Safety Reports Series
No. 119

Licensing Process for the Construction, Commissioning and Operation of Nuclear Power Plants

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LICENSING PROCESS FOR THE CONSTRUCTION, COMMISSIONING AND OPERATION OF NUCLEAR POWER PLANTS

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SAFETY REPORTS SERIES No. 119

LICENSING PROCESS FOR THE CONSTRUCTION, COMMISSIONING AND OPERATION OF NUCLEAR POWER PLANTS

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2023

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www.iaea.org/publications

Printed by the IAEA in Austria
October 2023
STI/PUB/2005

IAEA Library Cataloguing in Publication Data

Names: International Atomic Energy Agency.
Title: Licensing Process for the Construction, Commissioning and Operation of Nuclear Power Plants / International Atomic Energy Agency.
Description: Vienna : International Atomic Energy Agency, 2023. | Series: Safety Reports Series, ISSN 1020–6450 ; no. 119 | Includes bibliographical references.
Identifiers: IAEAL 23-01615 | ISBN 978–92–0–117523–6 (paperback : alk. paper) | ISBN 978–92–0–117623–3 (pdf) | ISBN 978–92–0–117723–0 (epub)
Subjects: Nuclear power plants — Commissioning. | Nuclear power plants — Design and construction. | Nuclear power plants — Safety measures.
Classification: UDC 621.039.5 | STI/PUB/2005

FOREWORD

The past two decades have seen an increase in the building of new nuclear power plants. In addition, many Member States have expressed an interest in embarking on nuclear power programmes. A decision to embark on a nuclear power programme calls for great responsibility on the part of the Member State and necessitates the establishment of an adequate legal, governmental and regulatory infrastructure within a defined framework.

IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety, addresses this issue and establishes the requirements that are considered necessary for ensuring safety while embarking on a nuclear power programme. One of the important aspects addressed in GSR Part 1 (Rev. 1) is related to establishing a system for authorization and licensing. This is further elaborated and explained in detail in IAEA Safety Standards Series No. SSG-12, Licensing Process for Nuclear Installations, which covers the licensing stages from the siting of a nuclear installation to its construction, commissioning, operation, decommissioning and release from regulatory control.

This publication provides additional guidance, mainly for Member States embarking on a nuclear power programme, on the licensing process and associated procedures needed during the construction, commissioning and operation of a nuclear power plant. It also elaborates on the generic guidance provided in SSG-12 and gives supplementary practical guidance.

The IAEA would like to express its appreciation to all the experts who contributed to the development and review of this publication. The IAEA officer responsible for this publication was U. Bezdeguemeli of the Division of Nuclear Installation Safety.

EDITORIAL NOTE

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CONTENTS

1. INTRODUCTION

1.1. BACKGROUND

Paragraph 3.8 of IAEA Safety Standards Series No. SF-1, Fundamental Safety Principles [1], states:

> "A properly established legal and governmental framework provides for the regulation of facilities and activities that give rise to radiation risks and for the clear assignment of responsibilities. The government is responsible for the adoption within its national legal system of such legislation, regulations, and other standards and measures as may be necessary to fulfil all its national responsibilities and international obligations effectively, and for the establishment of an independent regulatory body."

As the main element of a regulatory infrastructure, a well defined and effectively applied authorization system that encompasses review and assessment activities and inspection activities by the regulatory body is key to the achievement of a high level of safety throughout the lifetime of a nuclear power plant (NPP). The authorization of specific activities related to NPPs through a process of licensing is one of the principal functions of a regulatory body. 'Authorization' is a general term, but often, in the context of NPPs, the term 'licensing' is used for the authorization process. Licensing gives the regulatory body effective regulatory control over safety and the ability to apply the legal and regulatory framework in order to ensure that the responsibilities of the licensee are being adequately fulfilled in accordance with the legislation and regulations. IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety [2], addresses the establishment of a system for licensing in Requirements 2, 23, 24 and 25.

Additionally, the IAEA has provided guidance on the licensing process for all types of nuclear installation in IAEA Safety Standards Series No. SSG-12, Licensing Process for Nuclear Installations [3]. Further guidance on aspects of the authorization process is provided in IAEA Safety Standards Series No. GSG-12, Organization, Management and Staffing of a Regulatory Body for Safety [4], and IAEA Safety Standards Series No. GSG-13, Functions and Processes of the Regulatory Body for Safety [5]. Reference [6] outlines some of the key challenges that the regulatory body of a newcomer State will face throughout the lifetime of the first NPP, with suggestions on how the regulator and policy makers might address the requirements and take advantage of the opportunities from this experience for further development of nuclear power in the Member State.

