuclear installation, parts of a nuclear installation and activities, or a series of authorizations), its validity period and any incorporated conditions should be clearly defined by the regulatory body.
(k) The regulatory body should include conditions in the licence, as appropriate.
(l) A licence may be transferred, depending on national regulations; however, this should be done only with the authorization of the regulatory body, which may attach provisions and conditions to the transfer.
(m) The applicant and the regulatory body should take into account international good practices, as appropriate, throughout the licensing process.
(n) The analysis approach to safety should be clearly defined, including the use of deterministic and probabilistic methodologies and analytical tools.
(o) Safety reviews should be carried out by the licensee either on a periodic basis or as required by the regulatory body, and the results should be submitted to the regulatory body for review and assessment. Appropriate regulatory decisions may then follow, including a decision to suspend operation, if doing so is deemed necessary.
(p) The prime responsibility for safety is assigned to and assumed by the person or organization responsible for any facilities and activities that give rise to radiation risks [3]. Compliance with regulations and requirements imposed by the regulatory body does not relieve the person or organization responsible for any nuclear installations and their activities of the prime responsibility for safety. The person or organization responsible for any nuclear installations and their activities should demonstrate to the satisfaction of the regulatory body that this prime responsibility has been and will continue to be fulfilled.
(q) Clear conditions should be established for public participation in the licensing process.
(r) Integration of safety and security should be addressed, and the licensee's proposed means of addressing this integration should be evaluated by the regulatory body in the licensing process.
(s) The means of challenging or appealing against a licence or part of a licence should be made clear by the regulatory body or within the regulatory framework.

2.20. The legislative and regulatory framework should require unfettered access for regulatory staff to any facility, any activity and any documents related to safety and considered necessary for granting licences and authorizations.

2.21. At any stage of the nuclear installation's lifetime, changes or modifications to the site, the nuclear installation, the organizational structure of the licensee, procedures, processes or plans for future activities (e.g. decommissioning) may require (depending on factors such as the nature of the changes and the magnitude of the risks involved) prior review, assessment and approval by the regulatory body and revision of the licence or certain authorizations.

2.22. Security and safety should be viewed as being complementary, as many of the measures designed to address one will also serve the interests of the other. Synergies that exist between the processes applied to meet security and safety requirements should be fully exploited. It is important to note that safety and security measures should be designed and implemented in an integrated manner so that they do not compromise each other. Potentially conflicting requirements resulting from safety and security considerations should be identified as early as possible in the licensing process and should be carefully analysed to provide an acceptable solution with respect to both safety and security.

OBLIGATIONS, ROLES AND RESPONSIBILITIES OF THE REGULATORY BODY

2.23. The following section deals with the general obligations, roles and responsibilities of the regulatory body throughout the licensing process; stage specific responsibilities are included in Section 3.

2.24. The requirements for application for a new licence should be published, together with the address to which the application should be sent. The application should include, as a minimum:

(a) The name, address and any additional contact information of the applicant;
(b) The site for which the application is being made, if required;
(c) The nature of the activity that the applicant wishes to undertake;
(d) Details of any relevant existing licence;
(e) Any environmental assessment report, if required by national legislation;
(f) Information on whether the installation or activity is fully or primarily owned or controlled by a person from another State or by a foreign corporation, and, if so, details of the ownership structure.

2.25. Before an applicant submits an application, the regulatory body should implement a preparatory phase, during which basic safety requirements are set out and the process to be followed is made clear to the applicant. This may

include specification of, for example, the language, units, methodology and format of the proposed application. During this phase, the staff of the regulatory body should be trained so they have sufficient knowledge of the designs of nuclear installations that may be proposed. Basic safety requirements set out in the preparatory phase should be design neutral so that several designs may be considered at the beginning of a project to build a nuclear installation. Nevertheless, detailed and explicit design requirements should be developed during the early phases of the project.

2.26. The regulatory body should develop regulations for the licensing process of nuclear installations and should provide guidelines for applicants in order to provide clarity and transparency in the licensing process.

2.27. The regulatory framework should empower the regulatory body to conduct reviews, assessments and inspections of:

(a) The applicant's evidence of and plans to meet regulatory requirements regarding its competence (including the competence of contractors) and capability and the safety case for the nuclear installation and related activities;
(b) The descriptions and claims in the documentation of the applicant or licensee;
(c) The licensee's compliance with regulations, safety objectives, principles, requirements and criteria, the safety cases and safety analyses, and the conditions of the licence;
(d) The continued competence and capability of the licensee (and of its contractors and subcontractors) to meet the actual authorization, licence or regulatory requirements.

2.28. This regulatory framework should also empower the regulatory body to make regulatory decisions and to grant, amend, suspend or revoke licences, conditions or authorizations, as appropriate.

2.29. Early assessment of the competence and capability of the applicant should be conducted to ensure that the applicant will be able to manage the later phases of the project. The applicant should be encouraged to conduct a staffing study at the very beginning of the project to evaluate the staff and competencies it will need during the different project phases and should give consideration to how and from where it will recruit such staff.

2.30. The regulatory body should establish a formal management system for dealing with licence applications, both initial applications and subsequent applications. The system should set out arrangements for requesting further information from the licensee, for carrying out review and assessment of the licensee's application and for carrying out inspections, as appropriate and necessary. The system should define responsibilities within the regulatory body for making the decision on whether to accept the application. The applicant or licensee should be informed of the decision in an appropriate manner, in accordance with the legal framework. All documentation relevant to the issuing of a licence or authorization should be recorded and kept for the lifetime of the installation or activity, and for a specified period beyond such lifetime, in accordance with legal requirements.

2.31. The nature of the review, assessment and inspection by the regulatory body will depend on the type of nuclear installation, its activities and the stage in the lifetime of the nuclear installation.

2.32. The regulatory body may request a reassessment of safety at the nuclear installation and of the safety of its activities in the light of the following:

(a) Experience relevant to safety that has been gained at the nuclear installation, at similar nuclear installations and at other relevant nuclear and non-nuclear installations;
(b) Information from relevant tests and from research and development programmes, and new knowledge of technical matters;
(c) Changes in the regulatory framework, regulations and guides;
(d) Changes in the site conditions.

2.33. Following such a reassessment, operation may be halted or made subject to specific conditions, depending on the safety issue involved; operation should be authorized to continue only once the regulatory body is satisfied with the licensee's demonstration of safety. Specific conditions set by the regulatory body may include measures to be taken within a specified time frame.

2.34. Before a licence is granted, the regulatory body should monitor the applicant or licensee to verify that it has, as appropriate:

(a) A management system;
(b) Clear procedures, where safety may be concerned, for analysing and endorsing any modifications (including temporary modifications) to, or modifications having an impact on the safety of, the following: structures,

systems and components, the design, safety analyses including methodologies and codes, operational limits and conditions, procedures, safety related software and documentation, the management system, and management of safety (see Ref. [4] for more details);

(c) Certificates of sufficient liability insurance or other financial security;

(d) Proof of trustworthiness of all staff who will be engaged in responsible or sensitive positions.

2.35. Throughout the licensing process, the regulatory body should ensure that proposed modifications are categorized by the licensee according to their safety significance. This categorization should follow an established procedure, which should be subject to agreement or approval by the regulatory body. Modifications that are categorized as significant to safety should be submitted to the regulatory body for review and approval or agreement. The regulatory body should inspect compliance with categorization procedures on a regular basis.

2.36. Throughout the licensing process, the regulatory body should ensure that the licensee has an established feedback system for learning from experience (regarding engineering, human and organizational aspects). Review, assessment and inspections performed by the regulatory body to confirm the existence and the application of such experience feedback should also be considered.

2.37. Regulatory provisions should be put in place to ensure that, if licence expiry dates are established, they are such that the person or organization in charge of the nuclear installation is not relieved of the prime responsibility for safety until the regulatory body so decides.

OBLIGATIONS, ROLES AND RESPONSIBILITIES OF THE APPLICANT OR LICENSEE

2.38. The applicant or licensee has the following obligations:

(a) The applicant or licensee should prepare and submit a comprehensive application to the regulatory body that demonstrates that priority is given to safety; that is, that the level of safety is as high as reasonably achievable and that safety will be maintained at the site for the entire lifetime of the nuclear installation.

(b) The applicant or licensee must meet its responsibility for safety at the nuclear installation until the installation is released from regulatory control by the regulatory body.

