IAEA SAFETY STANDARDS
for protecting people and the environment

Step 11: Second review of the draft publication by the Review Committees

Licensing Process for Nuclear Installations

DS539
(revision of SSG-12)

DRAFT SAFETY GUIDE

CONTENTS

1. INTRODUCTION

BACKGROUND

1.1 Achieving a high level of protection and safety in relation to nuclear installations[1] requires an effective governmental, legal and regulatory framework. ~~—~~This framework includes~~including~~ a regulatory body with well-defined responsibilities and functions,~~—~~ as well as qualified vendors, manufacturers and operating organizations. The authorization[2] of nuclear installations (and, where appropriate, of activities undertaken at such installations) through a process of licensing is one of the core functions of a regulatory body. This process may result in the granting of one or more licences during the lifetime of a nuclear installation, depending on the regulatory framework.

1.2 ~~Recommendations~~ Requirements on the establishment and functions of a regulatory body are established in IAEA Safety Standards Series No. GSR Part 1 (Rev. 1) Governmental, Legal and Regulatory Framework for Safety [1].

1.3 Figure 1 shows the main stages of the licensing process dealt with in this Safety Guide. These include the six major stages of the lifetime of a nuclear installation as defined in the IAEA Nuclear Safety and Security Glossary [2]. Past experience from some States has shown that there is some overlapping of these stages; that is, one stage may start before the previous one is fully completed, as allowed by national legislation and/or regulatory requirements. Moreover, in a given stage, there may be one or more 'hold points' or required licensing actions, set by national legislation and/or regulatory requirements.

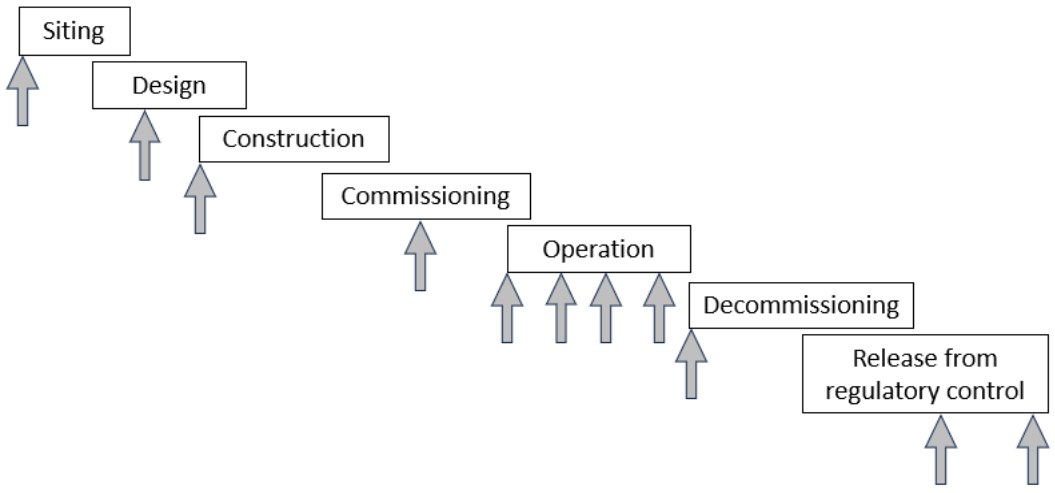

FIG. 1. Stages in the lifetime of a nuclear installation; the arrows provide examples of where a regulatory body may impose hold points.

[1] A nuclear installation is defined as any nuclear facility subject to authorization that is part of the nuclear fuel cycle, except facilities for the mining or processing of uranium ores or thorium ores and disposal facilities for radioactive waste [2].

[2] Authorization is defined as the granting by a regulatory body or other governmental body of written permission for a person or organization (the operator) to conduct specified activities. Authorization could include, for example, licensing (issuing a licence), certification (issuing a certificate) or registration [2]. In this Safety Guide, the term 'licensing' is used by default. The term 'authorization' is used where appropriate.

1.4 This Safety Guide supersedes IAEA Safety Standards Series No. SSG-12, Licensing Process for Nuclear Installations[3].

OBJECTIVE

1.5 This Safety Guide provides recommendations on meeting the requirements relating to authorization by the regulatory body established in GSR Part 1 (Rev. 1) [1], particularly Requirements 23 and 24. In particular, this Safety Guide provides recommendations on developing a licensing process to be applied by regulatory bodies for granting licences for nuclear installations and their activities. This includes 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.

1.6 This Safety Guide is aimed at regulatory bodies and applicants intending to pursue licensing of nuclear installations.

SCOPE

1.7 This Safety Guide provides recommendations on how the licensing process should be applied at the various stages of the lifetime of a nuclear installation (siting, design, construction, commissioning, operation and decommissioning) until release from regulatory control. Interactions between the regulatory body and the applicant or licensee (including during pre-licensing) are also considered. Recommendations on the application ~~by a regulatory body~~ of a graded approach to the licensing process by a regulatory body are also provided in this Safety Guide.

1.8 While this Safety Guide focuses on safety at nuclear installations, security and safeguards are also important considerations, and interfaces between safety, security and safeguards need also to be considered and evaluated by the regulatory body during the licensing process. The IAEA Nuclear Security Series covers security issues at authorized installations, and aspects of safeguards are covered by further publications, as noted in the IAEA Safeguards Glossary 2022 Edition [3].

STRUCTURE

1.9 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. Appendix I provides examples of documents to be submitted to the regulatory body. Appendix II provides recommendations on the licensing of small modular reactors and highlights key aspects of deployment models that should be taken into account throughout the licensing process.

[3] INTERNATIONAL ATOMIC ENERGY AGENCY, Licensing Process for Nuclear Installations, IAEA Safety Standards Series No. SSG-12, IAEA, Vienna (2010).

2. RECOMMENDATIONS ON THE GENERAL LICENSING PROCESS FOR NUCLEAR INSTALLATIONS

DEFINITIONS RELEVANT TO THE LICENSING OF NUCLEAR INSTALLATIONS

2.1 The regulatory body, whose status may vary from one State to another, is defined as an authority or system of authorities designated by the government of a State as having legal authority for conducting the regulatory process, including ~~issuing~~ granting authorizations [2].

2.2 A licence is a legal document issued by the regulatory body granting authorization to perform specified activities relating to a facility or activity [2]. A licence is a product of the authorization process, usually 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. Licensing may take different forms, such as granting of a permit, agreement, consent, regulatory approval or granting of another similar regulatory instrument, depending on the governmental, legal and regulatory framework of the particular State.

2.3 Licence conditions are legally binding~~additional~~ licence-specific requirements imposed by the regulatory body as part of the licensing process~~obligations with the force of law that may be incorporated into the licence for a nuclear installation,~~ to supplement general regulatory requirements or to define ~~make~~ them more precisely, if necessary. All licence conditions should be explicitly stated in the licence, or incorporated ~~Licences should state explicitly, or should include~~ by reference or attachment~~, all licence conditions imposed by the regulatory body~~.

2.4 An applicant is a person or organization who applies to a regulatory body for authorization to undertake specified activities [2].

2.5 The holder of a current licence is termed a licensee [2]. The licensee is the person or organization having overall responsibility for a facility or activity [2]. Within the context of this Safety Guide, the licensee is the organization possessing the licence(s) for the pertinent stage(s) of the lifetime of a nuclear installation and its activities. The person or organization having overall responsibility for a nuclear installation is required to apply to the regulatory body for permission to begin or continue to perform certain activities, as specified by the regulatory body (see Requirement 23 and 24 of GSR Part 1 (Rev. 1) [1]). A licensee might have its licence for operation expire or be suspended or revoked by the regulatory body, but should not be released from its prime responsibility for safety, security and safeguards unless so specified by the regulatory body.

2.6 Licences and other types of authorization are granted or denied in accordance with the national legal and governmental framework and are required to cover all stages of the lifetime of the nuclear installation, which usually include, siting ~~and site evaluation~~, design, construction, commissioning, operation and decommissioning (see para. 4.29 of GSR Part 1 (Rev. 1) [1]), until the installation is released from regulatory control.

BASIC LICENSING PRINCIPLES FOR NUCLEAR INSTALLATIONS

2.7 The licensing process should be understood by all the parties concerned and should be well defined, documented, clear, transparent and traceable. The licensing process should be established in a

systematic way to facilitate efficient progression of regulatory activities. The steps of the licensing process should follow a logical order.

2.8 In developing a licensing process, consideration should be given to 'pre-licensing' processes, for example, steps that provide for early feedback (and potentially approval) on potential sites and on design features for construction and operation of nuclear installations. Pre-licensing processes can include early engagement between vendors, licence applicants (or potential applicants) and the regulatory body. This approach may be especially appropriate for first-of-a-kind designs and designs with innovative technology that are still in various stages of development (see also para. 2.~~29~~25). A pre-licensing process could be designed to help minimize duplication of effort through the different steps and, where possible, allow for some steps to be conducted in parallel. When used, it should establish a clear division of responsibilities at the various steps, between the regulatory body, vendor and operating organization and should include options for early public information. Any such processes should ensure that the most important safety issues (including their interactions with security and safeguards) are dealt with properly in the pre-licensing phase. Pre-licensing does not replace the licensing process and does not provide an authorization. However, the outcomes of any pre-licensing engagement, if applicable, should be documented and referred to during subsequent licensing processes, and the outcomes of this engagement should be shared with the public (see para. 2.26)~~as applicable~~. Further recommendations are provided in para. 3.2.

2.9 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 established to ensure that the person or organization responsible for the nuclear installation and its activities remains responsible for safety, security and safeguards 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).

2.10 The licensing process should include demonstration of the 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, other authorities, and/or the applicant.

2.11 The legal framework of the State should ensure that nuclear related activities are only conducted after proper authorization by the regulatory body. The legal framework should also set out the responsibilities for issuing a licence or other type of authorization. Depending on the system used in the particular State, different authorizations may be issued by different authorities.

2.12 Once an application has been accepted and a licence has been issued, subsequent licensing activities and arrangements may be undertaken between the licensee and the regulatory body. These may include requests for additional documentation or safety demonstrations or for further activities, including, in some States, the construction of additional facilities on the site.

~~2.13 Requirement 23 of GSR Part 1 (Rev. 1) [1] states:~~

~~"**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.”

2.14 Requirement 24 of GSR Part 1 (Rev. 1) [1] states that “**The applicant shall be required to submit an adequate demonstration of safety in support of an application for the authorization of a facility or an activity.**”

2.15 Requirement 7 of GSR Part 1 (Rev. 1) [1] states:

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

2.162.13 Procedures for evaluating, approving, denying, and grantingissuing authorizations for each stage of the lifetime of the nuclear 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.

2.172.14 Licence conditions should cover, as appropriate, safety related aspects affecting the siting, 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 conditions, if applicable, should relate to variouscover all important aspects, including:

(a) Radiation protection;
(b) Maintenance programmes;
(c) Emergency planning and procedures;
(d) Modifications;
(e) The management system;
(f) Operational limits and conditions;
(g) Operating procedures;
(h) Radioactive waste management;
(i) Arrangements for decommissioning;
(j) Nuclear security;
(k) Safeguards provisions;
(l) Nuclear liability (insurance);
(m) Safety analysis;
(n) Periodic safety review;
(o) Human and financial resources;
(p) Fuel management;
(q) Outages;
(r) Ageing management;
(s) Safety and security culture;
(t) Authorization of personnel.

Licence conditions may refer to, but should not duplicate, regulatory requirements, to avoid discrepancies or inconsistencies when the regulations are revised. In some States, licence conditions could also include exemptions.