Moreover, IAEA Safety Standards Series No. SSG-38, Construction for Nuclear Installations [7], and IAEA Safety Standards Series No. SSG-28, Commissioning for Nuclear Power Plants [8], give guidance on construction and commissioning for nuclear installations, respectively, and provide detailed information regarding the regulatory oversight and authorization during these phases.

GSG-13 [5] recommends the following in paras 3.93 and 3.116:

> "(c) The regulatory framework for the authorization process should be explicitly established by the regulatory body.
>
> …….
>
> "The authorization process should be understood by the parties concerned and should be predictable (i.e. well defined, clear, transparent and traceable)."

Additionally, para. 2.54 of IAEA Safety Standards Series No. SSG-16 (Rev. 1), Establishing the Safety Infrastructure for a Nuclear Power Programme [9], states that: "To conduct licensing effectively, the processes to be used should be considered and communicated to all interested parties as early as possible in the development of the nuclear power programme."

Hence, a State embarking on a nuclear power programme needs to consider carefully, at an early stage, the process to be utilized to conduct licensing effectively. The licensing process is expected to be well defined in national regulations and/or guides and communicated to all interested parties as early as possible in the development of the nuclear power programme. The process is expected to be clear, transparent and traceable, and established in a systematic way to facilitate efficient conduct of regulatory activities. The applicant/licensee is also to be provided with the information that will be necessary to support licensing submissions at all main stages of the NPP lifetime, as well as information on substages that may require additional interaction between the regulatory body and the applicant/licensee.

The guidance provided in SSG-12 [3] is generic for all types of nuclear installation and covers the licensing process throughout their lifetime. However, it does not contain detailed practical and specific information and experience that can be used by Member States, particularly States embarking on a nuclear power programme, to develop the necessary components of a licensing process for NPPs in their national legal framework.

1.2. OBJECTIVE

The purpose of this publication is to provide practical guidance to the regulatory bodies of Member States, particularly States embarking on a nuclear power programme, when developing or revising their regulatory framework and defining their licensing process. The licensing process is a legal process and is applied in different ways in different Member States, depending on their national regulations and laws. Some of the stages in the lifetime of an NPP shown in Fig. 1 may be combined, depending on the national situation and regulations. For example, the licensing process may result in granting a single licence for the whole lifetime of an NPP or several licences for specific phases, such as the siting, construction, commissioning and operation of the plant.

This publication describes the fundamental and generic requirements of the licensing process, which are basically the same in all Member States, and presents the experience of some States in applying these requirements. It complements and elaborates on the existing guidance given in SSG-12 [3]. Moreover, it presents practical and technical considerations from Member States with experience of applying the IAEA safety standards in this area, describing how these States have addressed these considerations in the development or review of their regulatory framework.

The aim of this publication is to demonstrate how to establish a well defined, well structured, clear, transparent and traceable licensing process specifically for ensuring the safety of NPPs at the construction, commissioning and operation stages. Although it focuses only on the safety of the NPP, the interface between safety and security has to be considered and evaluated by the regulatory body during the licensing process.

The publication also provides guidance specific to the licensing of NPPs regarding the information and documentation to be submitted by an applicant/licensee to the regulatory body at the steps of a licensing process from construction to operation. The guidance is supported by the common features of global practices.

Guidance and recommendations provided here in relation to identified good practices represent expert opinion but are not made on the basis of a consensus of all Member States.

1.3. SCOPE

This publication describes how the licensing process is applied during the specific stages of construction, commissioning and operation of an NPP and outlines the use of substages, sometimes called hold points, within these stages

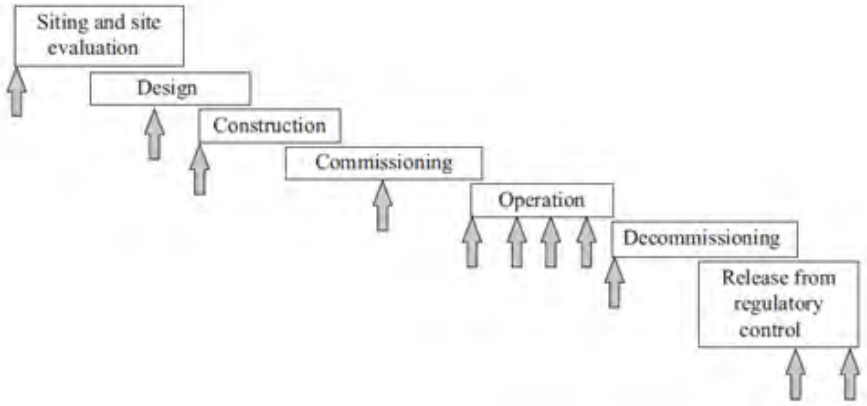

FIG. 1. Stages in the lifetime of a nuclear power plant. The arrows indicate where hold points may be imposed (reproduced from Ref. [3]).