(c) The applicant or licensee should have the capability within its own organization (either on-site or within the organization as a whole) to understand the design basis and safety analyses for the nuclear installation, and the limits and conditions under which it must be operated.
(d) The applicant or licensee should exercise control over the work of contractors, understand the safety significance of this work ('intelligent customer' capability) and take responsibility for its implementation.
(e) The applicant or licensee should submit a procedure or description to the regulatory body of the process for dealing with modifications, which may be subject to approval by the regulatory body, depending on national legislation, regulations and practices. Alternatively, requirements dealing with modifications may be established directly in the regulations, and the regulatory body may then carry out inspections to verify that the licensee meets such requirements.
(f) The applicant or licensee should have a design capability and a formal and effective external relationship with the original design organization or an acceptable alternative.
(g) The applicant or licensee should assess safety in a systematic manner and on a regular basis.
(h) The applicant or licensee should ensure physical protection and security at the nuclear installation.
(i) The applicant or licensee should demonstrate in its application for a licence that it has and will continue to maintain:
    (i) Adequate financial resources (e.g. depending on national legislation and regulation, for regulatory fees and liability insurance, and for funding of the construction, operation and decommissioning stages and of maintenance);
    (ii) Adequate human resources to safely construct, maintain, operate and decommission the nuclear installation, and to ensure that regulatory requirements and safety standards are met and will continue to be met.

2.39. The licensee should put into place procedures within its management system for each stage of the lifetime of the nuclear installation, including, where appropriate, procedures for the provision of independent advice. Throughout the licensing process, the regulatory body should ensure that the licensee properly carries out this task. Procedures should be put into place:

(a) For controlling the nuclear installation within the limits specified in the regulations;
(b) For managing anticipated operational occurrences and accident conditions;
(c) For responding to a nuclear or radiological emergency.

Procedures should be periodically assessed, reviewed and revised, as appropriate, to take into account operating experience, modifications, and national and international best practices. Requirements on the management system are established in Ref. [5] and further recommendations are provided in the associated Safety Guides.

MAIN CONTENTS OF A LICENCE

2.40. The licence should include (unless specified elsewhere in the legislation or in regulations):

(a) A unique licence identification.
(b) The issuing authority: the laws and regulations under which the licence is issued; the official designations of those who are empowered by those laws or regulations to issue the licence and whose signature and stamp should appear on the licence; and the authority to which the licensee will be accountable under the terms of the licence.
(c) Identification of the individual or organization legally responsible for the licensed installation or activity.
(d) A sufficiently detailed description of the nuclear installation, its location and its activities, including a clear depiction and description of the site boundaries, and other drawings, as appropriate.
(e) The maximum allowable inventories of sources covered by authorizations.
(f) The requirements for notifying the regulatory body of any modifications that are significant to safety.
(g) The obligations of the licensee with respect to both safety at the installation and the safety of its equipment, radiation source(s), personnel, the public and the environment.
(h) Any limits on operation and use (e.g. dose limits, discharge limits, action levels, limits on the duration of the authorization, permit or licence).
(i) Any separate additional authorizations that the licensee is required to obtain from the regulatory body.
(j) The requirements for reporting events and incidents at the installation.
(k) The requirements for providing routine reports to the regulatory body (see para. 3.61).
(l) The requirements for retention of records by the person or organization responsible for the nuclear installation and its activities, including the time periods for which records should be retained.
(m) The requirements for arrangements for emergency preparedness.

(n) The means and procedures for changing any information stated in the licence.
(o) The documentary basis: the documents in support of the application and those prepared and used by the regulatory body in the review and assessment process, which together form the basis for issuing the licence.
(p) The relationship to other licences; that is, whether the licence is contingent upon a prior authorization or is a prerequisite for a future authorization. Mechanisms should be established so that expiry of an authorization is avoided (if an expiry date is established by the regulatory regime).
(q) Procedures for, information about and identification of the legal framework for challenging the licence or part of the licence.
(r) Licence conditions dealing with safety aspects of the installation and its activities.

2.41. The licence conditions (see paras 2.14–2.16) may include or refer to: technical limits and conditions; a system for reporting events, modifications and incidents to the regulatory body; and other requirements, depending on the magnitude of the risk, the nature of the nuclear installation, the activities performed and the stage in the nuclear installation's lifetime. More detailed recommendations relating to such other requirements are provided in Section 3.

PUBLIC PARTICIPATION

2.42. The public should be given an opportunity to present their views during certain steps of the licensing process, where appropriate. If a site is near a State's national border, there should be appropriate cooperation, including public participation, with neighbouring State(s) in the vicinity of the nuclear installation.

2.43. Transparency, along with public participation and involvement in the regulatory process, reinforces the credibility of the regulatory body and enhances local public confidence in the nuclear regulatory regime. The process for public participation should allow individuals or societal groups to challenge the issuing of a licence or authorization if it appears to jeopardize health or safety.

2.44. Throughout the lifetime of the nuclear installation, the public participation process, including participation of local, national and international interested parties, should be open, transparent, well described and balanced, and should ensure that security sensitivities and commercial proprietary information are respected. For example:

(a) The regulatory body and licensee should provide easy access to relevant and comprehensive information relating to safety and to the licensing process and licensed activities. Such information should be published where it can be easily accessed, such as on the internet and in the mass media.
(b) Regular meetings, formal hearings and other appropriate means of communication should be:
    (i) Open to the public, the media and other interested parties;
    (ii) Announced a reasonable period of time before the meeting or hearing takes place.
(c) The public should be given the opportunity to present their opinions at meetings and formal hearings and via other appropriate means of communication.
(d) Comments from the public should be addressed at all steps of the licensing process.

2.45. A process for consideration and resolution of concerns should be established in national regulations and guides.

GRADED APPROACH

2.46. The text accompanying Principle 5 of the Fundamental Safety Principles [3] states that "The resources devoted to safety … have to be commensurate with the magnitude of the radiation risks". To apply this principle, a graded approach should be used in carrying out safety assessments and in issuing adequate regulations for the wide range of types of nuclear installation and the different levels of potential hazards and risks that they pose. Application of a graded approach by the regulatory body focuses the way that an installation and its activities are assessed, inspected and authorized on the basis of risks, without unduly limiting the operation of the nuclear installation or the conduct of its activities.

2.47. A graded approach should be used by the regulatory body in determining the scope, extent and level of detail of and the effort to be devoted to review, assessment and inspection, and the number of authorizations for any particular nuclear installation and its activities.

2.48. The main factor taken into consideration in the application of a graded approach to determining the level of regulatory control should be the magnitude of the risks associated with the activities performed at the nuclear installation.

Account should be taken of occupational doses, radioactive discharges and the generation of radioactive waste during operation, as well as the potential consequences of anticipated operational occurrences and accidents, including their probability of occurrence and the possibility of occurrence of very low probability events with potentially high consequences and their conditional temporal incidence.

2.49. A graded approach to safety assessment should also take account of other relevant factors such as the maturity of the licensee organization, and complexity and ageing related issues relating to the nuclear installation and its activities. Maturity relates to: the use of proven practices and procedures, proven designs and operating experience at similar nuclear installations and for similar activities; uncertainties in the performance of such a nuclear installation or activities; and the availability of competent staff and experienced managers, contractors and suppliers. Complexity relates to: the extent and difficulty of the effort required to construct, maintain, operate and decommission a nuclear installation or to conduct an activity; the number of the related processes for which control is necessary; the physical and chemical forms of the radioactive material and the extent to which the radioactive material has to be handled; the half-lives of the radionuclides concerned; and the reliability and complexity of systems and components and their accessibility for maintenance inspection, testing and repair. Similarly, a graded approach should be applied as the nuclear installation progresses through the stages of its lifetime.

2.50. The application of the graded approach should be reassessed as the safety assessment progresses. Adjustments to the safety assessment may be made as a better understanding is obtained of the risks associated with the nuclear installation and its activities. The scope, extent and level of detail of, and the effort devoted to, the review, assessment and inspection and the related licensing process should be revised accordingly.

3. STEPS OF THE LICENSING PROCESS

3.1. The licensing process for a nuclear installation will normally include the following steps, depending on national legislation: siting and site evaluation (which may include the environmental impact assessment), construction, design, commissioning, operation, decommissioning and release from regulatory

control.[1] Each step of the licensing process may be divided into several substeps or may be merged or combined as appropriate to facilitate the regulatory process. Combining authorizations or licences (e.g. for construction and operation) may also give more predictability to the process for the licensee. At each hold point set down by the regulatory body or in the licensing process, an authorization or a licence from the regulatory body may be required. Conditions may be attached to licences granted at each step and may require that the licensee obtain further, more specific, authorizations or approvals before carrying out particular activities.