~~2.18~~2.15 Licence conditions may vary in format; however, they should all have certain basic characteristics to ensure that they are 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. The grading of regulations can help in resolving contradictions in licence conditions. If 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:

(a) Licence conditions that set technical limits and thresholds;
(b) Licence conditions that specify procedures and modes of operation;
(c) Licence conditions pertaining to administrative matters;
(d) Licence conditions relating to inspection and enforcement;
(e) Licence conditions pertaining to the response to abnormal circumstances, including emergency situations.

~~2.19~~2.16 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. In cases where several licensees share items important to safety, arrangements should be made to ensure that the specific responsibilities of all licensees are identified so that overall safety is not compromised.

~~2.20~~2.17 The documents submitted to the regulatory body within the framework of the licensing process should be updated, as appropriate, during the lifetime of the nuclear installation. These documents should be incorporated into, and considered as part of, the licence, as necessary. The content of submissions to the regulatory body may be divided or combined into different documents, as appropriate, depending on regulatory requirements and the regulatory framework. Examples of such documents are given in Appendix I; the names and content of these documents may vary from one State to another. The safety analysis report is an important document for the entire licensing process. The required scope of the safety analysis is established in Requirement 14 and paras 4.49–4.52 of IAEA Safety Standards Series No. GSR Part 4 (Rev. 1), Safety Assessment for Facilities and Activities [4]. Recommendations for the safety analysis reports for nuclear power plants and for research reactors are provided in IAEA Safety Standards Series Nos SSG-61, Format and Content of the Safety Analysis Report for Nuclear Power Plants [5], and SSG-20 (Rev. 1), Safety Assessment for Research Reactors and Preparation of the Safety Analysis Report [6], respectively.

~~2.21~~2.18 Licensing principles should be established in the legal and regulatory framework. Examples of licensing principles include 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 structure, adequacy of resources, competence of managers and staff, appropriateness of management arrangements, and if applicable, financial arrangements for decommissioning of licensed activities to fulfil its safety obligations as the operating organization of the nuclear installation. This applies to a new licence, licence renewal, and the transfer of a licence.
(b) The regulatory framework for dealing with authorization requests should be clear, especially the process for applying for a licence or authorization, including the expectations for what constitutes a complete application.
(c) The regulations to which the licensing and approval processes refer should explicitly describe the

regulatory approach to be followed (i.e. prescriptive or performance-based, or a combination of both). See also paras 3.12 and 3.52 of IAEA Safety Standards Series No. GSG-13, Functions and Processes of the Regulatory Body for Safety [7].

(d) The licensing of a nuclear installation should be based on predefined documents that are to be submitted to the regulatory body by the person or organization responsible for the nuclear installation and its activities. These documents are required to be reviewed by the regulatory body (see Requirement 25 of GSR Part 1 (Rev. 1) [1]) and should be updated by the licensee, as appropriate, in accordance with the licence conditions or regulations.

(e) The expenses associated with the licensing process and the person or organization expected to pay these expenses (i.e. if they are not the responsibility of the State) should be clearly specified.

(f) A clear and explicit set of requirements, criteria and standards forming the licensing basis should be defined by regulations or by the regulatory body.

(g) Nuclear security and emergency preparedness requirements should be predefined and should be considered in the licensing process.

(h) A graded approach is required to be taken by the regulatory body when performing reviews, assessments or inspections throughout the authorization or licensing process (see Requirements 26 and 29 of GSR Part 1 (Rev. 1) [1]). Such an approach should be reflected in regulations and/or guides.

(i) The licensing process should be transparent to the public, and any licence or authorization should be published or made available to the public, except for security sensitive and/or commercial proprietary information.

(j) The scope of the licence (e.g. the site, a nuclear installation, maximum number of modules on the site at one time, parts of a nuclear installation and activities, or a series of authorizations), its duration and any conditions should be clearly defined by the regulatory body.

(k) The regulatory body may ~~include~~ impose licence conditions, 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 conditions to the transfer.

(m) The applicant and the regulatory body should take into account international and industry good practices, as appropriate, throughout the licensing process.

(n) The analysis approach to safety should be clearly defined, including the use of analytical tools and deterministic and probabilistic methodologies, for which clear acceptance criteria should be set by the regulatory body.

(o) Safety reviews and their independent verification are required to be performed by the licensee either on a periodic basis or as required by the regulatory body (see para. 4.39A of GSR Part 1 (Rev. 1) [1] and Requirement 21 of GSR Part 4 (Rev. 1) [4]), 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 the licence, if deemed necessary.

(p) The prime responsibility for safety is required to be assigned to and assumed by the person or organization responsible for any facilities and activities that give rise to radiation risks (see Requirement 5 of GSR Part 1 (Rev. 1) [1]). Compliance with regulatory requirements does not relieve the person or organization of this prime responsibility. The person or organization responsible for a nuclear installation should demonstrate to the satisfaction of the regulatory body that this prime responsibility has been and ~~is likely to~~ continues to be fulfilled.

(q) Clear conditions should be established for public participation in the licensing process (see paras 2.4~~6~~0–2.4~~9~~3).

(r) Interfaces between safety, security and safeguards should be addressed to ensure the accomplishment of the objectives of all three areas, including the integration of emergency management plans with safety and security considerations. The licensee's proposed means of addressing these interfaces should be evaluated by the regulatory body in the licensing process. Special attention should be paid to cases where different regulatory bodies are involved in these aspects, to ensure there is no gap or overlap in responsibilities.

(s) The means of challenging or appealing a licensing decision should be made clear by the regulatory body or within the regulatory framework.
(t) The site boundaries should be clearly defined in the licensing process and justified based on safety and security considerations.

~~2.22~~2.19 The regulatory body is required to have unfettered access for regulatory staff to any facility, and any safety related documents considered necessary for authorization purposes (see para. 2.13 of GSR Part 1 (Rev. 1) [1]).

~~2.23~~2.20 Changes or modifications to the site, nuclear installation, organizational structure, procedures, processes and plans for future activities (e.g. decommissioning) of the licensee may be needed at any stage of the nuclear installation's lifetime. The regulatory body should establish when review, assessment and/or approval and revision of the licence or certain licence conditions is needed (depending on factors such as the nature of the changes and the magnitude of the risks involved). Examples of where changes or modifications to a nuclear installation may require regulatory review include licence transfer, the replacement of major components or subsystems and, in some cases, wholesale replacement of the facility.

~~2.24~~2.21 The government is required to ensure that the legal framework contains infrastructural arrangements to address the interfaces between safety, security and safeguards (see Requirement 12 of GSR Part 1 (Rev. 1) [1]). Synergies that exist between the processes for safety, security and safeguards should be fully exploited. Safety, security and safeguards measures should be designed and implemented in an integrated manner so that they do not compromise each other. Potentially conflicting needs resulting from safety, security and safeguards considerations should be identified as early as possible in the licensing process and should be carefully analysed to provide a mutually acceptable solution with respect to all three areas. Additional information on addressing the safety–security interface is provided in Refs [6]~~[~~[8]~~8~~, [9]~~9~~, [10]~~10~~].

ROLES AND RESPONSIBILITIES OF THE REGULATORY BODY IN THE LICENSING PROCESS FOR NUCLEAR INSTALLATIONS

~~2.25~~2.22 The government is required to ensure that the regulatory body is empowered to make regulatory decisions and to grant, amend, suspend, transfer, or revoke licences, conditions or authorizations, as appropriate (see para. 2.7 of GSR Part 1 (Rev. 1) [1]). Recommendations on the organization and functions of the regulatory body are provided in IAEA Safety Standards Series Nos GSG-12, Organization, Management and Staffing of the Regulatory Body for Safety [11], and GSG-13, Functions and Processes of the Regulatory Body for Safety [7].

~~2.26~~2.23 The regulatory body should ensure that regulations address the licensing process for nuclear installations and should provide procedures or guidelines for applicants in order to provide clarity and transparency in the licensing process. The procedures or guidelines for applying for a new licence should be published by the regulatory body. It should be made clear what the application should include, for example:

(a) The name, address and any additional contact information of the applicant.
(b) A high-level description of the site for which the application is being made.
(c) The nature of the activity that the applicant wishes to undertake, the main risks associated with the activity and the requested time duration for the license.
(d) Details of any relevant existing licence(s).

(e) An environmental assessment report, in accordance with regulatory requirements.
(f) Information on the ownership of the installation and the site. This would include whether the installation or activity is fully or primarily owned or controlled by a person from another State or organization.
(g) A preliminary safety analysis report.

~~2.27~~2.24 The regulatory body should implement a preparatory phase before an applicant submits an application. During this phase, basic licensing requirements should be defined and the process to be followed should be made clear to the applicant. This could be, for example, specification of the language, units and format of the proposed application. During the preparatory phase, the staff of the regulatory body should be trained so they have sufficient knowledge of the design of nuclear installations that may be proposed. The basic licensing requirements set out in the preparatory phase should be design-neutral so that several designs may be considered at the beginning of a project. In addition, the applicability of non-nuclear requirements (e.g. for civil works, fire regulations, environmental permitting) may be discussed with the regulatory body and other relevant authorities in the preparatory stage. Detailed and explicit design requirements should then be developed during the early phases of the project.

~~2.28~~2.25 The regulatory body should encourage pre-licensing interactions (see para. 2.8) with the vendor and with the potential licensee, to allow for early identification and understanding of technical and policy issues that could affect licensing. This is particularly important for first-of-a-kind installations, and for matters relating to radioactive waste management and decommissioning. Design features within the context of safety, security, and safeguards may also be addressed in pre-licensing interactions. Early in the pre-licensing stage, the vendor and the potential licensee might not have yet developed everything that would be needed during the licensing processes.

~~2.29~~2.26 Regulatory bodies should publicly acknowledge that pre-licensing interactions with the vendor and potential licensee are taking place.

~~2.30~~2.27 The regulatory framework should empower the regulatory body to conduct reviews and assessments of:

(a) The applicant's evidence of (and plans for) regulatory compliance with regard to its organizational capability (including the competence of contractors) and the safety case for the nuclear installation and related activities;
(b) The descriptions and claims in the licensing documentation submitted by the applicant or licensee;
(c) The continued organizational capability of the licensee (and of its contractors and subcontractors) to meet the conditions of the licence and regulatory requirements.

~~2.31~~2.28 Early assessment of the competence and capability of the applicant should be conducted by the regulatory body to ensure that the applicant will be able to manage the later phases of the project for the nuclear installation. The applicant should be encouraged to conduct a resourcing assessment at the start of the project to evaluate the staff and competencies that will be needed during the different project phases. The applicant should give consideration to how and from where it will recruit such staff and how it will find additional external technical support and advice when needed. This is particularly relevant for applicants that have not previously applied for or held a licence for a nuclear installation.

~~2.32~~2.29 The regulatory body is required to establish a management system (see Requirement 3 of IAEA Safety Standards Series No. GSR Part 2, Leadership and Management for Safety [12]). This management system should include the processes 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, including any external resources that are needed. The management 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 the lifetime, in accordance with regulatory requirements.

~~2.33~~2.30 The regulatory body should consider whether a reassessment of safety at the nuclear installation is necessary, for example, due to the following:

(a) Experience relevant to safety that has been gained at the nuclear installation, at similar nuclear installations and/or 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 or modifications to the licensed activities important to the safety of a nuclear installation;
(d) Changes in the regulatory framework, regulations and guides;
(e) Changes in the licensee;
(f) Changes in the site conditions, such as those due to climate change or newly identified geotechnical conditions;
(g) Changes in the facility's arrangements for emergency preparedness and response;
(h) The lessons learned from a safety significant event;
(i) Identification of non-compliance with the licensing basis.

