IAEA SAFETY STANDARDS
for protecting people and the environment

Step 7

Licensing Process for Nuclear Installations

DS539
(revision of SSG-12)

DRAFT SAFETY GUIDE

CONTENTS

1. INTRODUCTION

BACKGROUND

1.1 Achievement of the highest level of safety that can reasonably be achieved in relation to nuclear installations requires an effective governmental, legal and regulatory framework — including a regulatory body with well defined responsibilities and functions — as well as qualified vendors, manufacturers and operating organizations. The authorization 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 This Safety Guide provides recommendations on meeting the requirements relating to authorization[1] by the regulatory body (in particular, Requirements 23 and 24) 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 dealt with in this Safety Guide regarding the licensing process. These stages 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 has shown that there is some overlapping of these stages; that is, one stage may start before the previous one is fully completed. Moreover, in a given stage, there may be one or more 'hold points' or required licensing actions, set by national legislation and/or regulatory requirements, such as first concrete, installation of major safety significant equipment, entering commissioning, etc.

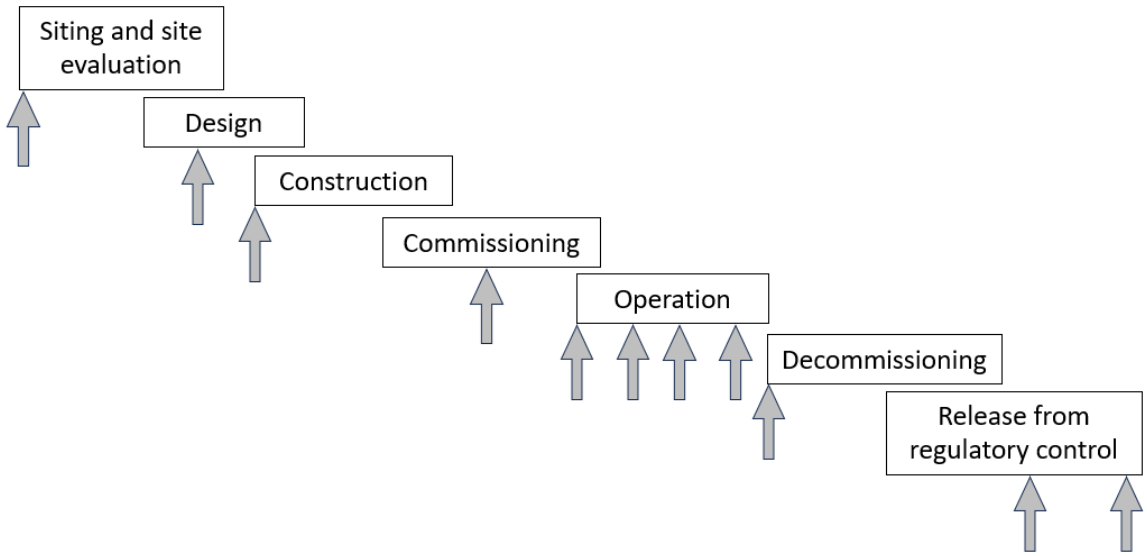

FIG. 1. Stages in the lifetime of a nuclear installation; the arrows indicate where hold points may be imposed.

[1] Authorization to operate a facility or to conduct an activity may be granted by the regulatory body or by another governmental body to an operator (an operating organization or a person). 'Authorization' takes the form of a written permission which could include, for example, licensing, certification or registration. See Ref. [2].

Licensing activity at these stages and associated hold points or required licensing actions give the regulatory body the power to ensure through safety assessment that risks to people and to the environment from nuclear installations and their activities are properly controlled by the persons or organizations responsible for the nuclear installations and their activities.

1.4 This Safety Guide supersedes IAEA Safety Standards Series No. SSG-12, Licensing Process for Nuclear Installations[2].

OBJECTIVE

1.5 The purpose of this Safety Guide is to provide 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.

SCOPE

1.6 This Safety Guide provides recommendations on how the licensing process should be applied at the various stages of the lifetime of a nuclear installation[3] (siting and site evaluation, 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 discussed. Recommendations on the application by a regulatory body of a graded approach to the licensing process are also provided in this Safety Guide.

1.7 While this Safety Guide focuses on safety at nuclear installations, security and safeguards are also critical considerations, and interfaces between safety, security and safeguards aspects 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].

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

[3] 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] Similar recommendations on the licensing process for disposal facilities for radioactive waste are provided in other IAEA Safety Standards (SSR-5, Disposal of Radioactive Waste [2011], and SSG-23, The Safety Case and Safety Assessment for the Disposal of Radioactive Waste [2012])

STRUCTURE

1.8 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.

2. GENERAL RECOMMENDATIONS ON THE LICENSING PROCESS FOR NUCLEAR INSTALLATIONS

DEFINITIONS RELEVANT TO THE LICENSING OF NUCLEAR INSTALLATIONS

2.1 A licence is a legal document issued by the regulatory body granting authorization to perform specified activities relating to a facility or activity [2]. The regulatory body, whose status may vary from one State to another, is one or more authorities designated by the government of a State as having legal authority for conducting the regulatory process, including issuing authorizations [2].

2.2 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 certification, granting of a permit, agreement, consent, regulatory approval or granting of another similar regulatory instrument, depending on the governmental and regulatory framework of the particular State.

2.3 The holder of a current 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 of GSR Part 1 (Rev. 1) [1]). A licensee might lose its licence for operation, for instance, but should not be released from its prime responsibility for safety, security and safeguards unless so specified by the regulatory body.

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

2.5 Licences and other types of authorizations 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

2.6 The licensing process should be understood by all the parties concerned and should be predictable (i.e. well defined, clear, transparent and traceable). The licensing process should be established in a systemic way to facilitate efficient progression of regulatory activities. The steps of the licensing process should follow a logical order.

2.7 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 feedback on the design features for construction or 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 applicable for first-of-a-kind designs and designs with innovative technology that are still in various stages of development (see also para. 2.28). 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 regulators, vendors and operating organizations and could 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 a certification. Further recommendations are provided in para. 3.2.

2.8 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).

2.9 The licensing process involves 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.

2.10 The legal framework of the State is required to set out the responsibilities for issuing a licence or other type of authorization and, in particular, determine who is empowered to issue licences or other authorizations (see Requirements 2 and 3 of GSR Part 1 (Rev. 1) [1]). Depending on the system used in the particular State, different authorizations may be issued by different authorities.

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

2.12 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."

2.13 Requirement 24 of GSR Part 1 (Rev. 1) [1] states:

> "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."

2.14 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."