ALTERNATIVE REGULATORY PROCESSES FOR COMBINED LICENCES

3.2. The licensing of nuclear installations typically involves discrete steps, as described in this Safety Guide, especially for States that are planning a first nuclear installation of a particular kind. However, alternative approaches do exist, especially for countries with experience in nuclear power where several similar nuclear installations have already been built and are proven. The licensing process of another country may be adopted or adapted in the regulatory regime to take advantage of similar designs, with the requirement that the standardized (i.e. not site specific) safety cases of the vendors and of an experienced operating organization be later supplemented by site specific and installation specific safety assessments (e.g. environmental impact assessment, confirmation that the site characteristics are compatible with the standardized design). In such contexts, the regulatory body may consider, in advance, early approval of sites and certification of standardized plant designs. International cooperation on design certification may also help to facilitate the licensing process. The applicant may then apply in due course for a specific combined licence authorizing, for example, construction, commissioning and operation. In this approach, the applicant may reference the early site permit and the certified standard design in its application. Depending on the national legislative regime, safety and environmental issues should be resolved before the site or design licence is granted, and the resolution of such issues should be considered final. The elements of such an alternative licensing process may include the following steps:

[1] At the time of writing, a Safety Guide for spent fuel storage facilities, which includes recommendations on licensing such facilities, was in preparation.

(a) Early site permits. In such a licensing process, a prospective applicant for a licence for construction, commissioning and operation can apply for an early site permit, notwithstanding the fact that the application for a licence to construct, commission and operate a nuclear installation has not been filed.

(b) Certified standard designs. In such a licensing process, any qualified company may obtain certification of a standardized design for a nuclear installation, notwithstanding the fact that the application for a licence for construction and operation with the certified design has not been filed. The regulations should allow for approval to be granted for an essentially complete standard design for an entire nuclear installation. The regulations should require that the application for certification of a standardized design contain sufficient information to enable a final conclusion to be reached on all safety questions associated with the design. Such a certification of a standardized design could help to ensure that two nuclear installations of the same design would not vary significantly from each other, except for variations required due to site requirements.

(c) Combined licence. In such a licensing process, an applicant can apply for a single licence to construct, commission and operate a nuclear installation. If the licence is issued, and if the installation is constructed in accordance with the requirements set forth in the licence, the regulatory body should then allow the plant to begin operation. In such a regulatory regime, considerable pressure is put on the regulatory body to maintain control over all the licensee's activities. If the licensing process is to be simplified in this manner, the inspection process should be made sufficiently rigorous to ensure that all safety requirements are fulfilled. The regulatory body will then need to have adequate capabilities and resources to manage its own inspection process and to monitor all safety related activities during the construction, commissioning and operation stages. Very few key hold points — such as fuel loading, power increase or other technical points, as appropriate — may be imposed on the licensee. In such a simplified licensing process, an applicant could be allowed to refer to an early site permit and a standard design certification as part of its application for a combined licence for construction, commissioning and operation of a nuclear installation. The regulatory body would then consider as resolved all matters that were resolved in connection with the granting of the early site permit and the standard design certification. The applicant, however, could be allowed to request an exemption from one or more elements of the certified design; such exemptions should be granted if regulatory requirements are fulfilled and safety is considered adequate after review and assessment by the regulatory body.

SITING AND SITE EVALUATION

3.3. The siting process for a nuclear installation generally consists of investigation of a large region to select one or more preferred candidate sites, followed by a detailed evaluation of those candidate sites. For a site close to a State's national border, consultations with neighbouring countries should be carried out.

3.4. After site selection, the regulatory body should be involved in the decision as to the acceptability of the selected site and should have the authority to establish conditions for the site or to reject a proposed site on the basis of safety concerns.

3.5. Site evaluation is an analysis of those factors at a site that could affect safety at the nuclear installation and the safety of its activities [2]. This includes site characterization and consideration of factors that could affect the safety features of the nuclear installation or its activities and result in a release of radioactive material and could affect the dispersion of such material in the environment. The site evaluation to be reviewed, assessed and approved by the regulatory body should also consider the potential impact of the nuclear installation and its activities on the environment, and a preliminary assessment should be carried out to verify that no incompatibilities are foreseen.

3.6. For a nuclear installation, following site selection, site evaluation typically involves the following stages [2]:

(1) Site characterization stage. This stage is further subdivided into:
   (i) Site verification, in which the suitability of the site to host a nuclear installation is verified, mainly according to predefined site exclusion criteria;
   (ii) Site confirmation, in which the characteristics of the site necessary for the purposes of analysis and detailed design are determined.
(2) Pre-operational stage. Studies and investigations which begin in the site characterization stage should be finalized before the start of construction. The site data obtained allow a final assessment of the simulation models used in the final design.
(3) Operational stage. Appropriate safety related site evaluation review activities are carried out throughout the operating lifetime of the facility, mainly by means of monitoring and periodic safety review.

3.7. Before construction begins, the regulatory body should issue a formal regulatory decision on the acceptability of the site, which should address how appropriate participation of all interested parties and authorities is to be ensured.

Safety assessment and environmental impact assessment

3.8. A radiological study of the region, including an appropriate baseline survey, should be carried out before commissioning of the nuclear installation is commenced. This study and survey should be reviewed and assessed against established regulatory criteria and may be approved, as appropriate, by the regulatory body.

3.9. Furthermore, there are a number of factors that should be adequately considered by the applicant in determining the acceptability of the site. Most of these factors may be covered by a specific environmental impact assessment, which may be mandatory due to the legal provisions of the State. In this case, a legal relation between this environmental impact assessment and the licensing process should be established. The following important factors for the licensing process for nuclear installations should be reviewed, assessed and inspected, as appropriate, by the regulatory body:

(a) Factors dealing with the risks for the nuclear installation:
    (i) The range of natural conditions, risks and hazards for the site (e.g. seismic hazards, geological hazards, hydrological hazards, meteorological hazards, geography, topology, flood hazards, extreme weather hazards, tsunami hazards, external fire hazards).
    (ii) The range of human induced risks and hazards for the site (e.g. adjacent hazardous industrial facilities, gas pipelines, transport of dangerous goods in the vicinity of the site, air traffic and the potential for aircraft crashes).
    (iii) Where multiple nuclear installations are considered for a single site, the site as a whole should be evaluated for interactions between the nuclear installations, for example, the potential for a 'domino effect' (i.e. an accident at one nuclear installation affecting other nuclear installations on the site), shared services, cumulative effects of discharges and common cause failures. Such interactions should also be considered at the design stage.
    (iv) The use of the land around the site boundary regarding activities or changes that may significantly affect safety and security at the nuclear installation. Such a use should be controlled for the entire lifetime of the nuclear installation.

(b) Factors dealing with risks for people and the environment[2], including transboundary aspects [6], as appropriate:
   (i) The location of the local population and population density, as well as health and socioeconomic aspects;
   (ii) The impact of the location on arrangements for emergency preparedness and response (e.g. the location of adjacent activities, homes, schools, hospitals, prisons and businesses, as well as roads and transport routes, and other types of traffic);
   (iii) The licensee's security of tenure and rights of access, and the relationship between the applicant/licensee and the owner of the site area;
   (iv) The existing environmental conditions at the site (e.g. pre-existing contamination; the condition of the air, water, earth, flora and fauna; the quality of the air, soil, groundwater, surface water and deep seated waters);
   (v) Marine or aquatic ecology (e.g. of seas, lakes, rivers);
   (vi) The effect of gaseous, liquid and solid discharges (e.g. radioactive, toxic);
   (vii) The potential for heat dissipation (including the ultimate heat sink).

3.10. Requirements for site evaluation are established in Ref. [7], and further recommendations are provided in the associated Safety Guides.

3.11. National regulations or the regulatory body should provide a clear definition of the main steps to be followed by the licensee when constructing a nuclear installation. For instance, a 'site preparation' step should be defined; the definition of this step may vary from one country to another and may include excavation, fence erection, preparation of roads and access routes, electricity and water supply, and other infrastructure. Likewise, a 'construction commencement' step should be defined; this step may be divided into several authorizations such as 'first stone', 'construction of administrative buildings and facilities' and 'construction of nuclear related buildings'.

[2] At the time of writing, a Safety Guide on radiological environmental impact analysis for facilities and activities was in preparation.

3.12. The design stage may include other tasks, such as a ‘feasibility study’, or a ‘pre-licensing’ step, depending on the national nuclear context (e.g. whether the State already has nuclear installations of the same type).

3.13. If sites and designs are considered separately early in the project to build a nuclear installation, then the regulatory body should establish a definition of ‘generic site’ and a definition of ‘generic design’. A process to ensure that both the site and the design are compatible in the licensing process should also be established. The site evaluation and the environmental impact assessment should be reviewed and, if necessary, enhanced after the bidding process through which the design is selected.