Following such a reassessment, the stage in the lifetime of the nuclear installation may be halted or made subject to specific conditions, depending on the safety issue involved; the stage 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~~2.31 As part of the licensing process and before a licence is granted, the regulatory body should monitor the applicant or licensee to verify that it has, as appropriate:

(a) A suitable management system (see GSR Part 2 [12][~~12~~]);
(b) An established and suitable safety culture programme.
(c) Clear procedures for analysing and approving any modifications (including temporary modifications) having an impact on safety (see also para. 2.3~~2~~5);
(d) Certificates of sufficient liability insurance or other financial security;
(e) Proof of trustworthiness of all staff who will be engaged in responsible or sensitive positions (further information is available in IAEA Nuclear Security Series No. NST065, Establishment and Implementation of a Trustworthiness Programme in Nuclear Security [13][~~13~~]);

~~2.35~~2.32 After granting of the first licence (e.g. the construction license), the regulatory body should ensure that proposed modifications are categorized by the licensee in accordance with their safety significance. This categorization should follow an established procedure, which may be subject

to approval by the regulatory body. Modifications that are categorized as significant to safety should be submitted to the regulatory body for review and approval. The regulatory body should inspect compliance with procedures for categorization of modifications on a regular basis. Recommendations on modifications in nuclear power plants and research reactors are provided in IAEA Safety Standards Series Nos SSG-71, Modifications to Nuclear Power Plants [14], and SSG-24, Safety in the Utilization and Modification of Research Reactors [14][15]~~[15]~~, respectively.

~~2.36~~2.33 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. Further recommendations are provided in IAEA Safety Standards Series No. SSG-50, Operating Experience Feedback for Nuclear Installations [16]).

~~2.37~~2.34 For each stage of the lifetime of a nuclear installation, the regulatory body should specify the kind of information and reports that should be sent to the regulator body, and the frequency of reporting.

~~2.38~~2.35 Regulatory provisions should be established 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.

ROLES AND RESPONSIBILITIES OF THE APPLICANT

~~2.39~~2.36 The applicant for a licence for a nuclear installation has the following roles and responsibilities:

(a) The applicant should prepare and submit a comprehensive application to the regulatory body that demonstrates that priority is given to safety, security and safeguards, if applicable, ensuring that regulatory requirements are met and that a high level of compliance with the requirements for safety, security and safeguards will be maintained for the lifetime of the nuclear installation.
(b) The applicant should perform an independent verification of the safety assessment before it is submitted to the regulatory body for review.
(c) The applicant should have the capability within its own organization (either on-site or within the organization as a whole), even when outsourcing licensed activities, to understand the design basis and safety analyses for the nuclear installation, and the associated operational limits and conditions.
(d) The applicant should exercise oversight over all of the work of contractors, especially when outsourcing licensed activities, understand the safety significance of this work and take responsibility for its implementation.
(e) The applicant should submit a procedure or description to the regulatory body of the process for configuration management, including for managing modifications, which may be subject to approval by the regulatory body. Alternatively, requirements for dealing with modifications may be established directly in the regulations, and the regulatory body may then perform inspections to verify that the licensee meets such requirements.

(f) The applicant should have capability of an informed customer[4] and a formal and effective external relationship with the original design organization or an acceptable alternative.
(g) The applicant should assess safety in a systematic manner on a regular basis and perform improvements, as necessary to maintain an adequate~~the~~ level of safety.
(h) The applicant should demonstrate that adequate arrangements for nuclear security and emergency preparedness and response are planned for the nuclear installation.
(i) The applicant should understand the obligations of the nuclear installation for accounting for, and control of, nuclear material and radioactive material.
(j) The applicant should demonstrate in its application for a licence that it has, or will have when necessary, and will continue to maintain:

    (i) Adequate financial resources (e.g. for regulatory fees and liability insurance (depending on the legal framework), 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.

(k) The applicant should be able to demonstrate that contractual arrangements do not compromise the independence or safety of its decision making process.

~~2.40~~2.37 The applicant should demonstrate that it will have procedures within its management system for each stage of the lifetime of the nuclear installation, including, where appropriate, procedures for obtaining independent advice. Throughout the licensing process, the regulatory body should confirm that the applicant ~~licensee~~ properly implements these procedures. The applicant ~~licensee~~ should also demonstrate that it will have the following procedures, at a minimum:

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

MAIN CONTENTS OF A LICENCE FOR A NUCLEAR INSTALLATION

~~2.41~~2.38 The licence for a nuclear installation should include the following elements (unless specified elsewhere in the legal and regulatory framework):

(a) A unique licence identification.
(b) The name of the issuing authority, the laws and regulations under which the licence is issued, the official designations of those who are empowered to issue the licence (e.g. whose signature is on the licence) and the authority to which the licensee will be accountable.
(c) The name 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 supporting drawings, as appropriate.

[4] Informed customer is "the capability of an organization to have a clear knowledge and understanding of the product being supplied or the service being provided." [2]

(e) The maximum allowable inventories of radioactive sources, including for any authorized future expansion of the installation~~, if relevant~~.
(f) The procedure 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 sources, personnel, the public and the environment.
(h) Any limits on operation and use (e.g. dose limits, dose constraints, discharge limits, emergency action levels, limits on the duration of the licence).
(i) Any separate additional authorizations that the licensee is required to obtain from the regulatory body.
(j) The procedure for reporting events and incidents at the installation.
(k) The procedure for providing routine reports to the regulatory body.
(l) The requirements for retention of records by the person or organization responsible for the nuclear installation, including the time periods for which records should be retained.
(m) Any requirements for nuclear security at the installation.
(n) The requirements for the arrangements for emergency preparedness and response.
(o) The procedures for changing any information stated in the licence.
(p) The documentary basis (i.e. the documents in support of the application and those used by the regulatory body in the review and assessment process, which together form the basis for issuing the licence).
(q) The relationship to other licences, for example 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).
(r) Procedures for challenging the licence or part of the licence.
(s) Licence conditions dealing with safety aspects of the installation and its activities.
(t) The duration of the licence.

~~2.42~~2.39 The licence conditions (see paras 2.1~~74~~ and 2.1~~85~~) 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. Further recommendations are provided in Section 3.

PUBLIC PARTICIPATION IN THE LICENSING PROCESS FOR A NUCLEAR INSTALLATION

~~2.43~~2.40 Members of public should be given an opportunity to present their views during the licensing process for a nuclear installation. If a site is near a State's national border, appropriate coordination, including public participation, with neighbouring State(s) in the vicinity of the nuclear installation, should be arranged.

~~2.44~~2.41 Public participation and involvement in the regulatory process, reinforces the credibility of the regulatory body and enhances local public confidence in the regulatory framework. The process for public participation should allow individuals or societal groups to challenge the issuing of a licence or authorization.

~~2.45~~2.42 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 other mass media. The goal of transparency should be balanced with applicable laws protecting intellectual property and sensitive information.

(b) Formal meetings, formal hearings or 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 and their resolution should be appropriately documented at appropriate steps of the licensing process, in accordance with the regulatory framework.

~~2.46~~2.43 A process for consideration and resolution of concerns expressed by the public should be established by the regulatory body.

GRADED APPROACH TO THE LICENSING OF NUCLEAR INSTALLATIONS

~~2.47~~2.44 Paragraph 3.24 of IAEA Safety Standards Series No. SF-1, Fundamental Safety Principles [17] states that "The resources devoted to safety by the licensee, and the scope and stringency of regulations and their application, have to be commensurate with the magnitude of the radiation risks and their amenability to control." A graded approach is required to be used in the licensing process for different types of nuclear installation and the different levels of risks that they pose (see para. 4.33 of GSR Part 1 (Rev. 1) [1]). Application of a graded approach by the regulatory body should focus on 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. A graded approach is required to 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 (see Requirements 26 and 29 of GSR Part 1 (Rev. 1) [1]).

~~2.48~~2.45 The main factor taken into consideration in the application of a graded approach to regulatory control is the magnitude of the risks associated with the activities performed at the nuclear installation. Account should be taken of occupational and public exposures, radioactive discharges, radioactive contamination, environmental impact and the generation of radioactive waste during operation, as well as the potential consequences of anticipated operational occurrences and accidents, including their ~~probability~~ frequency of occurrence and the possibility of occurrence of very low probability events with potentially high consequences.

~~2.49~~2.46 A graded approach to licensing should also take account of other relevant factors such as the maturity of the licensee and the technology[5] and the complexity[6] and ageing related issues relating to the nuclear installation and its activities.

~~2.50~~2.47 The application of a graded approach should be reassessed 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.

~~2.51~~2.48 During the licensing process, the regulatory body should ensure that the licensee has applied a graded approach to the arrangements for emergency preparedness and response (see para. 2.20 of GSR Part 1 (Rev. 1) [1]), in accordance with the requirements established in IAEA Safety Standards Series No. GSR Part 7, Preparedness and Response for a Nuclear or Radiological Emergency [18].

3.STEPS OF THE LICENSING PROCESS FOR NUCLEAR INSTALLATIONS

3.1 The licensing process for a nuclear installation normally includes the following steps:

(a) Siting ~~and site evaluation~~ (which may include an environmental impact assessment);
(b) Design;
(c) Construction (which may include procurement, manufacturing, ~~and~~ construction and installation stages on the site or off the site);
(d) Commissioning;
(e) Operation (which may include maintenance, refuelling, in-service inspection, extended shutdowns and other associated activities);
(f) Decommissioning;
(g) Release from regulatory control.

Each step of the licensing process may be divided into several sub-steps or may be merged or combined as appropriate to facilitate the regulatory process. Combining authorizations or licences for multiple stages (e.g. for siting and construction or for construction and operation) may also give more

[5] Maturity relates to: the use of proven practices and procedures and proven designs; data on operational performance of similar facilities or activities; uncertainties in the performance of the facility or activity; and the continuing and future availability of experienced manufacturers and constructors (see para. 3.4 of GSR Part 4 (Rev. 1) [4]).~~the use of proven practices and procedures, proven designs and operating experience at similar nuclear installations and for similar activities; uncertainties in the operation of a nuclear installation; and the availability of competent staff and experienced managers, contractors and suppliers.~~

[6] Complexity relates to: the extent and difficulty of the efforts required to construct a facility or to implement an activity; the number of related processes for which control is necessary; the extent to which radioactive material has to be handled; the longevity of the radioactive material; the reliability and complexity of systems and components; the accessibility of structures, systems and components (SSCs) for maintenance, inspection, testing and repair (see para. 3.4 of GSR Part 4 (Rev. 1) [4]).~~the extent and difficulty of the effort needed 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 estimated activity of the radionuclides concerned; the risk and uncertainty associated with activities and the reliability and complexity of structures, systems and components (SSCs) and their accessibility for maintenance, inspection, testing and repair.~~

predictability to the licensing process for the applicant. At each hold point specified by the regulatory body 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 LICENSING NUCLEAR INSTALLATIONS

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. However, alternative approaches do exist, especially for States with experience in nuclear power where several similar nuclear installations have already been built and are proven. The licensing process of another State may be adopted or adapted in the regulatory framework 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 are supplemented later 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 regulatory body may also consider using information from another regulatory body to make a regulatory decision, on the basis that the regulatory body receiving the information understands the regulatory basis and considers the local specificities and arrangements. The applicant may then apply in due course for a specific combined licence that authorizes, 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 legal and regulatory framework, safety and environmental issues may have to be resolved before the site or design licence is granted, and the resolution of such issues should be considered final. Pre-licensing interactions between the applicant and the regulatory body may be beneficial for such combined licences. The elements of such an alternative licensing process might include the following steps:

(a) Early site permits. In such a licensing process, a prospective applicant for a licence for construction, commissioning and operation can apply for approval for use of a specific site or sites, notwithstanding the fact that the application for a licence to construct, commission and operate a nuclear installation has not been submitted. Regulatory body approval of the site or sites may be done without the applicant having identified a specific design for the nuclear installation.
(b) Certified standard designs. In such a licensing process, any 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 submitted. The application should typically include bounding site conditions. 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 necessary due to site specific characteristics.
(c) Manufacturing licence. In such a licensing process, an applicant may apply for a manufacturing licence, to manufacture a nuclear installation, or parts thereof, notwithstanding that the application for a licence to construct, commission and operate a nuclear installation might not yet

have been submitted. An applicant could be allowed to refer to a certified standard design as part of its application for a manufacturing licence.