2.15 Procedures for evaluating, approving, denying, and issuing 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.

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

2.17 Licence conditions should cover, as appropriate, safety related aspects affecting the siting and site evaluation, design, construction, commissioning, operation and decommissioning of the nuclear installation and its subsequent release from regulatory control, so as to enable effective regulatory control at all stages. These conditions should cover important aspects, including but not limited to, design, radiation protection, maintenance programmes, emergency planning and procedures, modifications, the management system, operational limits and conditions, operating procedures, radioactive waste management, arrangements for decommissioning, nuclear security, cybersecurity, safeguards provisions, nuclear liability (insurance), safety analysis, periodic safety review, human and financial resources, fuel management, outages, aging management, safety culture, resources, and authorization of personnel. Licence conditions may refer to, but should not duplicate, regulatory requirements, to avoid discrepancies or inconsistencies when the regulations are revised. License conditions could also include exemptions of nuclear regulations or non-nuclear regulations.

2.18 Licence conditions may vary in format; however, there are 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 the case that it is necessary to specify several licence conditions addressing various technical and administrative aspects, it may be useful to group the conditions into categories, such as:

(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 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 common safety related features, arrangements should be made to ensure that overall safety is not compromised, the specific responsibilities of all licensees should be identified.

2.20 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 as part of the licence, as necessary. The content of such submissions to the regulatory body may be divided or combined into different documents, as appropriate, depending on national regulations, regulatory regimes and practices. Examples of such documents are given in Appendix I; the content and names of these documents may vary from one State to another. For nuclear power plants, primarily, the safety analysis report is an important document for the entire licensing process; recommendations on the format and content of safety analysis reports are provided in IAEA Safety Standards Series No. SSG-61, Format and Content of the Safety Analysis Report for Nuclear Power Plants [4].

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

(a) A facility and/or activity should be authorized only when the regulatory body has confirmed that the facility or activity is going to be used or conducted in a manner that does not pose an undue risk to workers, the public or the environment. This should include confirmation that the applicant has the organizational capability, organizational structures, adequacy of resources, competence of managers and staff, and appropriateness of management arrangements to fulfil its safety obligations as 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 presenting the licensing and approval processes should explicitly describe the regime to be followed by the applicant in its descriptions and justifications of the safety case in each design area of the licensing process.
(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, where required, should be updated regularly by the licensee, as indicated in licence conditions or regulations.
(e) Expenses associated with the licensing process and the person or organization that will be charged these expenses, 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 regulation and 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 (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 validity period and any incorporated conditions should be clearly defined by the regulatory body.

(k) The regulatory body should include conditions in the licence, as appropriate.

(l) A licence may be transferred, depending on national regulations; however, this should be done only with the authorization of the regulatory body, which may attach provisions and conditions to the transfer.

(m) The applicant and the regulatory body should take into account international 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 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 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 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 regulations and requirements imposed by the regulatory body does not relieve the person or organization responsible for any nuclear installations and their activities of the prime responsibility for safety. The person or organization responsible for any nuclear installations and their activities should demonstrate to the satisfaction of the regulatory body that this prime responsibility has been and is likely to continue to be fulfilled.

(q) Clear conditions should be established for public participation in the licensing process (see paras 2.46–2.49).

(r) Interfaces between safety, security and safeguards should be addressed to ensure the accomplishment of the objectives and requirements for all three areas, including the integration of emergency management plans with safety and security considerations, and 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 in responsibilities.

(s) The means of challenging or appealing against a licence or part of a licence should be made clear by the regulatory body or within the regulatory framework.

(t) The site boundaries should be clearly defined and justified based on safety (and security)

considerations.

2.22 The legislative and regulatory framework is required to enable unfettered access for regulatory staff to any facility, any activity and any documents related to safety and considered necessary for granting licences and authorizations (see para. 2.13 of GSR Part 1 (Rev. 1) [1]).

2.23 The regulatory framework should establish requirements or conditions (depending on factors such as the nature of the changes, the safety significance and the magnitude of the risks involved) that may require prior review, assessment and approval by the regulatory body of changes or modifications to the site (including a transfer of a licence to another organization), the nuclear installation, the organizational structure of the licensee, procedures, processes or plans for future activities (e.g. decommissioning), at any stage of the life of the nuclear installation. At any stage of the nuclear installation's lifetime, changes or modifications to the site (including a licence transfer to another organization), the nuclear installation, the organizational structure of the licensee, procedures, processes or plans for future activities (e.g. decommissioning) may require (depending on factors such as the nature of the changes and the magnitude of the risks involved) prior review, assessment and approval by the regulatory body and revision of the licence or certain licence conditions. Changes or modifications to a nuclear installation may include the replacement of major components or subsystems and, in some cases, wholesale replacement of the facility with a new or refurbished one.

2.24 Arrangements to address the interfaces between safety, security and safeguards are required (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 [5], [6] and [7].

OBLIGATIONS, ROLES AND RESPONSIBILITIES OF THE REGULATORY BODY FOR LICENSING OF NUCLEAR INSTALLATIONS

2.25 The regulatory framework should empower the regulatory body to make regulatory decisions and to grant, amend, suspend, transfer, or revoke licences, conditions or authorizations, as appropriate.

2.26 Paragraphs 2.27–2.41 provide recommendations on the general obligations, roles and responsibilities of the regulatory body throughout the licensing process; stage-specific responsibilities are covered in Section 3. 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 [8], and GSG-13 Functions and Processes of the Regulatory Body for Safety [9].

2.27 The procedures or guidelines for applying for a new licence should be published by the

regulatory body, together with the address to which the application should be sent. 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) 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 time duration for the required license;
(d) Details of any relevant existing licence;
(e) An environmental assessment report, if required by national legislation;
(f) Information on the ownership structure. 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.

2.28 Before an applicant submits an application, the regulatory body should implement a preparatory phase, during which basic licensing requirements are set out and the process to be followed is made clear to the applicant. This may include specification of, for example, the language, units and format of the proposed application. During this phase, the staff of the regulatory body should be trained so they have sufficient knowledge of the design of nuclear installations that may be proposed. The basic requirements set out in the preparatory phase should be design-neutral so that several designs may be considered at the beginning of a project to build a nuclear installation. In addition, possible exemptions on local non-nuclear specific rules (e.g. rules for civil works, fire regulations, requirements from environmental permitting) may be managed with regulators in the preparatory stage. Nevertheless, detailed and explicit design requirements should be developed during the early phases of the project.

2.29 Pre-licensing interactions (see para. 2.7) of the regulatory body with the vendor and the potential licensee are encouraged. These pre-licensing interactions not only benefit the regulatory body, but they also benefit vendors and potential licensees because they 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, as these are aspects that are particularly important to be considered at the earliest stages of the development of the design. Design features and an assessment of safety, security, and safeguards needs, may be addressed in pre-licensing interactions, including the interfaces between each of these areas. At an early pre-licensing stage, the vendor and the potential licensee may not have yet developed the arrangements and requirements that would be needed to be demonstrated during the licensing processes.

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

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

(a) The applicant’s evidence of and plans to meet regulatory requirements regarding its 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 documentation of the applicant or licensee;
(c) The licensee's compliance with regulations, safety objectives, principles, requirements and criteria, the safety cases and safety analyses, and the conditions of the licence;
(d) The continued organizational capability of the licensee (and of its contractors and subcontractors) to meet the actual authorization, licence or regulatory requirements.