3.14. The regulatory body should review and assess the acceptability of the selected design and should have the authority to approve, agree, comment on, question or reject such designs or parts thereof, as necessary, on the basis of safety concerns.

3.15. The basic design of the proposed nuclear installation should be such that safety requirements can be met in accordance with the design basis. The design basis is the range of conditions and events explicitly taken into account in the design of the nuclear installation, according to established criteria, such that the nuclear installation, through the planned operation of safety systems, can withstand them without exceeding authorized limits [2]. The applicant for authorization for construction should submit a basic design to the regulatory body before construction begins. This basic design can be approved or, depending on regulatory framework, frozen (i.e. no change may be made to the basic design without the regulatory body’s review and approval) or partly frozen with a regulatory instrument upon the review and assessment of the regulatory body.

3.16. During construction and throughout the lifetime of the nuclear installation, parts of the detailed design may be subject to approval or may be frozen. Such approvals or processes for freezing a detailed design should be carried out by means of regulatory instruments, and conditions should be attached, as appropriate. If the licence applications for construction and operation are made concurrently (i.e. a combined licence), parts of the detailed design should then be reviewed by the regulatory body in the course of application for the construction and operation licence.

3.17. Particularly at the design and construction stages, it is important to ensure that structures, systems and components comply with approved or accepted standards, codes and regulatory requirements, including quality assurance requirements. It is also necessary to ensure that construction work at the nuclear installation is undertaken in accordance with design specifications and that sufficient suitably qualified and experienced staff are available for design work, supply and manufacture, and for the control of these activities. The regulatory body should ensure that clear and explicit quality requirements are specified by the licensee or applicant for safety related activities. The regulatory body should check, either through the licensee or directly, depending on national legislation, whether all organizations and contractors involved in design and construction adequately implement these requirements, and should take appropriate actions if necessary.

3.18. Defence in depth is required to be considered in the design and later on, in operation:

> "Defence in depth is implemented primarily through the combination of a number of consecutive and independent levels of protection that would have to fail before harmful effects could be caused to people or to the environment. If one level of protection or barrier were to fail, the subsequent level or barrier would be available. When properly implemented, defence in depth ensures that no single technical, human or organizational failure could lead to harmful effects, and that the combinations of failures that could give rise to significant harmful effects are of very low probability. The independent effectiveness of the different levels of defence is a necessary element of defence in depth" [3].

3.19. The objectives of defence in depth are:

"—[T]o compensate for potential human and component failures;
—[T]o maintain the effectiveness of the barriers by averting damage to the [facility] and to the barriers themselves; and
—[T]o protect [workers,] the public and the environment from harm in the event that these barriers are not fully effective." [9]

3.20. The International Nuclear Safety Advisory Group [9] defines five levels of defence in depth:

— Level 1: Prevention of abnormal operation and failures;
— Level 2: Control of abnormal operation and detection of failures;

— Level 3: Control of accidents within the design basis;
— Level 4: Control of severe conditions, including prevention of accident progression and mitigation of the consequences of a severe accident;
— Level 5: Mitigation of the radiological consequences of significant external releases of radioactive material.

More details about defence in depth are provided in Ref. [8].

3.21. The following should be verified by the licensee to ensure that safety requirements are met:

(a) Design basis analyses and beyond design basis analyses, fault tree analyses, and probabilistic safety assessments, as appropriate;
(b) Protection against external and internal hazards;
(c) Radiation protection;
(d) Routine radioactive discharges;
(e) Evidence of learning from operating experience and programmes to evaluate human and organizational factors, the management system, etc.;
(f) The main safety functions (i.e. reactivity control or criticality issues, cooling aspects and containment integrity) and the reliability of the associated structures, systems and components.

The results of these verifications should be reviewed and assessed by the regulatory body, as appropriate.

3.22. The approach applied to safety and the safety standards and codes used in the design of the nuclear installation should be proven and appropriate for their purpose.

3.23. Safety analyses of the design should be performed or reviewed by the applicant or the licensee in accordance with its management system and should be used by the applicant or the licensee to specify or improve, as appropriate, the following:

(a) Requirements for commissioning;
(b) Categorization and classification of structures, systems and components (according to safety, quality, seismic qualification, environmental qualification, etc.);
(c) Operational limits and conditions, safety limits, rules and operating procedures;
(d) Requirements for in-service inspection and maintenance;

(e) Radiation protection requirements (for workers, the public and the environment);
(f) Emergency preparedness arrangements;
(g) Physical protection and security requirements, in accordance with national and local regulations;
(h) Human and organizational factors;
(i) Training requirements;
(j) Documented verification and validation activities in design, testing, construction, commissioning, operation, maintenance and ageing management activities to ensure that the qualification of systems, structures and components is valid for life;
(k) The programme for feedback of operating experience;
(l) Procedures and requirements for management of modifications.

3.24. These safety analyses may be reviewed, assessed and, if appropriate, challenged by the regulatory body at an early stage in the licensing process. The vendor can also be involved in this pre-licensing step, if appropriate. Additionally, the operating organization may have an internal process (which could include receipt of independent advice) for review of safety analyses before submission to the regulatory body to ensure that such analyses are appropriate.

3.25. The regulatory body should review, assess and inspect the information on the nuclear installation provided by the applicant or licensee, in particular, documents that form part of the preliminary safety analysis report, including:

(a) Safety analyses of anticipated operational occurrences and postulated initiating events [8], which may be caused by:
  (i) External hazards (e.g. tsunamis, flooding, seismic events, volcanic eruptions, aircraft crashes, tornadoes, cyclones, hurricanes, external fires, explosions of gases or liquids);
  (ii) Internal hazards (e.g. fire, spillages of corrosive material, internal flooding);
  (iii) Internal events (e.g. mechanical failures, electrical failures, human error);
(b) The assumptions and approximations used in the analyses;
(c) Analyses of combinations of events;
(d) A description, identification, categorization and classification of structures, systems and components important to safety;
(e) Operational limits and conditions, and permitted operational states;
(f) A list of barriers with their relative contributions to confinement of radioactive material and related limits;

(g) The means by which requirements for defence in depth are met;
(h) Planned activities for confirming safety performance;
(i) Analytical methods and computer codes used in the safety analyses and the verification and validation of such codes;
(j) Radioactive discharges and radioactive releases into the environment, and radiation exposure of workers and the public during normal operation and under accident conditions;
(k) Safety criteria for analyses, particularly those relating to common cause events, cross-link effects[3], the single failure criterion, redundancy, diversity and physical separation;
(l) Verification and validation of the safety analyses and evidence of their robustness (e.g. sensitivity studies, research, testing, operating experience in other nuclear installations).

3.26. This demonstration of safety should be carried out in compliance with the regulatory framework, including safety criteria and the applicable international standards, as appropriate, and in accordance with national requirements for the nuclear installation in question. Further details are provided in Refs [8, 10–12].

3.27. The regulatory body should ensure that the applicant has verified the adequacy of design parameters and site specific data in relation to safety criteria of the specified design basis (e.g. hazard protection requirements, cooling requirements).

3.28. The licensee or applicant should develop and implement an appropriate management system to review the detailed design of systems, structures and components important to safety manufactured by designers, vendors and manufacturers. The regulatory body may review, assess and inspect, as appropriate, the activities carried out by the licensee in that respect.

3.29. The licensee should propose arrangements for radioactive waste management. The regulatory body should review, assess and inspect proposals for on-site treatment and storage of radioactive waste, including the management of spent fuel, where appropriate, to ensure that the processed waste and the waste packages will be characterized in a manner compatible with the national strategy for radioactive waste, the applicable waste acceptance requirements for subsequent steps of waste management and regulatory requirements. Specifically, the regulatory body should satisfy itself that the waste or waste packages:

[3] Cross-link effects are effects that one system can have upon another system.

(a) Will be properly characterized and compatible with the anticipated nature and duration of storage pending disposal;
(b) Can be subjected to regular surveillance;
(c) Can be retrieved for further steps of predisposal waste management;
(d) Will be managed such that their volume and activity are kept as low as reasonably achievable.

3.30. The licensee should propose arrangements for managing radioactive discharges (liquid and gaseous and other discharges, including chemical and thermal discharges, as appropriate), which will have to be implemented throughout the lifetime of the nuclear installation. The regulatory body should review, assess and inspect these proposals. Specifically, the regulatory body should satisfy itself that radioactive discharges:

(a) Will be properly characterized and in compliance with national regulations;
(b) Can be subjected to regular surveillance;
(c) Will be kept as low as reasonably achievable.