(d) Combined licence. In such a licensing process, an applicant can apply for a single licence to perform multiple stages (e.g. construction and operation). If the licensing process is to be combined 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 processes and to monitor all safety related activities during the various stages. Key hold points — such as fuel loading, first criticality, power increase, installation of additional modules (when in the scope of the granted licence), or other technical points, as appropriate — may be imposed on the licensee.

AUTHORIZATION OF SITING OF A NUCLEAR INSTALLATION

3.3 Requirements for site evaluation are established in IAEA Safety Standards Series No. SSR-1, Site Evaluation for Nuclear Installations [19]; the steps of the site selection and evaluation process are described in IAEA Safety Standards Series No. SSG-35, Site Survey and Site Selection for Nuclear Installations [20].

3.4 The siting process for a nuclear installation generally consists first of a site selection stage, which involves the investigation of a large region to select one or more preferred candidate sites, followed by a detailed evaluation of those candidate sites. 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 or environmental impacts, if applicable. For a site near a national border, consultations with neighbouring States should be performed.

3.5 Site evaluation is analysis of those factors at a site that could affect the safety of a facility or activity on that site [2]. This includes site characterization, including identification of external hazards (natural and human induced), 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 is required to consider the potential impact of the nuclear installation and its activities on the environment and the neighbouring population (see Section 6 of SSR-1 [19]). The feasibility of planning effective emergency response actions on the site and off the site, given the site's geographical and logistical factors (e.g. accessibility for emergency services, population evacuation routes), is also required to be evaluated (see Requirement 13 of SSR-1 [19]).

Safety assessment and environmental impact assessment

3.6 A radiological study of the region, including an appropriate baseline survey, is required to be performed before commissioning of the nuclear installation (see para.7.3 of SSR-1 [19]). The results of this study and survey should be provided to the regulatory body as the baseline for future analyses following operation of the nuclear installation and establishment of end-state criteria after decommissioning of the nuclear installation.

3.7 There are a number of factors that are required to be adequately considered in determining the suitability of the site (see Requirement 4 of SSR-1 [19]). Many of these factors may be covered by a

specific environmental impact assessment (see IAEA Safety Standards Series No. GSG-10, Prospective Radiological Environmental Impact Assessment for Facilities and Activities [20][21]~~[21]~~). In such cases, the legal relationship between this environmental impact assessment and the licensing process should be established. To meet the requirements established in SSR-1 [19], the following important factors for the licensing process for nuclear installations should be reviewed, assessed and inspected, as applicable, by the regulatory body, applying a graded approach, as appropriate:

(a) Factors dealing with the risks for the nuclear installation:

(i) The range of natural conditions (e.g. hydrology, meteorology, geography, geology, topology, volcanism) and risks and hazards for the site (e.g. hydrological hazards, extreme weather hazards, flood and landslide hazards, seismic and other geological hazards, tsunami hazards, external fire hazards), including the effects of climate change in the future.

(ii) The range of human induced risks and hazards for the site (e.g. adjacent hazardous industrial facilities, gas pipelines, mining, transport of dangerous goods in the vicinity of the site, air traffic and the potential for aircraft crashes and security risks).

(iii) Where multiple nuclear installations are considered for a single site, the site as a whole should be evaluated for interactions between the installations, for example, the potential for an accident at one nuclear installation affecting other nuclear installations on the site, shared services, the 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 (including industrial activities) regarding activities or changes that might significantly affect safety and security at the nuclear installation. Such a use should be controlled for the entire lifetime of the nuclear installation.

(v) Where a nuclear installation would provide end-products (e.g. power, heat, electricity, hydrogen) to a nearby industrial or municipal user, the interactions and external hazards between the nuclear installation and end-product users should be evaluated for their safety implications. For example, the arrangement should be implemented such that economic considerations of the end-product user should not affect safety of the nuclear installation.

(b) Factors dealing with risks for people and the environment, including transboundary aspects (see Ref. [22]), as appropriate:

(i) The location of the local population and population density (including foreseen demographic changes), monitoring of population distribution and human activities in the site vicinity, 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 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) The land use and the cultivation types, crops and animal breeding and historical heritage;

(vi) Marine or aquatic ecology (e.g. of seas, lakes, rivers);

(vii) The effect of gaseous, liquid and solid discharges (e.g. radioactive, toxic);
(viii) The potential for heat dissipation (including the ultimate heat sink).

AUTHORIZATION OF THE DESIGN OF A NUCLEAR INSTALLATION

3.8 Requirements for the design of nuclear installations are established in IAEA Safety Standards Series Nos SSR-2/1 (Rev. 1), Safety of Nuclear Power Plants: Design [23], SSR-3, Safety of Research Reactors [24] and SSR-4, Safety of Nuclear Fuel Cycle Facilities [25].

3.9 The design stage may include other tasks, such as a 'feasibility study', or a 'pre-licensing' step, depending on the national context (e.g. whether or not the State already has nuclear installations of the same type).

3.10 If sites and designs are considered separately early in the project to build a nuclear installation, then the regulatory body or the vendor should establish a definition of 'generic site' and a definition of 'generic design'. The 'generic site' may include consideration of aspects of multiple sites. The 'generic design' may include bounding assumptions regarding the activities at the installation. A process to ensure that both the site and the design are compatible should be established in the licensing process, including the assessment of site-specific conditions. The site evaluation and the environmental impact assessment should be reviewed and, if necessary, enhanced after the process through which the design is selected.

3.11 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. The design of nuclear installations is typically carried out through two stages: basic design and detailed design; the contents of each stage should be specified by regulatory body.

3.12 The design of the proposed nuclear installation should be such that safety requirements can be met in accordance with the design basis[7]. The applicant for a licence for construction should submit a basic design to the regulatory body before construction begins. This basic design can be approved or, depending on the regulatory framework, frozen (i.e. no change may be made to the basic design without the regulatory body's review and approval; see also para. 3.14) or partly frozen using a regulatory instrument pending the review and assessment of the regulatory body. During the design, the systematic analysis of the interfaces between safety, security and safeguards should be implemented in order to support the demonstration of fulfilment of Requirement 8 of SSR-2/1(Rev. 1) [23], Requirement 11 of SSR-3 [24] and Requirement 75 of SSR-4 [25].

3.13 During construction (and throughout the lifetime of the nuclear installation), parts of the detailed design may be subject to approval or may be frozen by the regulatory body. Such approvals or processes for freezing a detailed design should be undertaken by means of regulatory instruments, and conditions should be attached, as appropriate. If the licence applications for construction and operation are made

[7] The design basis is the range of conditions and events taken explicitly into account in the design of SSCs and equipment of the nuclear installation, in accordance with established criteria, such that the nuclear installation can withstand them without exceeding authorized limits [2].

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.

3.14 At the design stage, it should be ensured that SSCs comply with approved or accepted standards, codes and regulatory requirements, including quality assurance requirements. It should also be ensured that construction work at the nuclear installation can be 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 applicant or licensee, or directly — whether all organizations and contractors involved in design adequately implement these standards, codes and requirements, and should take appropriate actions if any deficiencies are identified.

3.15 Defence in depth is required to be considered in the design and subsequently, in operation (see Requirement 7 of SSR-2/1 (Rev. 1) [23]). Requirement 10 of SSR-3 [24] and Requirement 10 of SSR-4 [25]). Paragraph 3.31 of SF-1 [16][17]~~[17]~~ states:

> "The primary means of preventing and mitigating the consequences of accidents is 'defence in depth'. 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."

3.16 The objectives of defence in depth for a nuclear installation are [26]:

(a) To compensate for potential human and component failures;
(b) To maintain the effectiveness of the barriers by averting damage to the plant and to the barriers themselves;
(c) To protect the public and the environment from harm in the event that these barriers are not fully effective.

3.17 The five levels of defence in depth for nuclear power plants, research reactors and fuel cycle facilities are described in para 2.13 of SSR-2/1 (Rev. 1) [23], para. 2.12 of SSR-3 [24] and para. 2.12 of SSR-4 [25]. Recommendations on the application of the concept of defence in depth for nuclear power plants are provided in Section 3 of IAEA Safety Standards Series No. SSG-88, Design Extension Conditions and the Concept of Practical Elimination in the Design of Nuclear Power Plants [27].

3.18 In preparing an application for a licence for the design of a nuclear installation, the following should be verified by the licensee or applicant:

(a) That suitable deterministic safety analyses for normal operations, anticipated operational occurrences and accident conditions, including design basis accidents and design extension conditions, and probabilistic safety assessments have been performed, as appropriate;
(b) That there is adequate protection against external and internal hazards, as well as adequate provision and margin against levels of natural hazards more severe than those considered for design or derived from the hazard evaluation for the site;

(c) That there are adequate provisions for radiation protection;
(d) That routine radioactive discharges have been estimated and the radiological consequences assessed;
(e) That there is evidence of learning from operating experience and programmes to evaluate human and organizational factors;
(f) That the fundamental safety functions (i.e. control of reactivity; removal of heat from the reactor and from the fuel store; confinement of radioactive material, shielding against radiation, control of planned radioactive releases and limitation of accidental radioactive releases) will be fulfilled and that there is adequate reliability of the associated SSCs;
(g) That there are adequate provisions for operational radioactive waste management;
(h) That adequate arrangements for decommissioning of the installation (including for the management of radioactive waste arising from decommissioning) are in place.

The results of these verifications should be reviewed and assessed by the regulatory body when considering the licence application.

3.19 Nuclear installations are required to be designed in accordance with the relevant national and international codes and standards based on proven engineering practices (see Requirement 9 of SSR-2/1 (Rev. 1) [23]). Requirement 13 of SSR-3 [24] and Requirement 12 of SSR-4 [25]).

3.20 Safety analyses of the design should be performed using proven computer codes appropriate for the purpose, and should be used to specify (or improve) the following:

(a) Arrangements for commissioning of the nuclear installation;
(b) Categorization and classification of SSCs (in accordance with safety, quality, seismic qualification and environmental qualification criteria);
(c) Operational limits and conditions, safety limits for items important to safety, and operating procedures;
(d) Arrangements for in-service inspection, testing, surveillance and maintenance;
(e) Arrangements for radiation protection (for workers, the public and the environment);
(f) Arrangements for waste management and spent fuel management, where appropriate;
~~(f)~~(g) Arrangements for emergency preparedness and response;
~~(g)~~(h) Arrangements for nuclear security;
~~(h)~~(i) Arrangements for safeguards;
~~(i)~~(j) Measures to identify interfaces between safety, security and safeguards and to ensure the consistent accomplishment of the objectives and requirements for all three areas;
~~(j)~~(k) Human and organizational factors;
~~(k)~~(l) Training and certification requirements;
~~(l)~~(m) Documented verification and validation activities in design, testing, construction, commissioning, operation, maintenance and ageing management activities to ensure that the qualification of SSCs is valid for their design life;
~~(m)~~(n) The programme for feedback of operating experience;
~~(n)~~(o) Procedures for management of modifications.

3.21 The safety analyses should 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 step, if appropriate. Additionally, the operating organization, which is required to perform an independent

verification of the safety assessment before it is used by the operating organization or submitted to the regulatory body (see Requirement 21 of GSR Part 4 [4]), should have an internal process (which could include receipt of independent advice) for review of the assessment before it is submitted to the regulatory body to ensure that it is appropriate.