2.32 Early assessment of the competence and capability of the applicant should be conducted to ensure that the applicant will be able to manage the later phases of the project for the nuclear installation. The applicant should be encouraged to conduct a resourcing strategy at the very beginning of the project to evaluate the staff and competencies it will need 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.

2.33 The regulatory body is required to establish a management system (see para. 1.7 of IAEA Safety Standards Series No. GSR Part 2, Leadership and Management for Safety [10]), and this should include dealing with licence applications, both initial applications and subsequent applications. The system should set out arrangements for requesting further information from the licensee, for carrying out review and assessment of the licensee's application and for carrying out inspections, as appropriate and necessary. The system should define responsibilities within the regulatory body for making the decision on whether to accept the application. The applicant or licensee should be informed of the decision in an appropriate manner, in accordance with the legal framework. All documentation relevant to the issuing of a licence or authorization should be recorded and kept for the lifetime of the installation or activity, and for a specified period beyond such lifetime, in accordance with legal requirements.

2.34 The nature of the review, assessment and inspection by the regulatory body will depend on the type of nuclear installation, its activities and the stage in the lifetime of the nuclear installation, and will follow a graded approach commensurate with the radiation risks of the installation, as outlined in GSR Part 1 (Rev.1) [1].

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

(a) Experience relevant to safety that has been gained at the nuclear installation, at similar nuclear installations and at other relevant nuclear and non-nuclear installations;
(b) Information from relevant tests and from research and development programmes, and new knowledge of technical matters;
(c) Changes in 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;
(g) Changes in the facility's preparedness to handle emergency situations;
(h) After a safety-significant event or accident.

2.36 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.

2.37 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 [10]);
(b) Clear procedures for analysing and endorsing any modifications (including temporary modifications) having an impact on safety (see also para. 2.38);
(c) Certificates of sufficient liability insurance or other financial security;
(d) Proof of trustworthiness of all staff who will be engaged in responsible or sensitive positions (further information is available in IAEA Nuclear Security Series No. NST065, Establishment and Implementation of a Trustworthiness Programme in Nuclear Security [11]).

2.38 After granting of the first license (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 agreement or approval by the regulatory body. Modifications that are categorized as significant to safety should be submitted to the regulatory body for review and approval or agreement. The regulatory body should inspect compliance with categorization procedures on a regular basis. Further recommendations related to nuclear power plant operation are provided in IAEA Safety Standards Series No. SSG-71, Modifications to Nuclear Power Plants [12].

2.39 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 information is available in SSG-50, Operating Experience Feedback for Nuclear Installations [13]).

2.40 For each stage of the installation's lifetime, the regulatory body should impose requirements or conditions on what kind of information and reports should be sent to the regulator body and their periodicity.

2.41 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.

OBLIGATIONS, ROLES AND RESPONSIBILITIES OF THE APPLICANT OR LICENSEE

2.42 The applicant or licensee for a nuclear installation has the following obligations, roles and responsibilities:

(a) The applicant or licensee should prepare, independently review, and submit a comprehensive application to the regulatory body that demonstrates that priority is given to safety, security and safeguards; that is, that the level of safety, security and safeguards meets regulatory requirements and that safety, security and safeguards will be maintained at the site for the entire lifetime of the nuclear installation.

(b) The applicant or licensee should carry out an independent verification of the safety assessment before it is submitted to the regulatory body for review.

(c) The applicant or licensee 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 limits and conditions under which it is to be operated.

(d) The applicant or licensee should exercise control over all of the work of contractors, especially when outsourcing licensed activities, understand the safety significance of this work ('informed customer' capability) and take responsibility for its implementation.

(e) The applicant or licensee should submit a procedure or description to the regulatory body of the process for configuration management, including 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 or licensee should have capability of an informed customer and a formal and effective external relationship with the original design organization or an acceptable alternative.

(g) The applicant or licensee should assess safety in a systematic manner and on a regular basis and perform necessary improvements, as required to maintain the level of safety.

(h) The applicant or licensee should implement nuclear security and emergency preparedness measures at the nuclear installation.

(i) The applicant or licensee should understand the obligations at a nuclear installation for accounting for, and control of, nuclear material and radioactive material.

(j) The applicant or licensee should demonstrate in its application for a licence that it has, or will have when necessary, and will continue to maintain:

(k) Adequate financial resources (e.g. depending on national legislation and regulation, for regulatory fees and liability insurance, and for funding of the construction, operation and decommissioning stages and of maintenance).

(l) 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.

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

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

(a) For controlling the nuclear installation within the limits specified in regulations and/ or licence conditions;

(b) For managing anticipated operational occurrences and accident conditions;
(c) For responding to a nuclear or radiological emergency.

These procedures should be periodically reviewed and revised, as appropriate, to take into account operating experience, modifications, and national and international good practices.

MAIN CONTENTS OF A LICENCE FOR A NUCLEAR INSTALLATION

2.44 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 issuing authority: the laws and regulations under which the licence is issued; the official designations of those who are empowered by those laws or regulations to issue the licence and whose signature and stamp should appear on the licence; and the authority to which the licensee will be accountable under the terms of the licence.
(c) Identification of the individual or organization legally responsible for the licensed installation or activity.
(d) A sufficiently detailed description of the nuclear installation, its location and its activities, including a clear depiction and description of the site boundaries, and other drawings, as appropriate.
(e) The maximum allowable inventories of radioactive sources, including the identification of 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 source(s), personnel, the public and the environment.
(h) Any limits on operation and use (e.g. dose limits, 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 and its activities, including the time periods for which records should be retained.
(m) The requirements for nuclear security at the installation.
(n) The requirements for arrangements for emergency preparedness.
(o) The procedures for changing any information stated in the licence.
(o) The documentary basis: the documents in support of the application and those prepared and used by the regulatory body in the review and assessment process, which together form the basis for issuing the licence.
(p) The relationship to other licences; that is, whether the licence is contingent upon a prior authorization or is a prerequisite for a future authorization. Mechanisms should be established so that expiry of an authorization is avoided (if an expiry date is established by the regulatory regime).
(q) Procedures for, information about and identification of the legal framework for challenging the licence or part of the licence.

(r) Licence conditions dealing with safety aspects of the installation and its activities.
(s) The length of the license.

2.45 The licence conditions (see paras 2.16–2.18) may include or refer to: technical limits and conditions; a system for reporting events, modifications and incidents to the regulatory body; and other requirements, depending on the magnitude of the risk, the nature of the nuclear installation, the activities performed and the stage in the nuclear installation's lifetime. More recommendations are provided in Section 3.

PUBLIC PARTICIPATION IN THE LICENSING OF NUCLEAR INSTALLATIONS

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

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

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

(a) The regulatory body and licensee should provide easy access to relevant and comprehensive information relating to safety and to the licensing process and licensed activities. Such information should be published where it can be easily accessed, such as on the internet and in the mass media.
(b) 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 at all steps of the licensing process.