3.31. In addition, the licensing process should ensure that the following aspects are considered in the design:

(a) The ability to safely transport radioactive and nuclear material to, from and within the nuclear installation.
(b) Safety aspects associated with the replacement of heavy and large components during the operating lifetime of the nuclear installation (e.g. steam generator, reactor pressure vessel heads for a nuclear power plant). The design should take into account:
    (i) Buried pipes and conduits;
    (ii) Openings in structures for access to equipment;
    (iii) Obstructions.
(c) Access to components important to safety for:
    (i) Maintenance;
    (ii) Inspection and testing, as appropriate;
    (iii) Replacement;
    (iv) Future decommissioning.
(d) Minimization of occupational exposure when gaining access to structures, systems and components.
(e) The way the nuclear installation will be decommissioned, and how radioactive waste generated during operation and decommissioning will be managed, according to national strategies.
(f) Minimization of the amount of radioactive waste.

(g) Features dealing with safe shutdown and remote shutdown facility, where appropriate.
(h) In the case of reactors, appropriate arrangements for temporary storage of the spent fuel (including, e.g., criteria for dry storage of spent fuel at reactor sites).
(i) The safe management of the radioactive waste and spent fuel generated throughout the lifetime of the installation.

3.32. Ageing issues should also be addressed in the design and construction phases to anticipate appropriate ageing management actions for the future. Furthermore, ageing considerations during design should also include the actions for ensuring plant integrity until the end of decommissioning.

3.33. The licensee should review, audit and be responsible for certifying suppliers and contractors with functions relating to safety. As appropriate, the regulatory body may review, assess and inspect such review, audit and certification processes. The regulatory body may also directly grant certificates or licences to suppliers and contractors in its own State, as appropriate, in accordance with the national regulatory framework.

3.34. Before construction begins, the licensee should set up a configuration management programme[4] for updating the design basis of the nuclear installation while ensuring that it remains in compliance with the original agreed or approved design basis.

3.35. More requirements and recommendations on design of nuclear power plants and the safety analysis report can be found in Refs [8, 10].

CONSTRUCTION

3.36. Before granting an authorization or a licence for the construction of a nuclear installation, the regulatory body should review, assess and inspect:

[4] Configuration management is the process of identifying and documenting the characteristics of a facility's structures, systems and components (including computer systems and software), and of ensuring that changes to these characteristics are properly developed, assessed, approved, issued, implemented, verified, recorded and incorporated into the facility documentation [2].

(a) The management system of the applicant or licensee and vendors, as necessary [5];
(b) The site evaluation;
(c) The design features important to safety and security;
(d) Documentation relating to demonstration of compliance of the selected design with safety objectives and criteria, including validated results from experiments and research programmes;
(e) Organizational and financial arrangements for decommissioning and for management of radioactive waste and spent fuel.

3.37. Construction of the nuclear installation and installation of its structures, systems and components should not be authorized by the regulatory body until it has been demonstrated by means of such regulatory control that safety requirements are met.

3.38. The licensee should exercise control over the manufacture of structures, systems and components important to safety, and this process should be reviewed, assessed and inspected, as appropriate, by the regulatory body. While controlling such manufacturers under its management system, the licensee should also control subcontractors, suppliers and vendors under its management system.

3.39. Before authorization of construction, there are several conditions that should be fulfilled to ensure that this stage can proceed in a manner that will ensure quality and safe operation of the nuclear installation. These conditions should include the following and should be reviewed, assessed and inspected by the regulatory body, as appropriate:

(a) The framework and schedule for construction and acquisition of structures, systems and components should be adequate.
(b) The applicant or licensee should have adequate financial capabilities.
(c) The nuclear installation should be designed and constructed in accordance with the relevant site parameters identified by the applicant and agreed with the regulatory body, and in an adequate manner.
(d) Planned deviations from the approved design should be fully analysed in relation to the original design intentions and submitted to the regulatory body for assessment and approval.
(e) Physical protection measures and fire protection should be put in place.
(f) Radiological monitoring equipment and devices should be clearly defined, installed and operational before radioactive material is brought onto the site.

(g) The licensee should conduct/upgrade the radiological study of the region and all the material used in the construction, including samples of construction concrete, before radioactive material is brought onto the site.
(h) Industrial codes, standards and rules (including health and safety regulations) should be put in place before construction is started.
(i) Regulatory control should be in place over licensee contractors and subcontractors performing tasks relevant to structures, systems and components important to safety.

3.40. Furthermore, prior to authorization of construction, conditions may be imposed on the licensee requiring that it obtain from the regulatory body certain additional approvals relating to the design, construction or manufacture of certain parts of the nuclear installation. The regulatory body should also:

(a) Review, assess and inspect, on a systematic basis, the development of the design of the installation as demonstrated in the safety documentation submitted by the applicant or licensee, in accordance with an agreed programme (which may include requirements to improve safety through design optimization);
(b) Review and assess the progress of research and development programmes relating to demonstration of the design, if applicable;
(c) Review and assess the potential impact of the construction on the safe operation of any neighbouring nuclear installations or other high hazard industrial installations.

3.41. Particular issues arise if part of the supply chain is in other States. The regulatory body should then ensure that there are legally binding arrangements in place allowing the necessary access to documents and to the premises of all organizations; alternatively, such arrangements may be made part of a licence condition, for instance. If a regulatory body intends to visit premises in another State, the visiting regulatory body should inform the regulatory body of the State in which the premises are located. Regulatory inspection in other States may not be possible, but it may be possible for the regulatory body to visit the premises of vendors or manufacturers in other States jointly with the regulatory body of that State. Wherever restrictions exist for joint regulatory review, it should be ensured by actual verification that the supply standard meets requirements. The regulatory body should, where appropriate, cooperate and exchange information and experience obtained from safety reviews, assessments and inspections with the regulatory bodies of other States that have experience in licensing installations of the same design. Such cooperation should not, however, jeopardize the independence of the decision making process, nor should it diminish the

responsibilities of a given regulatory body. In all cases, the licensee has the prime responsibility for safety and is required to ensure that manufacturing can be supervised as required by the regulatory body of the State in which the installation is built.

3.42. Before the first nuclear material is allowed to be brought onto the site, a decommissioning plan, including a waste management plan, is required to be submitted to the regulatory body [13, 14]. The plan should demonstrate that:

(a) Sufficient funds to decommission the nuclear installation will be available at the end of operation. This should include incidental costs such as spent fuel management and radioactive waste management and disposal.
(b) The total amount of the funds to decommission the nuclear installation is based on reasonable cost estimates. The assessed liability should be estimated on the basis of the price and cost levels prevailing at the time the decommissioning plan is submitted to the regulatory body, and should be reviewed periodically. Mechanisms should be implemented for accumulating funds through the projected lifetime of the nuclear installation. In addition, provisions should be made such that appropriate funds can be made available in the event that the nuclear installation is shut down prior to the end of its planned life.
(c) A system is in place for further development of the plan. Moreover, the plan should be reviewed periodically in the light of new techniques and expectations.

3.43. Furthermore, a legal framework should be put in place for securing decommissioning funds and for protecting them from being depleted for other purposes.

COMMISSIONING

3.44. The licensee or applicant should establish and justify plans and programmes for commissioning the nuclear installation. The regulatory body should conduct reviews, assessments and inspections to determine whether:

(a) The commissioning test programme is complete and contains a set of well defined operational limits, test acceptance criteria, conditions and procedures;

(b) The commissioning tests can be safely conducted as proposed by the licensee or applicant and their justification is appropriate.

3.45. There are several steps in the commissioning process for which the regulatory body may require the licensee to obtain prior approval and at which regulatory decisions may be made. The regulatory body should consider introducing such hold points at key steps in the commissioning programme relating to safety; for example, where it wishes to witness particular tests. In particular, the introduction of nuclear or certain types of radioactive material into the nuclear installation marks a significant step in the commissioning procedure and is often considered the point at which the main regulatory decisions are made.

3.46. Completed structures, systems and components important to safety should be put into service only when they have been inspected, tested and approved by the licensee as being in accordance with the requirements set out in the design as agreed by the regulatory body.

3.47. Before authorizing significant steps such as the introduction of nuclear or certain types of radioactive material, fuel loading, initial criticality or power raising, the regulatory body should complete the review, assessment and inspection of:

(a) The status of the nuclear installation:
  (i) The as-built design of the nuclear installation;
  (ii) The results of non-nuclear commissioning tests;
  (iii) Storage facilities for nuclear materials.
(b) Management aspects:
  (i) The management system and the programme for operation;
  (ii) The organizational structure of the licensee, including the arrangements for ensuring training and qualification of personnel, including staffing levels, fitness for duty and licensing of staff for certain positions, as specified in the regulations;
  (iii) The arrangements for periodic testing, maintenance and inspection;
  (iv) The organization and procedures for dealing with modifications;
  (v) The recording and reporting systems, including those for operational data, test results, and reporting of deviations and of incidents and events.