3.22 The regulatory body should review, assess and inspect, when applicable, 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 ~~postulated initiating events leading to~~ anticipated operational occurrences and design basis accidents, which might 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) Safety analyses of design extension conditions.
(c) The assumptions and approximations used in the analyses.
(d) The results of the analyses of combinations of events.
(e) A description, identification, categorization and classification of SSCs important to safety.
(f) The operational limits and conditions and permitted modes of operation.
(g) A list of barriers with their relative contributions to confinement of radioactive material and related limits.
(h) The means by which the concept of defence in depth is applied.
(i) Planned activities for confirming safety performance.
(j) Analytical methods and computer codes used in the safety analyses and the verification and validation of such codes.
(k) A description of the planned radioactive discharges and radioactive releases into the environment, and the radiation exposure of workers and the public from radioactive releases during normal operations and anticipated operational occurrences and under accident conditions.
(l) Safety criteria for analyses, particularly those relating to, if applicable, common cause events, cross-link effects, the single failure criterion, redundancy, diversity and physical separation;
(m) Verification and validation of the safety analyses and evidence of their robustness (e.g. sensitivity studies, research, testing, operating experience in other nuclear installations).

3.23 The regulatory body should ensure that the applicant or licensee has verified the adequacy of design parameters and site-specific data in relation to safety criteria of the specified design basis (e.g. for protection against hazards, for cooling). For a design without substantial operating experience, the applicant or licensee may have to incorporate additional features. These features should aim to provide sufficient margin to overcome uncertainties in the design due to the lack of operating experience and to avoid cliff edge effects[8].

3.24 The applicant or licensee should ensure that a process for review of the detailed design of SSCs important to safety, as produced by designers, vendors and manufacturers, is incorporated into the

[8] A 'cliff edge effect', in a nuclear power plant, is an instance of severely abnormal plant behaviour caused by an abrupt transition from one plant status to another following a small deviation in a plant parameter, and thus a sudden large variation in plant conditions in response to a small variation in an input (see SSR-2/1(Rev. 1) [23]).

management system. The regulatory body may review, assess and inspect, as appropriate, the management processes performed by the applicant or licensee in this respect.

3.25 The proposed arrangements for the safe management of radioactive waste should be included in the application for a licence for the design of a nuclear installation. The regulatory body should review and assess and, as appropriate, inspect proposals for on-site ~~treatment~~ processing and storage of radioactive waste and the management of spent fuel. The regulatory body should check if~~that~~ provisions for radioactive waste management are considered at the design stage in a manner compatible with the national strategy for radioactive waste (see Requirement 24 of SSR-4 [25])~~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 criteria for subsequent steps of waste management, and with regulatory requirements. Specifically, the regulatory body should verify that the waste and/or waste packages:

(a) Will be properly collected, characterized, segregated and processed in compliance with regulatory requirements and compatible with the anticipated nature and duration of storage and final~~pending~~ disposal;
(b) Can be subject to regular surveillance;
(c) Can be retrieved, where necessary, for further steps of predisposal waste management;
(d) Will be managed such that the volume and activity of radioactive waste are minimized;
(e) Will be properly cooled and shielded, as necessary;
(f) Will be evaluated for their potential impact on emergency response scenarios.

3.26 The applicant or licensee should, in compliance with national legislation, propose arrangements for managing radioactive discharges (liquid and gaseous) and other discharges, including chemical and thermal discharges, as appropriate, which are expected to occur over the lifetime of the nuclear installation. The regulatory body should review and assess these proposals. Specifically, the regulatory body should verify that radioactive discharges:

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

3.27 As part of the licensing process, the regulatory body should ensure that the following aspects are considered in the design of a nuclear installation:

(a) The safe and secure transport of radioactive material to and from the installation, and movement within the installation.
(b) Safety aspects associated with the replacement of heavy and large components during the operating lifetime of the nuclear installation (e.g. steam generators, reactor pressure vessel head). The design should take into account:
    (i) Buried pipes and conduits;
    (ii) Openings in structures for access to equipment;
    (iii) Obstructions.
(c) Access to items important to safety for:
    (i) Maintenance, inspection and testing, as appropriate;

(ii) Replacement;
(iii) Future decommissioning.

(d) Optimization of protection and safety when gaining access to SSCs.
(e) The way in which the nuclear installation will be decommissioned, and how radioactive waste generated during operation and decommissioning will be managed, in accordance with national strategies.
(f) Features for safe shutdown, including a remote shutdown facility, where appropriate.
(g) For reactors, appropriate arrangements for storage of spent fuel (including, where appropriate, criteria for dry storage of spent fuel at reactor sites).

3.28 The applicant or licensee should state how ageing effects on a nuclear installation are addressed in the design stage in order to identify appropriate ageing management measures to be implemented later. This should include the actions for ensuring the integrity of the nuclear installation until the end of decommissioning.

3.29 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, as appropriate, in accordance with the national regulatory framework.

3.30 Before construction begins, the applicant or licensee should set up a configuration management programme[9] for updating the design basis of the nuclear installation while ensuring that it remains in compliance with the original agreed or approved design basis.

AUTHORIZATION OF THE CONSTRUCTION OF A NUCLEAR INSTALLATION

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

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

(a) The management system of the applicant or licensee and vendors (see para. 2.31~~32~~);
(b) The site evaluation;
(c) The items important to safety and other design features important to safety, security and safeguards;
(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) The preliminary emergency plan;

[9] Configuration management is the process of identifying and documenting the characteristics of a facility’s SSCs (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].

(f) Organizational and financial arrangements for decommissioning and for management of radioactive waste and spent fuel.

3.33 The applicant or licensee should exercise control over the manufacture and assembly of SSCs important to safety, and this process should be reviewed, assessed and inspected, as appropriate, by the regulatory body.[10] The processes for this control, including the control of subcontractors, suppliers and vendors, should be part of the applicant or licensee's management system.

3.34 Before authorization of on-site construction, there are several conditions that should be fulfilled to ensure that this stage can proceed in a manner that ensures safe operation of the nuclear installation. These conditions 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 SSCs should be adequate.
(b) The applicant or licensee should have adequate financial and personnel 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) Nuclear security measures and emergency response (including fire protection measures) should be implemented.
(f) Radiological monitoring equipment should be clearly specified, installed and tested before radioactive material is brought onto the site.
(g) The applicant or licensee should conduct or update the radiological characterization of the region and include all the material used in the construction (including samples of construction concrete) before radioactive material is brought onto the site.
(h) Measures to comply with industrial codes, standards and rules (including conventional health and safety regulations) should be implemented before construction is started.
(i) Regulatory control should be applied to contractors and subcontractors performing tasks relevant to SSCs important to safety.
(j) The interfaces with safety of any design modifications arising from the preparation for security and safeguards implementation should have been addressed.
(k) Equipment to monitor the impacts of on-site construction on the environment should be clearly specified, installed and tested.
(l) The applicant or licensee should have implemented a safety culture programme and security culture programme.

3.35 As part of the licensing of on-site construction, conditions may be imposed by the regulatory body requiring that the applicant or licensee obtains additional approvals relating to the design, construction or manufacture of certain components of the nuclear installation. The regulatory body should also:

(a) Review and assess and, as appropriate, inspect any development of the design of the installation as demonstrated in the safety documentation submitted by the applicant or licensee, in accordance

[10] To manage the project schedule, applicants may apply for permission to start the manufacturing of long lead equipment before a construction licence is granted and after demonstrating compliance with relevant safety requirements.

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.

3.36 If part of the supply chain is in other States, the regulatory body should ensure that there are legally binding arrangements allowing the necessary access to documents and to the premises of all relevant organizations. Alternatively, such arrangements may be made (part of) a licence condition. 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 might 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 there are restrictions on joint regulatory review, the regulatory body should verify that the supply chain meets requirements.

3.37 The regulatory body should, where appropriate and under bilateral or international agreements, 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 the construction of a nuclear installation of the same design. Such cooperation should not, however, compromise the independence of the decision making process, nor should it diminish the responsibilities of a given regulatory body.

3.38 Before the first nuclear material is allowed to be brought onto the site, the applicant should submit an initial decommissioning plan, including a waste management plan, to the regulatory body. Requirements for preparing a decommissioning plan are established in IAEA Safety Standards Series No. GSR Part 6, Decommissioning of Facilities [28]. This initial decommissioning plan should demonstrate that:

(a) Sufficient funds to decommission the nuclear installation will be available at the end of operation (see Ref. [29]). This should include the costs associated with spent fuel management and radioactive waste management and disposal based on reasonable estimates. Costs related to research in relation to the decommissioning first-of-a-kind designs should also be included in the cost estimate.

(b) The assessed liability, estimated on the basis of costs prevailing at the time the decommissioning plan has been submitted to the regulatory body. This estimate should be adjusted for inflation through the projected licence termination date, and should be reviewed periodically.

(c) Mechanisms have been 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.

(d) As necessary, legal mechanisms have been established for securing decommissioning funds and for protecting them from being used for other purposes.

(e) A process has been established for further development of the decommissioning plan. The plan should be reviewed periodically (e.g. in light of new techniques or information, ageing management and design changes that might affect decommissioning) and submitted for approval by the regulatory body.

AUTHORIZATION OF THE COMMISSIONING OF A NUCLEAR INSTALLATION

3.39 Requirements for commissioning of nuclear installations are established in Requirements 25 of IAEA Safety Standards Series No. SSR-2/2 (Rev. 1), Safety of Nuclear Power Plants: Commissioning and Operation [30], Requirement 73 of SSR-3 [24] and Requirement 54 of SSR-4 [25]. Recommendations on commissioning are provided in IAEA Safety Standards Series Nos SSG-28, Commissioning for Nuclear Power Plants [31], and SSG-80, Commissioning for Research Reactors [32].

3.40 Commissioning of a nuclear installation is often divided into two main stages: (1) non-nuclear testing, which includes: individual pre-operational tests of systems and components; overall pre-operational system tests; and structural integrity tests, integrated leakage rate tests of the containment and of the primary system and secondary system; and (2) nuclear testing, which, for nuclear power plants, includes: initial fuel loading; subcritical tests; initial criticality tests; low power tests; and power ascension tests (see para. 2.19 of SSG-28 [31]).

3.41 Non-nuclear testing should be performed to ensure that the nuclear installation has been constructed, and equipment has been manufactured and installed, correctly and in accordance with the design specifications. The results of the non-nuclear testing should be used to inform the subsequent licensing process. If non-nuclear testing is performed at the manufacturing site, the licensing process should assess the validity of these tests once the equipment is brought and installed on the operating site.

3.42 Nuclear testing is a major step in the licensing process performed to confirm that the nuclear installation is safe before proceeding to routine operation. Commencement of nuclear testing should normally require an authorization or additional licence from the regulatory body since it involves the introduction of radioactive material.

3.43 The applicant or licensee 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, including the associated records;
(b) The commissioning tests can be safely conducted as proposed by the applicant or licensee and their justification is appropriate;
(c) Adequate oversight is performed if ~~T~~testing of SSCs is~~may be~~ performed at different sites.

3.44 There are several steps in the commissioning process for which the regulatory body may require the applicant or licensee to obtain prior approval and at which regulatory decisions may be made (see, for example, para. 6.2 of SSR-2/2 (Rev. 1) [30]). 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. The regulatory body may choose to witness these tests in the manufacturing premises, when applicable.

3.45 Completed SSCs important to safety should be put into service only when they have been inspected, tested and approved/accepted by the licensee, based on the documented results of acceptance tests, as being in accordance with the design requirements.

3.46 Before approving significant steps in the commissioning of a nuclear installation, such as the introduction of nuclear material or other 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 testing;
    (iii) The storage facilities for nuclear material and other radioactive material.
(b) Management provisions:
    (i) The management system and the programme for operation;
    (ii) The organizational structure of the operating organization, including the arrangements for ensuring training and qualification of personnel, adequate staffing levels, fitness for duty and licensing of staff for certain positions;
    (iii) The arrangements for periodic testing, maintenance and inspection;
    (iv) The organizational arrangements 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;
    (vi) Management and configuration control of multiple modules on a site, if applicable.
(c) Operational provisions:
    (i) The operational limits and conditions applicable during nuclear testing;
    (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 provisions for fire protection;
    (vi) 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;
    (vii) Arrangements for emergency preparedness and response;
    (viii) Nuclear security arrangements during commissioning;
    (ix) Measures for accounting for and control of nuclear and radioactive material;
    (x) Measures for meeting safeguards obligations.