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

GRADED APPROACH TO THE LICENSING OF NUCLEAR INSTALLATIONS

2.50 Paragraph 3.24 of IAEA Safety Standards Series No. SF-1, Fundamental Safety Principles [14] 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." To apply this principle, 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 focuses the way that an installation and its activities are assessed, inspected and authorized on the basis of risks, without unduly limiting the operation of the nuclear installation or the conduct of its activities.

2.51 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 Requirement 26 of GSR Part 1 (Rev. 1) [1]).

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

2.53 A graded approach to safety assessment should also take account of other relevant factors such as the maturity of the licensee, the maturity of the technology (see Safety Demonstration of Innovative Technology in Reactor Designs [15]) and complexity and ageing related issues relating to the nuclear installation and its activities. Maturity relates to: the use of proven practices and procedures, proven designs and operating experience at similar nuclear installations and for similar activities; uncertainties in the performance of such a nuclear installation or activities; and the availability of competent staff and experienced managers, contractors and suppliers. Complexity relates to: the extent and difficulty of the effort 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. Similarly, a graded approach should be applied as the nuclear installation progresses through the stages of its lifetime.

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

2.55 A graded approach should be applied to emergency preparedness and response requirements (see para. 4.19 of GSR Part 7 [16]). If a nuclear installation is sited near industrial sites or population centres, the impact of an emergency could have a significant impact on the nearby industrial site or population. Additionally, the impact of size, technology and possible underground siting of the nuclear installation should be assessed.

3. STEPS OF THE LICENSING PROCESS FOR NUCLEAR INSTALLATIONS

3.1 The licensing process for a nuclear installation will normally include the following steps, depending on national legislation:

(a) Siting and site evaluation (which may include the environmental impact assessment);
(b) Design;
(c) Construction (which may include procurement, manufacturing, and construction 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 (or closure for certain installations);
(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 (e.g. for construction and operation) may also give more predictability to the process for the licensee. At each hold point set down by the regulatory body or in the licensing process, an authorization or a licence from the regulatory body may be required. Conditions may be attached to licences granted at each step and may require that the licensee obtain further, more specific, authorizations or approvals before carrying out particular activities.

ALTERNATIVE REGULATORY PROCESSES FOR COMBINED LICENCES FOR 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 countries with experience in nuclear power where several similar nuclear installations have already been built and are proven. The licensing process of another country may be adopted or adapted in the regulatory 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 be later supplemented by site specific and installation specific safety assessments (e.g. environmental impact assessment, confirmation that the site characteristics are compatible with the standardized design). In such contexts, the regulatory body may consider, in advance, early approval of sites and certification of standardized plant designs. International cooperation on design certification may also help to facilitate the licensing process. The 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 filed. 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 filed. 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 power reactor, notwithstanding that the application for a licence to construct, commission and operate a nuclear installation may not be yet filed. 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 construct, commission and/or operate a nuclear installation. If the licence is issued, and if the installation is constructed in accordance with the requirements set forth in the licence, the regulatory body should then allow the plant to begin operation. In such a regulatory regime, considerable pressure is put on the regulatory body to maintain control over all the licensee's activities. If the licensing process is to be simplified in this manner, the inspection process should be made sufficiently rigorous to ensure that all safety requirements are fulfilled. The regulatory body will then need to have adequate capabilities and resources to manage its own inspection process and to monitor all safety related activities during the construction, commissioning and operation stages. Key hold points — such as fuel loading, power increase, addition of another type of installation or modules, or other technical points, as appropriate — may be imposed on the licensee. In such a simplified licensing process, an applicant could be allowed to refer to an early site permit and a standard design certification as part of its application for a combined licence for construction, commissioning and operation of a nuclear installation. The regulatory body would then consider as resolved all matters that were resolved in connection with the granting of the early site permit and the standard design certification. The applicant, however, could be allowed to request an exemption from one or more elements of the certified design; such exemptions should be granted if regulatory requirements are fulfilled and safety is considered adequate after review and assessment by the regulatory body.

APPROVAL OF SITING AND SITE EVALUATION FOR A NUCLEAR INSTALLATION

3.3 Requirements for site evaluation are established in IAEA Safety Standards Series No. SSR-1, Site Evaluation for Nuclear Installations [17].

3.4 The siting process for a nuclear installation generally consists of investigation of a large region to select one or more preferred candidate sites, followed by a detailed evaluation of those candidate sites. 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 close to a State's national border, consultations with neighbouring countries 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 should also consider the potential impact of the nuclear installation and its activities on the environment and the neighbouring population, and a preliminary assessment should be performed to verify that no incompatibilities are foreseen. 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), should be evaluated (see Requirement 13 of SSR-1 [17]).

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

(a) Site selection stage. One or more preferred candidate sites are selected after the investigation of a large region, the rejection of unsuitable sites, and screening and comparison of the remaining sites.
(b) Site characterization stage. This stage is further subdivided into:
    — Site verification, in which the suitability of the site to host a nuclear installation is verified, mainly in accordance with predefined site exclusion criteria;
    — Site confirmation, in which the characteristics of the site necessary for the purposes of analysis and detailed design are determined.
(c) Pre-operational stage. Studies and investigations begun in the previous stages are continued after the start of site preparation and construction and before the start of operation. The site data obtained allow a final assessment of the simulation models used in the final design.
(d) Operational stage. Appropriate safety related site evaluation review activities are performed throughout the operating lifetime of the facility, mainly by means of monitoring, periodic safety review.

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

Safety assessment and environmental impact assessment

3.8 A radiological study of the region, including an appropriate baseline survey, is required to be performed before commissioning of the nuclear installation (see para.7.3 of SSR-1 [17]). This study and survey should be provided to the regulatory body as the baseline for future analyses following operation of the nuclear installation.

3.9 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 [17]). 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 [18]). 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 [17], the following important factors for the licensing process for nuclear installations are required to be reviewed, assessed and inspected 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, topology, vulcanism) 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, 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. [19]), as appropriate:
    (i) The location of the local population and population density, 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).

APPROVAL OF THE DESIGN OF A NUCLEAR INSTALLATION

3.10 Requirements for the design of installations are established in IAEA Safety Standards Series Nos SSR-2/1 (Rev. 1), Safety of Nuclear Power Plants: Design [20], SSR-3, Safety of Research Reactors [21] and SSR-4, Safety of Nuclear Fuel Cycle Facilities [22].

3.11 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).

3.12 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 on regarding the activities at the installation. A process to ensure that both the site and the design are compatible in the licensing process should also be established, 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.

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

3.14 The design of the proposed nuclear installation should be such that safety requirements can be met in accordance with the design basis. The design basis is the range of conditions and events 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]. The applicant for authorization for construction should submit a basic design to the regulatory body before construction begins. This basic design can be approved or, depending on the regulatory framework, frozen (i.e. no change may be made to the basic design without the regulatory body's review and approval) or partly frozen with a regulatory instrument upon the review and assessment of the regulatory body. During the design, the systematic analysis of the interfaces between safety measures, security measures and safeguards arrangements should be implemented in order to support the demonstration of fulfilment of Requirement 8 of SSR-2/1(Rev. 1) [20], Requirement 11 of

SSR-3 [21] and Requirement 75 of SSR-4 [22].