(c) Operational provisions:
  (i) The operational limits and conditions applicable during nuclear commissioning;
  (ii) The commissioning programme and its progress;
  (iii) The conditions under which discharges will be managed, including radioactive, chemical, thermal and other discharges, as appropriate;
  (iv) The provisions for radiation protection;
  (v) The adequacy of operating instructions and procedures, especially the main administrative procedures, operating procedures for normal operation and anticipated operational occurrences and emergency operating procedures;
  (vi) Arrangements for on-site emergency preparedness and off-site liaison;
  (vii) Physical protection arrangements important for safety;
  (viii) Measures for accounting for and control of nuclear and radioactive material.

3.48. There is some overlap between the construction and commissioning stages in that individual structures, systems and components may already be commissioned before construction of the entire nuclear installation is complete.

3.49. Commissioning can be divided into two main stages: non-nuclear testing (before the introduction of nuclear or certain types of radioactive material) and nuclear testing (after the introduction of nuclear or certain types of radioactive material).

3.50. Non-nuclear testing as part of commissioning is carried out to ensure, to the extent possible, that the nuclear installation has been constructed, and the equipment has been manufactured and installed, correctly and in accordance with the design specifications. Non-nuclear testing also includes required tests to prove the design performance. If deviations from design specifications have occurred, they should be recorded, and it should be shown that the safety analysis remains valid and that safety has not been compromised. The results of the non-nuclear tests should also be used to confirm the operational features of the nuclear installation and should lead to the development of detailed instructions for the licensee. The results of the non-nuclear tests should be verified in the subsequent nuclear testing stage.

3.51. Nuclear testing is a major step in the licensing process carried out to confirm that the performance of the nuclear installation is safe before proceeding to routine operation. Commencement of nuclear testing may require an

authorization from the regulatory body. If there are deviations from design parameters, they should be analysed by the licensee and reported to the regulatory body, which should carry out the necessary review and assessment and may approve the proposed manner of dealing with the deviations, as appropriate.

3.52. As the nuclear testing stage of commissioning moves closer to completion, review, assessment and inspection should be concentrated on operational capabilities and how the nuclear installation is operated and maintained, and on the procedures for controlling and monitoring operation and for responding to deviations or other occurrences. Before authorizing routine operation, the regulatory body should review, assess and inspect the results of commissioning tests for consistency. If the regulatory body finds inconsistencies in these results, it should assess any corrections of non-conformances and modifications to the design and to operating procedures that were made as a result of commissioning. The regulatory body should review and assess any proposed changes to the limits and conditions.

3.53. Before the start of nuclear commissioning tests, staff members with functions relating to safety should be suitably trained and qualified, and licensed where appropriate, and should only then be allowed to perform their functions. The regulatory body may review, inspect and license, as appropriate, during the commissioning stage and later on during operation, any organization that provides training and qualification for staff with safety related functions.

3.54. The results of commissioning tests should be subject to:

(a) Self-assessment and internal audits of the licensee. Appropriate actions and measures should be taken whenever deviations from design parameters are identified. These should be analysed by the licensee and reported to the regulatory body.
(b) Review, assessment and inspection by the regulatory body. The aim of these regulatory controls is to assess whether the test results are adequate for confirming the adequacy of all safety related features of the nuclear installation.

3.55. Further recommendations on commissioning are provided in Refs [15, 16].

OPERATION

3.56. Commencement of operation should be authorized only when regulatory requirements are met, including completion of commissioning tests, recording of the results and their submission to the regulatory body for approval, as appropriate.

3.57. Before operation is authorized or licensed, all regulatory requirements should be met, including inspection, review and assessment by the regulatory body of:

(a) Results of commissioning tests;
(b) Operational limits and conditions;
(c) Operating instructions and procedures and adequacy of staffing to implement them properly, with account taken of the need to work in shifts, when appropriate;
(d) Arrangements for emergency preparedness and response;
(e) The final safety analysis report.

3.58. Before and during operation, the person or organization responsible for the nuclear installation and its activities should demonstrate to the satisfaction of the regulatory body that it has in place the following:

(a) Safety expectations:
    (i) A policy at the nuclear installation that establishes that the demands of safety take precedence over those of production;
    (ii) A programme for the assessment of safety performance;
    (iii) A mechanism for setting safety goals or targets;
    (iv) A programme for training in safety and security cultures.
(b) Management issues:
    (i) A management system compliant with international standards, including a system for carrying out regular audits with independent assessors;
    (ii) Processes and procedures for the control of modifications to the nuclear installation, including design modifications and their implementation;
    (iii) Mechanisms for configuration management for the nuclear installation and related documentation;
    (iv) Adequate staffing levels for the operation of the nuclear installation that take account of absences, training needs, shift work and restrictions on overtime;

(v) Formal arrangements for employing and controlling contractors;
(vi) A process for dealing adequately with corrective actions.

(c) Competence issues:
(i) Qualified staff available at all times, on duty if necessary;
(ii) Systematic and validated methods for the selection of staff, including testing for aptitude, knowledge and skills;
(iii) Staff training facilities and programmes;
(iv) Programmes for initial, refresher and upgrade training, including the use of full scale simulators, where appropriate;
(v) Guidelines on fitness for duty in relation to hours of work, health and substance abuse;
(vi) Competence requirements and knowledge management for operating, maintenance, technical and managerial staff.

(d) Operating experience issues:
(i) Comprehensive, readily retrievable and auditable records of baseline information and operating and maintenance history;
(ii) Programmes for the feedback of operating experience, including feedback of experience relating to failures in human performance;
(iii) Programmes for the feedback of operating experience relevant to safety from similar nuclear installations, and from other nuclear and industrial installations;
(iv) Formal procedures for event reporting.

3.59. The following are operational programmes that the licensee should have in place before and during operation. The regulatory approach to reviewing, assessing and inspecting such programmes should be graded according to the type of nuclear installation and its activities. Such programmes may be subject to approval by the regulatory body, as appropriate:

(a) Radiation protection;
(b) Emergency preparedness;
(c) A management system for operations (engineering design, procurement, maintenance, etc.);
(d) Fire protection;
(e) Security;
(f) Access authorization;
(g) Fitness for duty;
(h) Training and qualification of licensed personnel;
(i) Training of non-licensed staff of the installation;
(j) Maintenance;
(k) Initial testing of the nuclear installation and commissioning;

(l) Pre-service inspection and testing;
(m) In-service inspection and testing;
(n) Surveillance;
(o) Environmental qualification;
(p) Design, review and implementation of modifications to the installation, procedures and organizational structures, as well as operation qualification and requalification after modifications;
(q) Surveillance of pressure vessel material;
(r) Testing for the containment leakage rate;
(s) Monitoring and sampling of effluents;
(t) Management of spent fuel and radioactive waste;
(u) Ageing management;
(v) Environmental surveillance around the site;
(w) Feedback of operating experience.

3.60. The regulatory body should attach or include conditions such as the following to the operating licence, as necessary:

(a) The person or organization responsible for the nuclear installation and its activities should not operate the nuclear installation outside the operational limits and conditions authorized or approved by the regulatory body.
(b) The person or organization responsible for the nuclear installation and its activities should ensure that in-service inspection, surveillance and testing programmes are in place at the nuclear installation and that such activities are carried out as specified for structures, systems and components important to safety in accordance with a time schedule, which may be subject to approval by the regulatory body, in addition to any technical safety aspects, if appropriate.
(c) The person or organization responsible for the nuclear installation and its activities should ensure that the maintenance programme for safety related structures, systems and components is carried out in accordance with a time schedule, which may be subject to approval by the regulatory body.
(d) Changes[5], including changes to procedures, the management system, processes, structures, systems and components, that may affect safety

[5] 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 nuclear technology, the need for replacement of systems, structures or components, plant modifications proposed by the person or organization responsible for the installation and its activities, or new regulatory requirements.

should be reviewed, assessed and inspected, and should be subject to internal agreement before being submitted to the regulatory body for approval, as appropriate.

(e) The person or organization responsible for the nuclear installation and its activities should ensure that the nuclear installation is operated only under the control and supervision of duly authorized personnel in adequate numbers that are acceptable to the regulatory body.

(f) Criteria for starting the nuclear installation after long term shutdown.

(g) Criteria for refuelling outages or for major maintenance programmes.