3.47 There may be some overlap between the construction, commissioning and operation activities; for example, individual SSCs, or an entire unit, may already be commissioned or in operation before construction of the nuclear installation is complete. The applicant or licensee should demonstrate that these interactions are considered in the safety case.

3.48 As commissioning moves closer to completion, review, assessment and inspection by the regulatory body within the context of the licensing process 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 operational limits and conditions.

3.49 Before the start of nuclear testing, staff members with functions relating to safety should be suitably trained and qualified and, where appropriate, should be licensed before being allowed to perform their functions. The regulatory body should review, inspect and, where appropriate, license, any organization that provides training and qualification for staff with safety related functions.

3.50 The results of commissioning tests should be subject to:

(a) Self-assessment and internal audits by~~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, as appropriate, 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.

AUTHORIZATION OF THE OPERATION OF A NUCLEAR INSTALLATION

3.51 Requirements for operation of nuclear installations are established in SSR-2/2 (Rev. 1) [30], SSR-3 [24] and SSR-4 [25].

3.52 Before operation of a nuclear installation is licensed, it should be demonstrated that all regulatory requirements are met, based on validation and assessment activities of operating organisation and on review and assessment by the regulatory body of:

(a) The results of the 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.

3.53 To obtain a licence for the operation of a nuclear installation, the applicant or licensee should demonstrate that the following meet the regulatory body's expectations:

(a) Safety:
    (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:
    (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 and their implementation ~~by graded approach~~;
(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:
(i) Qualified staff available at all times (and on duty as 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:
(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.

3.54 To obtain a licence for the operation of a nuclear installation, the applicant or licensee should demonstrate that operational programmes have been established before operation and will be implemented throughout the operation of the nuclear installation. The regulatory approach to reviewing, assessing and inspecting such programmes should be graded in accordance with the type of nuclear installation and its activities. Consideration should be given to shared programmes between nuclear installations and installations with multiple modules. The following are examples of programmes that may be subject to approval by the regulatory body, as appropriate:

(a) Radiation protection;
(b) Emergency preparedness and response (on the site and off the site);
(c) Management system~~programmes~~ for operations (e.g. engineering design, procurement, maintenance);
(d) Fire protection;
(e) Nuclear security;
(f) Safeguards;
(g) Access authorization;
(h) Fitness for duty;
(i) Training and qualification of licensed personnel;
(j) Training of non-licensed staff of the installation;
(k) Maintenance;
(l) Initial testing of the nuclear installation and commissioning;

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

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

(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 implemented at the nuclear installation and that such activities are performed as specified for SSCs 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 and ageing management programme for SSCs important to safety accounts for the results of in-service testing and is implemented in accordance with a time schedule, which may be subject to approval by the regulatory body.
(d) Changes[11], including changes to procedures, the management system, processes, SSCs, that might affect safety 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 or after module replacement.
(g) Criteria for refuelling outages or for major maintenance programmes.

3.56 Before issuing a licence for the operation of a nuclear installation, the regulatory body should verify that:

(a) The licensee has appropriate arrangements for reporting any deviation from normal operation to

[11] 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 SSCs, plant modifications proposed by the person or organization responsible for the installation and its activities, or new regulatory requirements.

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.

(b) The licensee has 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, as appropriate.

(c) Offsite emergency plans are established and that offsite authorities can effectively implement public protective actions (if required) for the lifetime of the nuclear installation.

(d) The licensee has plans for radioactive waste management and for decommissioning (including technical solutions, waste streams, the policy framework for disposal and funding), and that these will be reviewed and updated periodically during operation.

3.57 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 operating licence. Resumption of operation may be subject to approval by the regulatory body, which should attach licence conditions, as appropriate.

Safety review

3.58 Over the full operating lifetime of a nuclear installation, as part of the licensing process 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[12] that the installation remains fit to continue operation. For time-limited licences, this may be part of the licence renewal process. The objective should be 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;

(f) That interfaces between safety, security and safeguards are assessed so that conflicts are minimized and any synergies are leveraged.

3.59 Safety reviews that underpin the licensing process for a nuclear installation 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, regulations and guides, practices, and analytical methods, or significant lessons learned from operating experience.

(b) To determine the effects of ageing at the installation.

(c) In case of major evidence of changes in external hazards or other site characteristics.

(d) In case of major modifications to the installation or activity or if improvements and modifications to the installation are necessary to maintain safety.

(e) To complement routine safety assessments, which are usually limited in scope and quite specific

[12] In many States, a systematic reassessment of safety at a nuclear installation is performed at regular intervals, typically of around ten years. This reassessment is often termed a periodic safety review, but it may be performed 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.

compared with safety reviews, which offer a wider assessment of safety at the nuclear installation.

(f) If features of the installation have a limited lifetime.

(g) If a nuclear installation is put into service after a prolonged period of time after testing.

(h) To address cumulative effects of modifications and ageing at the installation, including aspects related to staffing, competence and management structures.

(i) 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 at the installation and modifications implemented or needed in the light of current safety standards.

(j) To address frequent failures of SSCs.

3.60 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. The regulatory body should ensure that safety reviews also cover aspects that might expose workers, the public or the environment to radiation risks. In safety reviews, the regulatory body should also take into account:

(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;

(f) Proposed future operation timescale.

3.61 A detailed review of SSCs should be performed to demonstrate that the nuclear installation remains in compliance with the updated design basis and can continue to meet the conditions of the operating licence. The regulatory body should review and assess and, where appropriate, inspect the results of this review, to verify that the licensee has performed it in an adequate and comprehensive manner.

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

(a) Should develop requirements and guidance for the safety review process, including on the scope of 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 on a basis document, developed by the licensee, to govern the periodic safety review. This basis document should include the safety review methodology used by the licensee, the major milestones, cut-off dates, structure of the associated documents and the regulations, standards, guides, and operating practices to be used in the review.

(e) Should review and assess, and should approve, where appropriate, corrective actions, safety improvements and good practices, determined by the licensee and submitted to the regulatory body.

(f) Should authorize, if appropriate, 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.

Further recommendations on periodic safety reviews of nuclear power plants are provided in IAEA Safety Standards Series No. SSG-25, Periodic Safety Review of Nuclear Power Plants [33].

3.63 Recommendations on ageing management are provided in IAEA Safety Standards Series Nos SSG-48, Ageing Management and Development of a Programme for Long Term Operation of Nuclear Power Plants [34], and SSG-10 (Rev. 1), Ageing Management for Research Reactors [35]. Ageing management plays a central role in the periodic safety review. As part of the licensing process, the regulatory body should verify the existence of an ageing management programme. There are certain essential elements of ageing management, and these should be considered by the regulatory body in assessing the licensee's safety analyses. These 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 stressors on SSCs;
(f) A knowledge of the ageing of SSCs due to physical and chemical processes, or due to SSCs 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;
(g) A systematic ageing management programme.

3.64 After review, assessment and inspection, depending on regulatory requirements and the outcome of the safety review, the regulatory body may decide to renew, amend, suspend or revoke the operating licence for the nuclear installation and its activities.

Long term operation

3.65 For nuclear power plants, ~~L~~long term operation ~~of a nuclear power plant~~ is operation beyond an established time frame defined by the licence term, the original plant design, relevant standards or national regulations. Long term operation should be justified by safety assessment and, depending on the State, this justification may take place within a broader regulatory process, such as licence renewal or a periodic safety review (see paras. 2.30 and 2.32 of SSG-48 [34]). Requirements for long term operation of nuclear power plants~~installations~~ are established in SSR-2/2 (Rev. 1) [30], and recommendations ~~on long term operation of nuclear power plants~~ are provided in SSG-48 [34]. When a licensee decides to pursue long term operation of a nuclear ~~installation~~power plant, this should be subject to authorization by the regulatory body.

Long term shutdown

3.66 The licensee should submit to the regulatory body the specifications for maintaining the safety, security and safeguards needs of the nuclear installation during long term shutdown[13]. The regulatory

[13] Long term shutdown is a state in which there is no current intention in return to normal operation in the near term. Long term shutdown is different from refuelling outage, maintenance, inspection or refurbishment, during which the nuclear installation is not in operation (e.g., a nuclear installation may be in long term shutdown just before its decommissioning, or for economic, political and other reasons).

body should review and assess these specifications and may attach conditions to the licence for the installation.

3.67 Long term shutdown should be justified by the licensee, and related plans and programmes should be subject to approval 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 should be subject to regulatory control, especially regarding:

(a) Storage of radioactive waste;
(b) Spent fuel management;
(c) Fire protection and suppression;
(d) Radiation protection;
(e) Fulfilment of safety functions.

3.68 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 and to re-engage with the licensing process, as appropriate.

Post-operational activities

3.69 At the end of its operating lifetime, the licensee should inform the regulatory body that it is shutting down a nuclear installation, at which time the installation enters a phase of post-operational decontamination and reduction of hazardous materials to move towards a more passively safe state. Post-operational activities should be performed under an authorization that is appropriate for the activities (see para. 7.8 of GSR Part 6 [28]) (e.g. the current operating licence or a decommissioning licence). Radiation protection considerations may necessitate that certain activities are delayed to allow for radioactive decay and for radiation exposures to be reduced. To facilitate this process, some activities relevant to decommissioning (see paras 3.7~~2~~1–3.8~~4~~3) may be performed after the permanent shutdown of the nuclear installation under licence provisions carried over from the operating stage. Such activities relevant to decommissioning include:

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

~~Further recommendations on decommissioning are provided in IAEA Safety Standards Series No. SSG-47, Decommissioning of Nuclear Power Plants, Research Reactors and Other Nuclear Fuel Cycle Facilities [36].~~

3.70 After post-operational decontamination and removal of hazardous materials, interim safe storage may be permitted; for example, to allow for significant safety benefits from radioactive decay.

AUTHORIZATION OF THE DECOMMISSIONING OF A NUCLEAR INSTALLATION

3.71 Requirements for decommissioning[14] of facilities are established in GSR Part 6 [28]~~[28]~~, and supporting recommendations for nuclear installations are provided in IAEA Safety Standards Series No. SSG-47, Decommissioning of Nuclear Power Plants, Research Reactors and Other Nuclear Fuel Cycle Facilities~~SSG-47~~ [36]. Information on the transition from operation to decommissioning is provided in Ref. [37].

3.72 The decommissioning stage consists of one or more substages, which may be subject to separate regulatory approval or licensing. Different human resources and competences to those during operation are needed for decommissioning. Furthermore, staff motivation is crucial to maintaining a strong safety culture in an installation that is undergoing decommissioning.

3.73 Before granting an authorization for the decommissioning of a nuclear installation, the regulatory body should also review and assess and, as appropriate, inspect the licensee's management system to verify that it covers all aspects of decommissioning (See Requirement 7 of GSR Part 6 [28]).

3.74 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.

3.75 Decommissioning should only be authorized after the licensee has demonstrated the safe management of radioactive waste in accordance with a waste management strategy that is part of the decommissioning plan. Large volumes of radioactive waste may be generated in a short period of time, and the waste may vary greatly in type and activity. The regulatory body should review and assess and, as appropriate, inspect the decommissioning plan, and should verify that radioactive waste can be managed safely through existing and, as necessary, new routes.

3.76 Requirements for radioactive waste management are established in IAEA Safety Standards Series Nos GSR Part 5, Predisposal Management of Radioactive Waste [38], and SSR-5, Disposal of Radioactive Waste [39].