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

3.16 At the design stage, it is important to ensure that SSCs comply with approved or accepted standards, codes and regulatory requirements, including quality assurance (QA) requirements. It is also necessary to ensure 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 licensee, applicant, or directly, depending on national legislation, whether all organizations and contractors involved in design adequately implement these requirements, and should take appropriate actions if necessary.

3.17 Defence in depth is required to be considered in the design and subsequently, in operation (see Requirement 7 of SSR-2/1 (Rev. 1) [20]). Requirement 10 of SSR-3 [21] and Requirement 10 of SSR-4 [22]). Paragraph 3.31 of SF-1 [13] 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.".

3.18 The objectives of defence in depth for a nuclear installation, as stated in Ref. [23], are:

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

3.19 Paragraph 2.13 of SSR-2/1 (Rev. 1) [20] defines five levels of defence in depth for a nuclear power plant, as follows:

> Level 1: Prevention of deviations from normal operation and the failure of items important to safety.

Level 2: Detection and control of deviations from normal operational states to prevent anticipated operational occurrences from escalating to accident conditions.
Level 3: Control of accidents within the design basis.
Level 4: Prevention of accident progression and mitigation of the consequences of a severe accident.
Level 5: Mitigation of the radiological consequences of radioactive releases from accidents.

Recommendations from SSG-88, Design Extension Conditions and the Concept of Practical Elimination in the Design of Nuclear Power Plants [24], should be addressed as well.

3.20 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 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/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. (1) control of reactivity; (2) removal of heat from the reactor and from the fuel store; and (3) confinement of radioactive material, shielding against radiation and control of planned radioactive releases, as well as 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 the radioactive wastes 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.

3.21 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) [20]). Requirement 13 of SSR-3 [21] and Requirement 12 of SSR-4 [22]).

3.22 Safety analyses of the design should be performed using proven 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, surveillance and maintenance;
(e) Arrangements for radiation protection (for workers, the public and the environment);
(f) Arrangements for emergency preparedness and response;
(g) Arrangements for nuclear security;
(h) Arrangements for international nuclear safeguards;
(i) 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) Human and organizational factors in the design organization;
(k) The training and certification requirements for design personnel;
(l) 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 life;
(m) The programme for feedback of operating experience;
(n) Procedures for management of modifications.

3.23 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 carry out an independent verification of the safety assessment before it is used by the operating organization or submitted to the regulatory body, should have an internal process (which could include receipt of independent advice) for review of safety analyses before submission to the regulatory body to ensure that such analyses are appropriate (see Requirement 21 of GSR Part 4 [25]).

3.24 The regulatory body should, in particular, review and assess documents that form part of the preliminary safety analysis report for the design of a nuclear installation, 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) Analyses of combinations of events.
(e) A description, identification, categorization and classification of SSCs important to safety.
(f) 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.

3.25 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). In the case of a design without substantial operating experience, the applicant or licensee may have to employ additional features. These features should aim to provide enough margin to overcome uncertainties in the design due to the lack of operating experience.

3.26 The applicant or licensee should ensure that a review of the detailed design of SSCs important to safety, as produced by designers, vendors and manufacturers, is incorporated into the management system required by GSR Part 2 [10]. The regulatory body may review, assess and inspect, as appropriate, the management processes performed by the applicant or licensee in this respect.

3.27 The proposed arrangements for the safe management of radioactive waste may be included in the application for a licence for the design of a nuclear installation. The regulatory body should review, assess and inspect proposals for on-site treatment and storage of radioactive waste, including the management of spent fuel, where appropriate, to ensure that the processed waste and the waste packages will be characterized in a manner compatible with the national strategy for radioactive waste, the applicable waste acceptance criteria for subsequent steps of waste management, and regulatory requirements. Specifically, the regulatory body should satisfy itself that the waste and/or waste packages:

(a) Will be properly characterized and compatible with the anticipated nature and duration of storage pending disposal;
(b) Can be subjected to regular surveillance;
(c) Can be retrieved, 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 required;
(f) Will be evaluated for impact on emergency response scenarios.

3.28 The applicant or licensee should 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, assess and inspect these proposals. Specifically, the regulatory body should satisfy itself 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 minimized in terms of activity and volume.

3.29 In addition, the licensing process should be designed to ensure that the following aspects are considered in the design of a nuclear installation:

(a) The safe and secure transport of radioactive materials 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 occupational exposure 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, e.g. criteria for dry storage of spent fuel at reactor sites).

3.30 Ageing effects should be addressed in the design stage in order to identify appropriate ageing management measures for the future. This should include the actions for ensuring the integrity of the nuclear installation until the end of decommissioning.

3.31 The application for a licence for design should include proposals for the certification of suppliers and contractors with functions relating to safety of the nuclear installation, and for the audit and review of the certification process. As appropriate, the regulatory body may review and assess these proposals. The regulatory body may also directly grant certificates or licences to suppliers and contractors in its own State, as appropriate, in accordance with the national regulatory framework.

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

APPROVAL OF THE CONSTRUCTION OF A NUCLEAR INSTALLATION

3.33 National 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 need to 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. Likewise, the regulatory body may need to 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’.

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

(a) The management system of the applicant or licensee and vendors, as required by GSR Part 2 [10];

[4] 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].

(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) A preliminary plan for emergency preparedness;
(f) Organizational and financial arrangements for decommissioning and for management of radioactive waste and spent fuel.

3.35 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.[5] The processes for this control, including the control of subcontractors, suppliers and vendors, should be part of the applicant or licensee's management system.

3.36 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 will ensure 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) Environmental monitoring equipment to monitor the impacts of on-site construction on the environment should be clearly specified, installed and tested.

[5] Applicants may apply for permission to start manufacturing of long lead equipment before grant of construction license to manage the project schedule after demonstrating compliance with relevant safety requirements.

3.37 Prior to or in the authorization 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 parts of the nuclear installation. The regulatory body should also:

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

3.38 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, for instance. If a regulatory body intends to visit premises in another State, the visiting regulatory body should inform the regulatory body of the State in which the premises are located, after approval from both States. 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 restrictions exist for joint regulatory review, it should be ensured by actual verification that the supply chain meets the necessary standards.

3.39 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 one or more nuclear installations 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.