3.61. Appropriate arrangements should be put in place for reporting any deviation from normal operation to the regulatory body and for providing the regulatory body with routine reports on safety performance, adherence to regulatory requirements and efforts being made to enhance safety, as required by the regulatory body.

3.62. The licensee should put in place a programme for analysing accessible information regarding developments and changes in regulations, procedures, documents and recommendations from organizations that collect information on experiences relevant to nuclear safety. Such information should be taken into account in operation, if appropriate.

3.63. Plans for radioactive waste management and decommissioning (including technical solutions, waste streams, the policy framework for disposal and funding) should be reviewed and updated periodically during operation [13, 17–19].

3.64. Before a nuclear installation is brought back into operation following a refuelling outage, major maintenance activities, long term shutdown or other significant activities, the person or organization responsible for the nuclear installation and its activities should demonstrate to the regulatory body that the nuclear installation will be able to continue to operate in compliance with the safety requirements. Resumption of operation may be subject to approval or agreement by the regulatory body, which should attach conditions, as appropriate.

3.65. Further safety requirements on operation of nuclear installations are established in Refs [20, 21]; further recommendations are provided in Refs [4, 22–26].

Safety review

3.66. Over the full operating lifetime of a nuclear installation, the regulatory body should require the person or organization responsible for the nuclear installation and its activities to provide, when necessary or at appropriate intervals, evidence in the form of a safety review that the nuclear installation remains fit to continue operation. The objective of a safety review in the licensing process is to verify:

(a) That the nuclear installation adheres to current safety standards and national regulations;
(b) That the licensing basis remains valid;
(c) That any necessary safety improvements are identified;
(d) That the required level of safety is maintained until the next safety review is due for completion;
(e) That any measures necessary to ensure a high level of safety for the full expected operating lifetime, such as additional monitoring, are implemented.

3.67. In many States, a systematic reassessment of safety at a nuclear installation is carried out at regular intervals, typically of around ten years. This reassessment is often termed a periodic safety review, but it may be carried out at any time at the request of the regulatory body when concerns about safety arise, or may be initiated by the licensee. It is recognized that in some States alternative arrangements to periodic safety reviews may be preferred. These alternative arrangements should nevertheless be consistent with IAEA guidance, including the recommendations provided in Ref. [27].

3.68. Safety reviews should be performed on a periodic basis or when requested by the regulatory body for any of the following reasons:

(a) If there are substantial developments in safety standards and guides, practices, and analytical methods, or significant lessons learned from operating experience.
(b) To determine the effects of ageing at the installation.
(c) To complement routine safety assessments, which are usually limited in scope and quite specific compared with safety reviews, which offer a wider assessment of safety at the nuclear installation.
(d) If improvements and modifications to the installation are necessary to maintain safety.
(e) If features of the installation reveal and indicate limited lifetime.

(f) To address cumulative effects of modifications to and ageing at the installation, including aspects related to staffing, competence and management structures.
(g) To address requests for extension of the operating licence. Safety reviews are a key regulatory instrument that provide reassurance that there continues to be a valid licensing basis, with respect to plant ageing and modifications implemented or needed in the light of current safety standards.
(h) To address frequent failures of structures, systems and components.

3.69. Safety reviews, whether they are periodic, requested by the regulatory body or initiated by the licensee, should be updated routinely to take account of all risks and hazards, and should be considered as 'living' from one review to another.

3.70. The regulatory body should ensure that such safety reviews also cover aspects which may expose workers, the public or the environment to radiation risks.

3.71. In safety reviews, account should be taken by the regulatory body of:

(a) The nature and magnitude of the potential hazards associated with the nuclear installation and its activities;
(b) Operating experience;
(c) Significant changes to safety or regulatory standards, criteria or objectives;
(d) Technical developments and new safety related information from relevant sources;
(e) Outcomes of the ageing management programme established by the licensee.

3.72. A detailed check of structures, systems and components should be carried out to demonstrate that the nuclear installation remains in compliance with the updated design basis. The regulatory body should review, assess and inspect this detailed review, where appropriate, to verify that the licensee has carried out this review in an adequate and comprehensive manner.

3.73. Where the performance of periodic safety reviews is provided for in the regulatory process, the regulatory body:

(a) Should develop requirements and guidance for the entire safety review process, including requirements and guidance on what aspects should be included in the review (e.g. safety, radiation protection, emergency planning, environmental impact, time intervals, agreement on the implementation plan).
(b) Should divide the periodic safety review into a number of tasks or 'safety factors' and should establish clear regulatory requirements for these tasks or factors.
(c) Should review and assess the analysis of each safety factor performed by the licensee against current safety standards and practices.
(d) Should agree, if appropriate, on the methodology used by the licensee.
(e) Should review and assess, and should approve if adequate, as appropriate, corrective actions, safety improvements and good practices, determined by the licensee and submitted to the regulatory body.
(f) Should authorize, if adequate, the licensee's implementation plan for the safety review. This plan should be reviewed, assessed and audited, as appropriate, before such an authorization is granted. The plan should include time schedules, to be agreed between the licensee and the regulatory body.

3.74. Ageing management plays a central role in the periodic safety review. The regulatory body should verify the existence of an ageing management programme as an essential element of the safety review.

3.75. Reference [27] provides recommendations and information on periodic safety reviews and alternative approaches for nuclear power plants.

3.76. There are certain essential elements of ageing management, and these should be considered by the regulatory body in assessing the licensee's safety analyses. Such essential elements include:

(a) An understanding of the installation's design basis;
(b) A rigorous programme for equipment qualification (for design, construction and modifications);
(c) Identification of actual service conditions (actions to be taken during the design, construction, commissioning and operation stages);
(d) An understanding of material properties and possible ageing mechanisms;
(e) Identification of mechanical and thermal loadings;
(f) Ageing of structures, systems and components due to physical and chemical processes or to such structures, systems and components becoming out of date or obsolete due to knowledge and technology evolution, the associated

changes in codes and standards or ageing of human skills, knowledge, competence, etc.;

(g) The existence of a systematic ageing management programme, which should address issues such as:
  (i) Scope and identification of systems, structures and components involved;
  (ii) Mitigation of ageing effects;
  (iii) Condition monitoring;
  (iv) Performance monitoring;
  (v) Acceptance criteria (to ensure that licensing bases and the safety envelope are maintained);
  (vi) Necessary corrective actions;
  (vii) A confirmation process for ensuring that corrective actions are adequate and effective;
  (viii) Administrative controls (reviews and approvals in accordance with the quality management system);
  (ix) A system for feedback of operating experience;
  (x) Evidence of the effectiveness and efficiency of the ageing management programme.

Recommendations on ageing management are provided in Ref. [26].

3.77. At this point, after review, assessment and inspection, depending on national regulations and the outcome of the safety review, the regulatory body may decide to revoke, suspend, amend or renew the authorization of the person or organization responsible for the nuclear installation and its activities.

Long term shutdown

3.78. Long term shutdown is a state that is different from refuelling outage, maintenance, inspection or refurbishment, during which the nuclear installation is not in operation. (For example, a nuclear installation may be in long term shutdown just before its decommissioning, or for economic, political and other reasons.)

3.79. Long term shutdown should be justified by the licensee, and related plans and programmes should be subject to agreement by the regulatory body. Long term shutdown needs to be managed in a safe manner by the person or organization responsible for the nuclear installation and its activities, and should be subject to regulatory control, especially regarding: waste storage, spent fuel management, fire protection and suppression, radiation protection and fulfillment

of safety functions. During long term shutdown, a safety review should also be carried out to help maintain safety.

3.80. The licensee should submit to the regulatory body for authorization the specifications for maintaining the safety and security of the nuclear installation during long term shutdown. The regulatory body should review, assess and inspect such specifications and may attach conditions.

3.81. If a nuclear installation has been shut down for a long period, before it is returned to operation the regulatory body may require the licensee to perform a safety review including all the elements described in this Safety Guide and to carry out parts of the licensing process, as appropriate.

DECOMMISSIONING

3.82. An updated, detailed final decommissioning plan and its supporting safety assessment should be submitted by the licensee to the regulatory body for approval, prior to commencement of dismantling activities.

3.83. Decommissioning comprises: the preparation and approval of a detailed decommissioning plan; the actual decommissioning activities; the management of waste arising from these activities; demonstration that the decommissioning end point is achieved; and the updating of all existing safety related documents, as appropriate, including documents on physical protection and emergency response and the plan for remediation of the site.

3.84. The decommissioning stage consists of one or more substages, which may be subject to regulatory approval. Different human resources and competences from the operation stage are needed for decommissioning. Furthermore, staff motivation is crucial to maintaining a good safety culture in a plant that is undergoing decommissioning.