3.77 As part of the licensing process for a nuclear installation, an up to date, final decommissioning plan and its supporting documents are required to be submitted by the licensee to the regulatory body for approval, prior to commencement of decommissioning activities (see Requirement 11 of GSR Part 6 [28]). 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 (further recommendations are provided in section 7 of IAEA Safety Standards Series No. SSG-90, Radiation Protection Aspects of Design for Nuclear Power Plants [40]). The decommissioning plan is required to include the selected decommissioning strategy; the schedule, type and sequence of decommissioning actions; the waste management strategy; and the proposed end state for the nuclear installation (see para. 7.10 of GSR Part 6 [28]. The decommissioning plan should also specify the requirements for on-site and off-site monitoring, as well as for nuclear security and surveillance during decommissioning.

[14] 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 nuclear security and emergency response, safeguards, and the plan for cleanup of the site.

3.78 The progressive and definitive shutdown of SSCs 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, as part of the licensing process.

3.79 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 licence conditions (i.e. because the sanction of stopping activities at the nuclear installation or revoking the licence might not be effective at this stage).

3.80 In situations where off-site decommissioning is considered (see para. II.~~18~~14), the regulatory body should ensure specific licence conditions are included to address this.

3.81 The preferred decommissioning strategy is required to be immediate dismantling (see 5.1 of GSR Part 6 [28]). Where it is proposed to defer dismantling 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 dismantling. Deferral of dismantling should be justified on a case-by-case basis to the regulatory body. For example, proposals for deferral of dismantling 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.

3.82 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) Storage of radioactive waste;
(b) Spent fuel management (see also para. 8.10 of GSR Part 6 [28]);
(c) Fire protection and suppression;
(d) Radiation exposure of workers, the public and the environment;
(e) Movement of radioactive material on the site and off the site;
(f) Non-radiological hazards, which should be dealt with by coordinated activities between the relevant regulatory authorities under clear memoranda of understanding;
(g) Integrity 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) The suitability of decontamination and dismantling techniques and equipment;
(j) Emergency plans;
(k) Effects of decommissioning activities on civil structures;
(l) Effects of decommissioning activities on other nuclear installations on the same site.

3.83 A final decommissioning report is required to be prepared and be submitted to the regulatory body for review and approval (see para. 9.1 of GSR Part 6 [28]. Further information is provided in annex II of SSG-47 [36]).

RELEASE OF A NUCLEAR INSTALLATION OR SITE FROM REGULATORY CONTROL

3.84 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 spent fuel and contaminated structures and components (see paras 1.8 and 9.2 of GSR Part 6 [28]). Supporting recommendations are provided in IAEA Safety Standards Series No. WS-G-5.1, Release of Sites from Regulatory Control on Termination of Practices [41]. If spent fuel storage facilities or radioactive waste storage facilities remain on the site after the end of decommissioning, they should be licensed as new operating facilities (see para. 9.4 of GSR Part 6 [28] and para. 6.15 of SSG-47 [36]) .

3.85 The legal and regulatory framework is required to establish criteria for the release of the decommissioned nuclear installation and the site from regulatory control (see para. 2.5(17) of GSR Part 1 (Rev. 1) [1] and para. 3.3 of GSR Part 6 [28]). The regulatory body should ensure that a system is implemented for properly managing this release.

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

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

3.87 Before termination of the licence and release of the site from regulatory control, a final radiological survey is required to be performed by the licensee (see para. 3.4 of GSR Part 6 [28]). 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.

3.88 Once the regulatory body has accepted all the evidence provided by the licensee, the licence can be terminated, and the licensee can be relieved of further licensing responsibilities.

Appendix I
EXAMPLES OF DOCUMENTS TO BE SUBMITTED TO THE REGULATORY BODY WHEN APPLYING FOR A LICENCE FOR A NUCLEAR INSTALLATION

I.1 The following are examples of documents that may submitted by the applicant or licensee to the regulatory body during the licensing process for a nuclear installation. The content of these documents may be divided or combined, as appropriate:

(a) A construction report (including a quality manual), which consists of a description of the nuclear installation, the process and technologies used, justification of related activities and considerations for decommissioning;
(b) 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;
(c) A preliminary plan for the project, including the phases and the anticipated schedule (including technical research and development, if necessary);
(d) A prior economic study regarding the necessary financial investments and the expected costs;
(e) A site evaluation report, including a report of the results of environmental radiation monitoring;
(f) Reports on the use of cooling sources;
(g) The environmental impact assessment and reports on discharges into the environment;
(h) The strategy and plans for public involvement in the licensing process;
(i) A report on the management and organization of the design and construction project, including responsibilities and a list of contractors;
(j) A report on the acquisition programme, including a list of the SSCs and their origin, and, as applicable, details of the manufacturing process for SSCs important to safety;
(k) 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);
(l) 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;
(m) The preliminary plans relating to the operating organization and the application of its management system to all licensing steps;
(n) Technical design documents;
(o) Nuclear security plans prepared using national design basis threat or representative threat statement, and especially interfaces with safety measures;
(p) Plans for an equipment qualification programme;
(q) Fire protection plans;
(r) Plans for accounting and control of nuclear material;
(s) Training and qualification plans for operating personnel;
(t) Proof of trustworthiness of all staff who will be engaged in responsible or sensitive positions;
(u) Commissioning programmes and reports;
(v) Final safety analysis reports on the site evaluation, design, construction, commissioning and operation stages and on provisions for decommissioning;
(w) Ageing management plans;
(x) General operating rules and operating procedures;
(y) Technical specifications, including operational limits and conditions;
(z) A plan for collecting and applying feedback from operating experience;
(aa) Plans for evaluating and improving safety performance;
(bb) Emergency operating procedures and severe accident management guidelines;
(cc) Emergency preparedness and response plan;

(dd) The radiation protection programme and associated reports;
(ee) Reports on radioactive waste and spent fuel management, including proposals for treatment, packaging, storage, predisposal and final disposal of waste (including decommissioning wastes) and a description of the system for the classification and characterization of waste, and rules and criteria to release waste;
(ff) An indicative list or detailed inventory of sources;
(gg) Modification rules (which may be included in the general operating rules);
(hh) Details of the maintenance programme and the periodic testing programme;
(ii) Reports of periodic safety reviews or other safety reviews;
(jj) Decommissioning plans and reports, including details of final shutdown, and decommissioning substages, actions and safety analyses.

Appendix II

LICENSING OF SMALL MODULAR REACTORS

II.1 The recommendations in this Safety Guide are generally applicable to all nuclear installations, including small modular reactors. Many of the safety considerations applied to the licensing processes for traditional nuclear power plants are also applicable to the licensing of small modular reactors. However, this appendix highlights the potential impact of the new deployment models and design considerations on the licensing process, and it provides additional considerations to ensure that regulatory bodies are able to license different types of nuclear installation and have adequate capabilities and resources for their regulatory activities.

II.2 The characteristics of small modular reactors and their associated deployment models[15] introduce some differences compared to those of land-based large nuclear power plants [9]~~[9]~~, ranging from factory manufacturing and testing to factory construction, and new programmes for maintenance and decommissioning. The licensing process of small modular reactors may also involve additional safety and regulatory considerations, particularly for those reactors that are constructed, commissioned, refuelled, refurbished or decommissioned away from the deployment site. However, it should be recognized that those stages such as siting, design, construction, commissioning, operation and decommissioning are six major stages of the lifetime of a nuclear installation and of the associated licensing process [2], and a small modular reactor should also follow these basic stages during its lifetime. For examples of differences, the following list shows the potential additional stages of the lifetime of a small modular reactor, noting that each of these stages might not be needed for all small modular reactor designs:

(a) Siting;
(b) Design;
(c) Off-site construction or manufacturing;
(d) Off-site commissioning;
(e) Transport (both to and from facility or from one site to another);
(f) On-site construction;
(g) On-site commissioning;
(h) Operation;
(i) On-site decommissioning;
(j) Off-site decommissioning;
(k) Release from regulatory control.

Some of these are new stages that are not relevant to land-based large nuclear power plants. The new stages might have an impact on how the licensing process is conducted for a small modular reactor. For example, the licensing of such a reactor may include new hold points.

CAPACITY OF THE LICENSEE OF A SMALL MODULAR REACTOR TO FULFIL ITS RESPONSIBILITIES

Influence from external stakeholders in relation to small modular reactors

II.3 Commercial arrangements may be made between various stakeholders involved in the

[15] In this Safety Guide, ‘deployment model’ refers to the features of a project that determine where and when it will be deployed. It also includes aspects related to how the project is managed.

deployment of a small modular reactor, for example for establishing energy production projects (electricity, heat, hydrogen) or industrial applications. These arrangements can lead to one or more organizations being involved in the different stages of development of a small modular reactor. The regulatory body should hold a single licensee responsible for safety, security and safeguards for all stages of the lifetime of the reactor regardless of commercial arrangements. The regulatory body should seek assurances on the organizational capability of this licensee to effectively oversee safety, security and safeguards at all stages of the lifetime of the small modular reactor.

II.4 To fulfil its responsibilities, a licensee is requiredexpected to give an overriding priority to safety (see Requirement 5 of SSR-2/2 [30][30]). Consequently, licensees should make provisions in terms of organization and funding to ensure it meets its obligations regarding any decision that can impact safety in the short and in the long term.

II.5 The regulatory body should assess the ways in which external stakeholders could influence licensees in the conduct of their licensed activities to ensure that the licensee will be able to perform their obligations and exercise their responsibility without undue interference from commercial stakeholders. This includes assessing the interfaces between organizations (e.g. licensee, neighbouring entities, shareholders) to evaluate how arrangements can impact the licensee.

Licence transfer for small modular reactors

II.6 During the lifetime of a small modular reactor, for some designs, the licence may be transferred from one organization to another, but any transfer of licences should not impact the basic licensing process. The regulatory body should ensure that there is a process for a licence transfer in which the regulatory body ensures the new licensee is capable of maintaining safety, as well as the arrangements for nuclear security and safeguards. For example:

(a) AnThe application by the recipient organization should be submitted to the regulatory body and should demonstrate the applicant's capability and capacity to meet regulatory requirements. This includes any proposals of significant changes in the licensed activities.
(b) AnThe application should demonstrate adequate provisions will be implemented to maintain safety, security, and safeguards and identify the responsibilities of both the foregoing licensee and the applicant.

Reliance on contractors and capacity for oversight of small modular reactors

II.7 Deployment models for small modular reactors may include an increase in outsourced activities, such as plant operations, remote monitoring, refuelling, maintenance, and configuration management between similar installations. Licensees might outsource these types of activity to contractors to perform a wide range of specialized activities or all maintenance activities across many sites.

II.8 When the licensee is outsourcing activities, the regulatory body should verify that the licensee has made suitable arrangements to maintain:

(a) Prime responsibility for safety of the nuclear installation(s);
(b) Proper and adequate oversight of all activities;
(c) An informed customer capability [2] for the activities being undertaken;
(d) Configuration management, which includes personnel access to applicable configuration management documentation;
(e) Adequate quality management of activities;
(f) A commitment to fostering strong safety and security cultures;
(g) Technical knowledge and skills within the licensee organization;
(h) Proper interface mechanisms and procedures for any activities that are outsourced to several contractors.