3.40 Before the first nuclear material is allowed to be brought onto the site, an initial decommissioning plan, including a waste management plan, should be submitted to the regulatory body. Requirements for preparing a decommissioning plan are established in IAEA Safety Standards Series No. GSR Part 6, Decommissioning of Facilities [26]. The decommissioning plan submitted during the construction stage of a nuclear installation should demonstrate that:

(a) Sufficient funds to decommission the nuclear installation will be available at the end of operation (see Ref. [27]). This should include costs associated with spent fuel management and radioactive waste management and disposal and be based on reasonable cost estimates. The assessed liability should be estimated on the basis of the price and cost levels prevailing at the time the decommissioning plan is submitted to the regulatory body, and should be reviewed periodically. Mechanisms should be implemented for accumulating funds through the projected lifetime of the nuclear installation. In addition, provisions should be made such that appropriate funds can be made available in the event that the nuclear installation is shut down prior to the end of its planned life. As necessary,

a legal framework should be established for securing decommissioning funds and for protecting them from being used for other purposes.

(b) A system has been established for further development of the decommissioning plan. The plan should be reviewed periodically in the light of new techniques or information.

APPROVAL OF THE COMMISSIONING OF A NUCLEAR INSTALLATION

3.41 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 [28], Requirement 73 of SSR-3 [21] and Requirement 54 of SSR-4 [22]. Recommendations on commissioning are provided in IAEA Safety Standards Series Nos SSG-28, Commissioning for Nuclear Power Plants [29], and SSG-80, Commissioning for Research Reactors [30].

3.42 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 includes: initial fuel loading; subcritical tests; initial criticality tests; low power tests; and power ascension tests. (see Ref. [29]).

3.43 Non-nuclear testing is performed to ensure, to the extent possible, that the nuclear installation has been constructed, and the equipment has been manufactured and installed, correctly and in accordance with the design specifications. 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.

3.44 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 (see para. 6.3 of SSR-2/2 (Rev. 1) [28])).

3.45 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) Testing of SSCs may be performed at different sites.

3.46 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. 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.

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

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

(a) The status of the nuclear installation:
    (i) The as-built design of the nuclear installation;
    (ii) The results of non-nuclear 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.

3.49 There may be some overlap between the construction, commissioning and operation stages in that individual SSCs, or an entire reactor, may already be commissioned or in operation before construction of the entire nuclear installation is complete. The applicant or licensee should demonstrate that the safety case considers all potential interactions between collocated units or nuclear installations and their safety implications.

3.50 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.

3.51 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 may review, inspect and license, as appropriate, during the commissioning stage and later on during operation, any organization that provides training and qualification for staff with safety related functions.

3.52 The results of commissioning tests should be subject to:

(a) Self-assessment and internal audits of the licensee. Appropriate actions and measures should be taken whenever deviations from design parameters are identified. These should be analysed by the licensee and reported to the regulatory body.
(b) Review, assessment and inspection, 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.

LICENSING OF THE OPERATION OF A NUCLEAR INSTALLATION

3.53 Requirements for operation of nuclear installations are established in SSR-2/2 (Rev. 1) [28], SSR-3 [21] and SSR-4 [22].

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

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

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

(a) Safety expectations:
    (i) A policy at the nuclear installation that establishes that the demands of safety take precedence over those of production;

(ii) A programme for the assessment of safety performance;
(iii) A mechanism for setting safety goals or targets;
(iv) A programme for training in safety, security and safeguards culture.

(b) Management issues:
(i) A management system compliant with international standards, including a system for carrying out regular audits with independent assessors;
(ii) Processes and procedures for the control of modifications to the nuclear installation, including design modifications and their implementation 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 issues:
(i) Qualified staff available at all times, on duty if necessary;
(ii) Systematic and validated methods for the selection of staff, including testing for aptitude, knowledge and skills;
(iii) Staff training facilities and programmes;
(iv) Programmes for initial, refresher and upgrade training, including the use of full scale simulators, where appropriate;
(v) Guidelines on fitness for duty in relation to hours of work, health and substance abuse;
(vi) Competence requirements and knowledge management for operating, maintenance, technical and managerial staff.

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

3.56 Operational programmes should be established by the licensee before operation and 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 programmes 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 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;
(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.

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

(a) The person or organization responsible for the nuclear installation and its activities should not operate the nuclear installation outside the operational limits and conditions authorized or approved by the regulatory body.
(b) The person or organization responsible for the nuclear installation and its activities should ensure that in-service inspection, surveillance and testing programmes are 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 results of tests mentioned in 3.57(b) and is implemented in accordance with a time schedule, which may be subject to approval by the regulatory body.
(d) Changes[6], 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.

[6] In the operation of the plant, changes in operational limits and conditions or significant safety related modifications may be necessary because of operating experience feedback, advances in 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.

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

3.58 Before issuing an operating licence for a nuclear installation, the regulatory body should verify that:

(a) The licensee has appropriate arrangements for reporting any deviation from normal operation to the regulatory body and for providing the regulatory body with routine reports on safety performance, adherence to regulatory requirements and efforts being made to enhance safety, as required by the regulatory body.

(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, if appropriate.

(c) Offsite emergency plans are in place 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.

3.59 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 or agreement by the regulatory body, which should attach licence conditions, as appropriate.

Safety review of a nuclear installation

3.60 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[7] that the installation remains fit to continue operation. The objective

[7] 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. Recommendations are provided in IAEA Safety Standards Series No. SSG-25, Periodic Safety Review of Nuclear Power Plants [31].

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.

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

(a) If there are substantial developments in safety standards and guides, practices, and analytical methods, or significant lessons learned from operating experience.
(b) To determine the effects of ageing at the installation.
(c) In case of major evidence of changes in external hazards or other site characteristics.
(d) When a substantial part of the installation, such as a reactor, is replaced.
(e) To complement routine safety assessments, which are usually limited in scope and quite specific compared with safety reviews, which offer a wider assessment of safety at the nuclear installation.
(f) If improvements and modifications to the installation are necessary to maintain safety.
(g) If features of the installation have a limited lifetime.
(h) When a nuclear installation that is put into service after a prolonged period of time after testing.
(i) To address cumulative effects of modifications and ageing at the installation, including aspects related to staffing, competence and management structures.
(j) To address requests for extension of the operating licence. Safety reviews are a key regulatory instrument that provide reassurance that there continues to be a valid licensing basis, with respect to plant ageing and modifications implemented or needed in the light of current safety standards.
(k) To address frequent failures of SSCs.

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

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

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

(a) The nature and magnitude of the potential hazards associated with the nuclear installation and its activities;
(b) Operating experience;
(c) Significant changes to safety or regulatory standards, criteria or objectives;

(d) Technical developments and new safety related information from relevant sources;
(e) Outcomes of the ageing management programme established by the licensee;
(f) Proposed future operation timescale.

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

3.66 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, that will 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.

Additional information and recommendations on periodic safety reviews are provided in IAEA Safety Standards Series No. SSG-25, Periodic Safety Review of Nuclear Power Plants [31].

3.67 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 [32], and SSG-10 (Rev. 1), Ageing Management for Research Reactors [33]. 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. Such essential elements include:

(a) An understanding of the installation's design basis;
(b) A rigorous programme for equipment qualification (for design, construction and modifications);
(c) Identification of actual service conditions (actions to be taken during the design, construction, commissioning and operation stages);

(d) An understanding of material properties and possible ageing mechanisms;
(e) Identification of mechanical and thermal loadings;
(f) 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.