3.85. The nuclear installation should remain licensed throughout the period of decommissioning, with appropriate control retained by the licensee and with appropriate oversight by the regulatory body.

3.86. Decommissioning should only be authorized after the safe management of radioactive waste has been demonstrated in a waste management plan that is part of the decommissioning plan [28].

3.87. The decommissioning plan should be reviewed, assessed and inspected by the regulatory body to verify that decommissioning activities can be accomplished safely with a progressive and systematic reduction of radiological hazards. The decommissioning plan should also include conditions to be observed during decommissioning and the proposed end state for the nuclear installation, including the radiological status and radiation dose. The decommissioning plan should specify the requirements for on-site and off-site monitoring, as well as for physical protection and surveillance during decommissioning.

3.88. The progressive and definitive shutdown of systems and components important to safety should be adequately planned and managed by the licensee, and the regulatory body should review, assess and inspect for approval this shutdown or parts thereof, as appropriate.

3.89. At the end of its operating lifetime, the nuclear installation should enter post-operational decontamination and reduction of hazards to move towards a more passively safe state. Radiation protection aspects may require certain activities to be delayed to allow radioactivity to decay and radiation exposure to be reduced. To facilitate this process, some activities relevant to decommissioning may be carried out after shutdown of the nuclear installation under licence provisions carried over from the operating stage [26]. Such activities may include:

(a) Management of operational waste;
(b) Measurements to determine the inventory of radioactive material;
(c) Removal of nuclear fuel;
(d) Post-operational decontamination and reduction of hazards (including removal of liquids, materials relating to the original operation and other mobile hazardous materials for disposal or safe storage).

3.90. The management of radioactive waste from decommissioning should be a significant feature of the decommissioning plan. Large volumes of radioactive waste may be generated in a short time, and the waste may vary greatly in type and activity. In the review, assessment and inspection of the decommissioning plan by the regulatory body, it should be verified that radioactive waste can be managed safely through existing and new, qualified routes.

3.91. In authorizing the decommissioning of a nuclear installation, the regulatory body should take particular care in specifying measures to ensure the licensee's compliance with the terms of the licence, since the sanction of stopping activities

at the nuclear installation or revoking the licence may not be effective at this stage.

3.92. After post-operational decontamination and removal of hazards, mothballing (safe storage or enclosure) and interim storage may be permitted; for example, to allow for radioactive decay. Where it is proposed to defer decommissioning in whole or in part, it should be demonstrated that there will be no undue burden on future generations and that the benefits outweigh immediate decommissioning. Deferral of decommissioning should be justified on a case by case basis to the regulatory body. For example, proposals for deferral of decommissioning should address:

(a) Care and maintenance of the nuclear installation during the deferral period;
(b) Identification of ageing mechanisms;
(c) Knowledge management, including expected loss of staff and expertise.

3.93. In dismantling a nuclear installation, activities such as decontamination, cutting and handling of large equipment, and the progressive dismantling or removal of some existing safety systems have the potential to create new hazards. The safety analyses for the nuclear installation should therefore be reviewed and updated as dismantling progresses. In particular, in reviewing an application for a licence for decommissioning, the regulatory body should consider the following aspects during the decommissioning stage:

(a) Waste storage;
(b) Spent fuel management;
(c) Fire protection and suppression;
(d) Radiation exposure of workers, the public and the environment;
(e) Movement of radioactive material on-site and off-site;
(f) Non-radiological hazards, which should be dealt with by coordinated activities between the relevant regulatory bodies under clear memoranda of understanding;
(g) Tightness of vessels and systems for preventing leakage;
(h) Supply systems to prevent failure and to maintain the installation under proper control (e.g. electricity supply, ventilation);
(i) Integrity of hoisting devices to prevent falling of loads.

3.94. A final decommissioning report should be prepared, supported by appropriate records, and should be submitted to the regulatory body.

3.95. Requirements for decommissioning are established in Ref. [14]; further recommendations are provided in Refs [19, 30].

RELEASE FROM REGULATORY CONTROL

3.96. The release of a nuclear installation or a site from regulatory control requires, among other things, completion of decontamination and dismantling and removal of radioactive material, radioactive waste and contaminated components and structures.

3.97. The regulatory body should provide guidance on radiological criteria for the removal of regulatory controls over the decommissioned nuclear installation and the site, and should ensure that an adequate system is in place for properly managing this removal.

3.98. Before a nuclear installation is released from regulatory control, the regulatory body should review, assess and inspect the evidence for the following:

(a) That all responsibilities covered by all authorizations have been satisfactorily discharged by the licensee and that there is no reasonable expectation that the licensee will have further responsibilities with respect to anything remaining on the site;
(b) That any necessary institutional controls, including continuing environmental monitoring, are in place;
(c) That the final radiological status of the nuclear installation is fully documented;
(d) That the radiological history of workers and contractors is fully documented;
(e) That documentation is made publicly available (unless protected by law from disclosure, such as nominative dose records).

3.99. Before termination of the licence and release of the site from regulatory control, a final radiological survey should be conducted by the licensee or an accredited contractor. The survey should be conducted at the completion of the decommissioning activities and should be examined by the regulatory body to verify that the regulatory criteria and decommissioning objectives have been fulfilled. The results of the survey should be archived and kept for a suitable period, as appropriate.

3.100. Once the regulatory body has accepted the evidence provided, the licence can be terminated and the licensee can be relieved of further licensing responsibilities. Further recommendations on the release of sites from regulatory control are provided in Ref. [31].

Appendix

EXAMPLES OF DOCUMENTS TO BE SUBMITTED TO THE REGULATORY BODY

A.1. All the following documents should be updated, as appropriate, and submitted to the regulatory body during the licensing process. The content of these documents may be divided or combined into different documents, as appropriate:

(1) A descriptive construction report (including a quality manual), which consists of a description of the fundamental elements including basic information on the nuclear installation, the process and technologies used, justification of related activities and provisions for decommissioning;
(2) References to and benchmarks against other relevant nuclear installations, including those in other States, if any, and a summary of the most significant differences between the installations;
(3) A draft plan for the project, including phases and anticipated schedule (including technical research and development, if necessary), a prior economic study regarding the necessary financial investments and the expected costs;
(4) A site evaluation report, which may include a report on the environmental radiation monitoring programme and all or some of the elements described in paras 3.3–3.11 dealing with the site evaluation;
(5) Reports on the use of cooling sources and discharges into the environment, and a report on the environmental impact assessment;
(6) Public inquiry strategy plans and reports according to each State's framework and practices;
(7) A report on the management and organization of the design and construction project, including responsibilities and a list of contractors;
(8) A report on the acquisition programme, including a list of the structures, systems and components and their origin, and, as applicable, details of the manufacturing process for structures, systems and components important to safety;
(9) The strategic plan for the licensing process, including the set of requirements, guides, codes and standards to comply with, which may be partly adopted from the vendor State (if any);

(10) A preliminary safety analysis report before authorization to begin construction, which may include information on site evaluation, the design basis, nuclear and radiation safety, deterministic analyses and complementary probabilistic safety assessment;
(11) Plans relating to the operating organization and its management system for all licensing steps;
(12) Technical design documents;
(13) Physical protection plans prepared using design related threat analyses, and especially interfaces with safety measures;
(14) Fire protection plans;
(15) Plans for accounting for and control of nuclear material;
(16) Training and qualification plans for operations personnel;
(17) Proof of trustworthiness of all staff who will be engaged in responsible or sensitive positions;
(18) Commissioning programmes and reports, including the elements described in paras 3.44–3.55 dealing with the commissioning stage;
(19) Final safety analysis report, which may include all or parts of the elements described in paras 3.3–3.100 on the site evaluation, design, construction, commissioning and operation stages and on provisions for decommissioning;
(20) Ageing management plans;
(21) General operating rules, including details of all elements described in paras 3.56–3.81 dealing with the operation stage, and operating procedures;
(22) Technical specifications, including all operational limits and conditions (may be included in the general operating rules);
(23) A plan for collecting and applying feedback on operating experience;
(24) Plans for evaluating and improving safety performance;
(25) Operating procedures for accident management;
(26) Emergency preparedness and response plans;
(27) Reports and manuals on the radiation protection programme;
(28) Reports on radioactive waste and spent fuel management, including a description of the system for the classification and characterization of waste, and rules and criteria to release waste;
(29) Modification rules (may be included in the general operating rules);
(30) Details of the maintenance programme and the periodic testing programme;
(31) Reports of periodic safety reviews or other safety reviews;
(32) Decommissioning plans and reports, including details of final shutdown, and decommissioning substages, actions and safety analyses.

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