SITING A SMALL MODULAR REACTOR NEAR AN INDUSTRIAL SITE OR POPULATION CENTRE

II.9 Requirements for site evaluation for nuclear installations are established in SSR-1 [19]. A small modular reactor can be used for purposes other than electricity production, such as heat production for district heating or industry, hydrogen production or desalination. This may involve installing reactors near another industrial site or a population centre. In some cases, part of the nuclear installation might have an interface with the neighbouring industrial site or population centre ~~and be separated by a single barrier (e.g. a heat exchanger)~~. In such cases:

(a) Deployment of a small modular reactor near an industrial site may need additional planning and coordination to ensure that:
  (i) There are adequate arrangements for emergency preparedness and response;
  (ii) Any activities or changes to activities in the adjacent installation, with direct relation to the small modular reactor (e.g. increase in power demand, modification of electrical power supply) or in any other nearby installation, do not negatively impact reactor safety;
  (iii) Major activities at the industrial site, such as heavy lifting, blasting or excavation do not negatively impact reactor safety, for example, due to the risk of unintended projectiles originating from the neighbouring industrial site;
  (iv) Where systems are shared between the small modular reactor and the adjacent installation, their operation and any change or modification should be closely followed as part of the small modular reactor's operation to maintain the capability to perform their functions under all conditions;
  ~~(v) Where SSCs important to the safety of the small modular reactor are shared with the adjacent installation, they should be considered in the licensing process as a part of the small modular reactor.~~
(b) The site boundaries of the small modular reactor should be defined and based on safety, security, and safeguards considerations.
(c) The licensee should demonstrate that site-based infrastructure supports safety, security, safeguards as part of the overall licensing activity.
(d) For commonalities, such as security, emergency preparedness and response, and accident management, coordination among the licensee, the end user, and other stakeholders should be implemented.
(e) When deploying a small modular reactor near a population centre (e.g. to provide district heating), the licensee is also required to assess the impact of an emergency on the surrounding population and environment (see Requirement 5 of SSR-1 [19]). Size, technology, location, and siting characteristics, along with remoteness of the community might significantly affect the impact.
(f) The safety throughout decommissioning should also be assessed when siting a small modular reactor close to industrial sites or population centres.

DEPLOYMENT OF MULTIPLE SMALL MODULAR REACTORS

Standardized fleet deployment for small modular reactors

II.10 For the purposes of this appendix, fleet deployment is the deployment of multiple small modular reactors of the same or similar design, possibly at different sites. Fleet deployment depends on the minimization of design changes between reactors in the same fleet. Possible approaches to fleet deployment of small modular reactors, contingent on compatibility with the regulatory framework, include:

(a) A deployment model, in which a reactor design is approved[16] by a regulatory body, and that

[16] In some States, the approval of a reactor design could include a certification process, as described in Section 3.2(b).

design is deployed in multiple locations as a standardized design. Subsequent licensing efforts in that State then may focus on site-specific and organizational aspects.

(b) A deployment model where the design may be modified from one plant to the next. For this model, the regulatory body should review the first-of-a-kind reactor at the same level of assessment as the approved design described in (a), and then its efforts may focus on the differences from one plant to the next for both the design, site-specific and organizational aspects.

II.11 For a licence application of a reactor that is part of a fleet, the applicant should demonstrate that proper configuration management processes are established to track changes in each plant as well as differences between plants.

Multiple units or reactor modules or replacement of major components of a small modular reactor at a single site

II.12 Some deployment models for small modular reactors could allow for different reactor types or the addition or replacement of reactor units or reactor modules[17] or major components or systems at various times throughout the lifetime of the facility. Additional units or reactor modules may be in close proximity to or sharing the same infrastructure as operating reactor modules (See also para 3.~~7~~8(a)(iii)). The potential for evolution of the design over time could mean differences among the reactor modules installed at a single facility. As such:

(a) The licensing process should consider the number of reactor modules that could be present at the site simultaneously and operated over the lifetime of the facility.

(b) A licensing activity that considers multiple reactor modules of essentially the same design at a facility may undergo a single review and safety evaluation by the regulatory body in the case when these reactor modules are licensed at the same time.

(c) When different reactor designs are proposed for a single site, separate licences should be considered necessary for each reactor design because of the likelihood of significant differences in construction, commissioning, operation, maintenance and decommissioning introduced by the design.

(d) The licensing process should consider the possibility of incrementally bringing reactor modules or units into and out of service as well as the replacement of reactor modules. This should include how construction, commissioning, operation, and decommissioning of a reactor module might impact the other reactor modules. Even in these circumstances, the fundamental safety functions of the remaining individual reactors should be maintained with their own items important to safety.

(e) If an entire reactor module is being replaced, the licensee should demonstrate that the new components and systems are within the licensing basis of the small modular reactor. This may involve off-site assessment of replacement components. Alternatively, the licensee may need to obtain approval from the regulatory body or a new licence for the replacement.

(f) When the reactor module is no longer being used for its intended purpose, the licensee should inform the regulatory body and ensure any decommissioning licensing requirements are met.

(g) The licensee should describe their programmes and processes that control how activities for multiple units and configuration differences are to be managed. The impact of any reactor design changes should be well understood, documented, and accounted for.

(h) The licensing process should consider the impact of common aspects at the site, such as environmental review, emergency response plans, security, and safeguards.

(i) The licensee should implement an emergency plan for the entire site. When personnel and/or services are shared among multiple units or modules in a site, the licensee should ensure that processes are implemented so that sufficient shared personnel or services are available when needed for the most resource-intensive design basis event scenario for the site.

[17] Reactor module (sometimes abbreviated as ‘module’) is defined as “A nuclear reactor with its associated structures, systems and components. This term is used in multi-module units” [42].

RADIOACTIVE WASTE AND SPENT FUEL MANAGEMENT FOR SMALL MODULAR REACTORS

II.13 Small modular reactor operations are expected to result in the generation of a wide range of radioactive waste and spent fuel, influenced by the interaction of the fuel system (e.g. fuel composition, shape, enrichment, and assembly form), moderator (for thermal reactors), and coolant selection [9]. Consequently, it is important that the regulatory body, during the licensing process, reviews and assesses the facility's safety measures for the predisposal management of all radioactive waste types, including spent fuel, arising from commissioning, operation, and decommissioning of a small modular reactor facility. In this licensing context, the following key areas for radioactive waste and spent fuel management[18] at a small modular reactor facility should be considered:

(a) The design of the facility should provide means (i.e. material selection, modularity construction) for minimization of the generation of radioactive waste (by volume and activity).
(b) The facility should have an on-site or off-site radioactive waste management system, if applicable, capable of characterization, pretreatment, treatment, and storage of radioactive waste (solid, liquid, and gaseous) throughout commissioning, operation, and decommissioning. The system should be designed for handling radioactive waste streams from normal operations, anticipated operational occurrences and accident conditions.
(c) The types and quantities of radioactive waste and spent fuel should be specified, to allow review and assessment by the regulatory body within the licensing process.
(d) The annual volume of radioactive waste generated, and the capabilities needed to manage it during operation and future disposal should be determined, preferably during the design phase.
(e) System requirements for spent fuel management (cooling times, wet or dry storage capacity, as applicable) at the small modular reactor facility should be clearly defined, including the expected annual generation of spent fuel quantities.
(f) The facility effluents released due to commissioning and operation should be identified and quantified. The radioactive waste management system should have sufficient capacity to manage effluents during normal operations, anticipated operational occurrences and accident conditions.
(g) The design should ensure that spent fuel and radioactive waste generated during the facility's lifetime can be safely stored and disposed of. Storage options and disposal routes for spent fuel and radioactive waste should be identified and feasible within the national strategy.
(h) Options for interim on-site storage of spent fuel should be evaluated.
(i) Arrangements for transport of radioactive waste and spent fuel off the site should be established.
(j) Existing disposal solutions for radioactive waste, including spent fuel, should be assessed for their suitability to the waste expected from small modular reactors.

OFF-SITE CONSTRUCTION, COMMISSIONING, AND DECOMMISSIONING OF SMALL MODULAR REACTORS

II.14 Some deployment models for small modular reactors propose to perform some of the manufacturing, assembly, and commissioning activities at the manufacturing site, possibly prior to the identification of an operating licensee. The specific mechanisms of control of the manufacturing and construction activities in the absence of a licensee are out of scope of this Safety Guide. Some deployment models also propose off-site decommissioning. For cases involving such off-site activities:

(a) The off-site facilities and locations where activities such as fuel loading, nuclear testing, or decommissioning of a reactor module are performed should be licensed.
(b) The regulatory body should review, assess, and inspect licensee provisions for the oversight of activities important to safety, including those performed off the site. These provisions, as well as the regulatory body's oversight, should follow a graded approach that is proportionate to the safety significance of the systems being manufactured, assembled, and tested off the site. The regulatory body may apply the same level of practices on ~~This may result in the application of~~

[18] For some small modular reactor deployment models, these considerations might not be applicable to the reactor but are applicable to the manufacturing and/or decommissioning facility.

~~the same level of~~ review, assessment and inspection of a small modular reactor as for large power reactors.

(c) The regulatory body should be able to assess the way that safety related activities are conducted, including those performed off the site. This may be achieved or supported by direct oversight of manufacturing sites through qualification, certification, or licensing of the off-site facility or activity, or by leveraging the review of the relevant activities performed by the regulatory body of the State in which the activities are undertaken. The assessment may also be achieved or supported through the oversight of the licensee's management system of its supply chain.

(d) The licensee should maintain thorough and traceable documentation of inspections, tests, analyses, and acceptance criteria of activities important to safety, to demonstrate that these activities meet the expectations from the safety case. This may need to be ensured by the vendor or the manufacturer, as these activities could be performed in the absence of a licensee.

(e) The potential effects of transport of manufactured and/or assembled SSCs on their quality and qualification and the validity of the tests performed off the site should be assessed in the licensing process. ~~For deployment models where fuel is loaded to the reactor module off the site, the assessment should include safety considerations such as the potential for and consequences of criticality events during transport.~~

(f) The licensing process should ensure there are adequate provisions for testing before and after transport of a reactor module to the deployment site, if applicable.

(g) The regulatory body should ensure that the licensee provides sufficient information in the decommissioning plan that is to be maintained throughout the lifetime of the small modular reactor, to be submitted with the licence application to ensure that the facility can be safely decommissioned (e.g. information on material selection to reduce neutron activation, the generation of complex radioactive waste during operation, the use of a modular design to enable use of well-established dismantling technologies, the transport for decommissioning).

(h) The regulatory body should verify that under the proposed decommissioning strategy, the licensee ensures there is sufficient funding to complete the decommissioning project and for the site to be released. Immediate decommissioning and unrestricted release of sites from regulatory control should be the primary objective.

SHARING AND LEVERAGING INFORMATION ON SMALL MODULAR REACTORS

II.15 At the time of writing this Safety Guide, States have limited experience of the licensing of siting, construction, operation, and decommissioning of small modular reactors. While some experimental facilities are operational or in various stages of design and construction, broader experience in commissioning, operating, and decommissioning small modular reactors is needed. States are therefore encouraged to share with one another the early experiences gained in novel areas.

II.16 As small modular reactors are expected to deploy more standardized designs worldwide, collaboration among regulatory bodies in different States may be beneficial, and regulatory bodies may choose to leverage work that has already been performed by the regulatory body in another State. Leveraging of another regulatory body's work should not relieve the regulatory body from its oversight responsibilities.

II.17 When considering the use of information from other regulatory bodies, the regulatory body receiving information should ensure that it:

(a) Has full access to all necessary documents, including the design details and background information (to the full extent allowed by applicable laws) to make regulatory decisions and should validate the information received;

(b) Understands the information (i.e. maintains an informed customer capability [2]);

(c) Understands what the information was previously assessed against and what it will be subsequently assessed against (i.e. what regulations, policies, and safety standards the original assessment was performed against);

(d) Independently verifies fulfilment of their applicable regulatory requirements;

(e) Takes responsibility for its own regulatory decisions.

II.18 When leveraging information, regulatory bodies should ensure they properly document how leveraged information was used in their decision making process and ensure that this documentation contains enough detail to ensure that regulatory oversight capability can be maintained over the lifetime of the facility. In this context, regulatory bodies are also encouraged to share their experience leveraging previous work with other regulatory bodies, when applicable.

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