3.68 After review, assessment and inspection, depending on national regulations 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 shutdown of a nuclear installation

3.69 The licensee should submit to the regulatory body for authorization the specifications for maintaining the safety, security and safeguards needs of the nuclear installation during long term shutdown[8]. The regulatory body should review, assess and inspect such specifications and may attach conditions.

3.70 Long term shutdown should be justified by the licensee, and related plans and programmes should be subject to agreement by the regulatory body. Long term shutdown needs to be managed in a safe manner by the person or organization responsible for the nuclear installation and its activities, and should be subject to regulatory control, especially regarding: waste storage, spent fuel management, fire protection and suppression, radiation protection and fulfilment of safety functions. During long term shutdown, a safety review should also be performed to help maintain safety.

3.71 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

3.72 At the end of its operating lifetime, the nuclear installation should enter a phase of post-operational decontamination and reduction of hazards to move towards a more passively safe state. Post-operational activities could be carried out under the current operating licence or the decommissioning licence. Radiation protection considerations may necessitate that certain activities are delayed to allow radioactivity to decay and radiation exposures to be reduced. To facilitate this process, some activities relevant to decommissioning (see paras 3.74–3.86) may be performed after shutdown of the nuclear installation under licence provisions carried over from the operating stage. Such activities include:

(a) Management of operational waste;
(b) Measurements to determine the inventory of radioactive material;
(c) Removal of nuclear fuel;

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

(d) Post-operational decontamination and reduction of hazards (including removal of liquids, materials relating to the original operation and other mobile hazardous materials for disposal or safe storage).

3.73 After post-operational decontamination and removal of hazards, safe storage or enclosure ('mothballing') and interim storage may be permitted; for example, to allow for radioactive decay.

APPROVAL OF THE DECOMMISSIONING OF A NUCLEAR INSTALLATION

3.74 Requirements for decommissioning[9] of facilities are established in GSR Part 6 [26], 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 [34]. Information on the transition from operation to decommissioning is provided in Ref. [35].

3.75 An updated, detailed final decommissioning plan and its supporting safety assessment is 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 [26]).

3.76 The decommissioning stage consists of one or more substages, which may be subject to separate regulatory approval or authorization. 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.

3.77 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.

3.78 Decommissioning should only be authorized after the safe management of radioactive waste has been demonstrated in a waste management strategy that is part of the decommissioning plan. Large volumes of radioactive waste may be generated in a short time, and the waste may vary greatly in type and activity. In the review, assessment and inspection of the decommissioning plan by the regulatory body, it should be verified that radioactive waste can be managed safely through existing and, as necessary, new transportation routes.

3.79 Requirements for radioactive waste management are established in IAEA Safety Standards Series Nos GSR Part 5, Predisposal Management of Radioactive Waste [36], and SSR-5, Disposal of Radioactive Waste [37].

3.80 As part of the licensing process for a nuclear installation, 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

[9] 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.

reduction of radiological hazards (further recommendations can be found in SSG-90, Radiation Protection Aspects of Design for Nuclear Power Plants [38]). 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 [26]. 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.

3.81 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.

3.82 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).

3.83 In situations where off-site decommissioning is considered (see Appendix II para. II.15), the regulatory body should ensure specific licence conditions are included to address this.

3.84 Where it is proposed to defer dismantling in whole or in part (see para. 1.9 of GSR Part 6 [26]), 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.

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

(a) Waste storage;
(b) Spent fuel management;
(c) Fire protection and suppression;
(d) Radiation exposure of workers, the public and the environment;
(e) Movement of radioactive material on-site and off-site;
(f) Non-radiological hazards, which should be dealt with by coordinated activities between the relevant regulatory 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) Integrity of hoisting devices to prevent falling of loads;

(j) Emergency preparedness and response plans.

3.86 A final decommissioning report is required to be prepared, supported by appropriate records, and should be submitted to the regulatory body (see para. 9.1 of GSR Part 6 [26] and Annex II of SSG-47 [34]).

RELEASE OF A NUCLEAR INSTALLATION FROM REGULATORY CONTROL

3.87 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 [26] and IAEA Safety Standards Series No. WS-G-5.1, Release of Sites from Regulatory Control on Termination of Practices [39]). 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 6.15 of SSG-47 [34]) .

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

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

(a) That all responsibilities covered by all authorizations have been satisfactorily discharged by the licensee and that there is no reasonable expectation that the licensee will have further responsibilities with respect to anything remaining on the site;

(b) That any necessary institutional controls, including continuing environmental monitoring, are 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).

3.90 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 [26]). The survey is to 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.

3.91 Once the regulatory body has accepted the evidence provided, 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

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

(a) A descriptive 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 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 on 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) Fire protection plans;
(q) Plans for accounting and control of nuclear material;
(r) Training and qualification plans for operating personnel;
(s) Proof of trustworthiness of all staff who will be engaged in responsible or sensitive positions;
(t) Commissioning programmes and reports;
(u) Final safety analysis reports on the site evaluation, design, construction, commissioning and operation stages and on provisions for decommissioning;
(v) Ageing management plans;

(w) General operating rules and operating procedures;
(x) Technical specifications, including operational limits and conditions;
(y) A plan for collecting and applying feedback from operating experience;
(z) Plans for evaluating and improving safety performance;
(aa) Emergency operating procedures and severe accident management guidelines;
(bb) Emergency preparedness and response plan;
(cc) The radiation protection programme and associated reports;
(dd) Reports on radioactive waste and spent fuel management, including proposals for treatment, packaging, storage 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;
(ee) An indicative list or detailed inventory of sources;
(ff) Modification rules (may be included in the general operating rules);
(gg) Details of the maintenance programme and the periodic testing programme;
(hh) Reports of periodic safety reviews or other safety reviews;
(ii) 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 characteristics of small modular reactors and their associated deployment models[10] introduce some differences compared to those of land-based large nuclear power plants [6], 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, or decommissioned away from the 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 (see Ref. [2]), and a small modular reactor should also follow this basic stage during its lifetime. For examples of differences, the following list shows the potential 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 and site evaluation;
(b) Design;
(c) Off-site construction or manufacturing;
(d) Off-site commissioning;
(e) Transport (both to and from facility);
(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 may 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.

II.2 The recommendations in this Safety Guide are generally applicable to small modular reactors. This appendix highlights the potential impact of the new deployment models for small modular reactors on the licensing process and 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.

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 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

[10] 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.

more organizations of the different stages of development of a small modular reactor. The regulatory body should hold a single licensee responsible for safety for all stages of the lifetime of the reactor regardless of commercial arrangements. The regulatory body should seek assurances on this licensee's organizational capability to effectively oversee safety considerations at all stages of the lifetime of the small modular reactor.

II.4 To fulfil its responsibilities, a licensee is required to give an overriding priority to safety. 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 exercise its responsibility without undue interference from commercial stakeholders. This may include assessing the interfaces between organizations (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 licenses 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) An 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) An 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 will maintain:

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

(h) Proper interface mechanisms and procedures for any activities that are outsourced to several contractors.

II.9 The licensing process should include provisions to ensure that the licensee maintains independence and the ability to perform their obligations.

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

II.10 Requirements for site evaluation are established in SSR-1 [17]. 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 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;
  (iv) Where systems are shared between the small modular reactor and the adjacent installation, their operation and any change/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) Radiological impact to the population and environment is reduced as much as possible.
(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. Size, technology, location, and possible underground siting of the installation, along with remoteness of the community might affect the impact significantly.

DEPLOYMENT OF MULTIPLE SMALL MODULAR REACTORS

Standardized fleet deployment for small modular reactors

II.11 Possible approaches to fleet deployment[11] of small modular reactors include:

(a) A ‘certified design’ model, where a reactor design is certified by a regulatory body or jointly by several regulatory bodies. Once a design is certified, licensing efforts then focus on site-specific aspects and any changes to the certified design.
(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 certified design described in II.11(a), and then its efforts will focus on the differences from one plant to the next for both the design and site-specific aspects.

II.12 When reviewing a licensing application of a reactor that is part of a fleet, the regulatory body could consider focusing their review efforts on the differences from one plant to the next.

II.13 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/reactor modules or replacement of major components of a small modular reactor at a single site

II.14 Some deployment models for small modular reactors could allow for different reactor types or the addition or replacement of reactor units or reactor modules (see IAEA TECDOC-1936, Applicability of Design Safety Requirements to Small Modular Reactor Technologies Intended for Near Term Deployment [40]) or major components or systems at various times throughout the lifetime of the facility. Additional units/reactor modules may be in close proximity to or sharing the same infrastructure as operating reactor modules (See para 3.9(a)(iii) for additional information on multiple nuclear installations on the same site.). The potential for evolution of 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. If the timing of licensing is different, additional considerations may be needed.
(c) When different reactor designs are proposed for a single site, separate licenses should be 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/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 occasions, fundamental safety function of remaining individual reactors is required to 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.

[11] For the purposes of this appendix, fleet deployment is the deployment of multiple small modular reactors of the same or similar design. Fleet deployment aims to minimize the design changes between reactors in the same fleet.

This may involve off-site assessment of replacement components. Alternatively, the licensee may need to obtain a new licence for the replacement.

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

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

(h) The licensee should implement an emergency plan for the entire site. The licensee should ensure that processes are implemented so that shared personnel or services are available when needed for safety or security or emergency reasons.

RADIOACTIVE WASTE AND SPENT FUEL MANAGEMENT

II.15 SMR operations are expected to result in the generation of a wide range of radioactive wastes and spent fuels, influenced by the interaction of the fuel system (e.g., fuel composition, shape, enrichment, and assembly form), moderator (for thermal reactors), and coolant selection [6]. 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 an SMR facility. In this licensing context, the following key areas are recommended for safety considerations in radioactive waste and spent fuel management:

(a) The design of the SMR facility(ies) should provide means and consideration (i.e. material selection, modularity construction) for minimization of radioactive waste generation (by volume and activity).

(b) The SMR facilities should have an on-site radioactive waste management system 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 SMR operation and future disposal should be determined, preferably during the design phase and through licensing application.

(e) System requirements for spent fuel management (cooling times, wet/dry storage capacity, as applicable) at the SMR 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 proximity of SMRs to industrial sites or large population areas should be assessed to ensure safety throughout decommissioning.

(h) The design should ensure that spent fuel and radioactive waste generated during the facility's lifetime are storable and disposable. Disposal routes for spent fuel and radioactive waste should be identified and feasible within the Member State's national strategy.

(i) Options for interim storage of spent fuel on-site should be evaluated.

(j) Transportation requirements for moving radioactive waste and spent fuel off-site should be established.

(k) Existing disposal solutions for radioactive waste, including spent fuel, should be assessed for suitability to the waste expected from SMRs.

II.16 Many of the safety considerations applied to the licensing processes for traditional nuclear power plants are also applicable to the licensing of SMRs. However, key areas of novelty in the review process include the modularity of reactor units within the same facility, the proximity to industrial zones or large population areas, and the unique waste streams and spent fuel associated with non-light water SMRs.

II.17 At the time of writing this Appendix, Member States have limited experience with the licensing, construction, operation, or decommissioning of SMR facilities. While some experimental facilities are operational or in various stages of design and construction, broader experience in commissioning, operating, and decommissioning SMR power plants is needed. Member States are therefore encouraged to share with one another the early experiences gained in novel areas.

OFF-SITE CONSTRUCTION, COMMISSIONING, AND DECOMMISSIONING

II.18 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. Some deployment models also propose off-site decommissioning. For such cases:

(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 they should be proportionate to the safety significance of the systems being manufactured, assembled, and tested off the site. The regulatory body should apply the same level of practices on review, assessment and inspection to small modular reactor as those of large power reactors, with some consideration of the configuration of reactors.
(c) The regulatory body should be able to assess the way safety related activities are conducted, including those performed off the site. This may be achieved by direct oversight of manufacturing sites through qualification, certification, or licensing of the off-site facility or activity, or review of the same carried out by a regulatory body in another State. This may also be achieved 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. The specific mechanisms of control of the manufacturing and construction activities in the absence of a licensee are out of scope for this document.
(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.
(f) The licensing process for transportable nuclear power plants should ensure there are adequate provisions for testing before and after transport of a reactor module to the deployment site.
(g) The regulatory body should ensure that the licensee provides sufficient information in

the licence application to ensure that the facility can be safely decommissioned (i.e. appropriate material selection to reduce neutron activation, generation of complex radioactive waste during operation, the modular design to enable use of well-established dismantling technologies, etc.).

(h) The regulatory body should ensure that under the proposed decommissioning strategy, there is sufficient funding (accrued during the operation of the SMR facility) to complete the decommissioning project and for the site to be released. Unrestricted release of sites from regulatory control should be the primary objective.

SHARING AND LEVERAGING INFORMATION ON SMALL MODULAR REACTORS

II.19 As small modular reactors are expected to deploy more standardized designs worldwide, collaboration amongst regulatory bodies in different States may be necessary and regulatory bodies may choose to leverage work that has already been performed in another State. In addition, with reactor lifetimes projected to be many decades, it can be assumed that design changes will be needed over the reactor lifetime to cover, for example, improvements or changes in design due to operating experience, as well as changes needed to support obsolescence of components (e.g. instrumentation and controls). As such, States need to ensure they properly understand and document how leveraged information was used in their decision making process, and also ensure that their documentation is done with enough detail that regulatory oversight capability can be maintained over the lifetime of the facility.

II.20 When leveraging information from other regulatory bodies, the regulatory body receiving information should have full access to the design details and background information to make regulatory decisions and should validate the information received.

II.21 When considering the use of information from other regulatory bodies, the regulatory body receiving information should ensure that it:

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

(b) 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);

(c) Takes responsibility for its own regulatory decisions.

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