(see Fig. 1). It discusses the topics, required documents and information that need to be prepared by the applicant/licensee and submitted to the regulatory body for review and assessment at each step in the licensing process. Complementary detailed information can be found in the references. Recommendations on the application by a regulatory body of a graded approach to the licensing process are also provided in SSG-12 [3].

Additionally, examples are given for generic and specific conditions that can be attached to a licence at a main licensing step or substep. The importance of review and assessment, as well as inspection, by the regulatory body during each step to ensure compliance with licence conditions and legal and regulatory requirements is emphasized.

Although some Member States licence individuals for specific roles, such as control room supervisor, this publication does not cover this form of licensing, and concentrates on the licensing process for ensuring the safety of NPPs.

Since considerable guidance has been developed by the IAEA on the siting and site evaluation process and on the basic design requirements for an NPP, this publication concentrates specifically on the licensing process for the construction, commissioning and operation stages of NPPs, assuming that the earlier stages of siting, choice of NPP design, environmental impact assessment (EIA) and recognition of the applicant/licensee have already been completed satisfactorily.

In some States, security and safeguards considerations are included in the licensing process, depending on the State's legal framework and internal arrangements. This publication does not discuss the interactions between the systems and management arrangements necessary for safety, security

and safeguards and their effect on the licensing process. The IAEA Nuclear Security Series covers issues concerning security in the licensing of NPPs; issues concerning safeguards implementation are mainly covered in the IAEA Services Series.

1.4. STRUCTURE

This publication comprises five sections, three appendices and two annexes. Section 1 provides the introduction and background. Section 2 gives some general features of licensing and Section 3 covers the structure of the licensing process. Section 4 covers the prerequisites from the preceding siting and design stages for granting a construction licence. Finally, Section 5 contains three major subsections, covering construction licensing, commissioning licensing and operational licensing, respectively. Appendices I–III present typical processes for granting a licence, the typical content of a licence and the content of the safety analysis report (SAR) at different licensing steps, respectively. Annex I provides examples of authorization steps and submission requirements in various Member States. Annex II sets out the principles of a manufacturing follow-up document for structures, systems and components (SSCs).

1.5. TERMINOLOGY

Unless stated otherwise, all safety related terms used in this publication are to be understood as defined in the IAEA Safety Glossary [10].

The 'regulatory body' is: "An authority or a system of authorities designated by the government of a State as having legal authority for conducting the regulatory *process*, including issuing *authorizations*, and thereby regulating… *nuclear*…*safety*."

A 'licence' is: "A legal document issued by the *regulatory body* granting *authorization* to perform specified *activities* relating to" an NPP. It is the product of the authorization/licensing process, generally covering a particular stage of the lifetime of an NPP. In this publication, the term 'licence' is used for a particular type of authorization, normally representing the primary authorization for major activities.

'Authorization' is defined as "the granting by a *regulatory body* or other governmental body of written permission" to a legal person or organization (the applicant/licensee) "to conduct specified *activities*. Authorization could include, for example, licensing (issuing a licence), certification (issuing a certificate)",

a permit or registration. This term "is also sometimes used to describe the document granting such permission."

The 'licensee' is the holder of a current and valid authorization/licence and is the legal person or organization having overall responsibility for the NPP and its activities. Therefore, the term 'licensee' is used to designate the authorized party. For the purpose of this publication, it is assumed that the same organization holds the licence through all stages of the lifetime of the NPP. An application needs to be submitted to the regulatory body for authorization to begin or continue to carry out certain activities, as specified by the regulatory body.

The 'applicant' is defined as the appropriate legal person or organization who applies for an authorization to carry out certain activities, as specified by the regulatory body. The most significant of these activities are at the different stages of the lifetime shown in Fig. 1, but additional hold points may also be subject to regulatory authorization during any licensing step.

2. OVERVIEW OF THE LICENSING PROCESS

2.1. BASIC ATTRIBUTES AND MAIN FEATURES

In accordance with the legal systems in Member States, the licensee is the legal entity responsible for fulfilling the safety obligations and any other obligations (e.g. financial, commercial) that may arise in connection with the operation of an NPP. This publication deals only with those obligations that are necessary to ensure the safe operation of the NPPs that are under the control of the licensee, irrespective of the licensee's other obligations and responsibilities.

In accordance with the licensee's licensing obligations, the licensee establishes a policy for adherence to safety requirements and procedures for the safe control of the plant under all conditions, including startup and shutdown, maintenance and surveillance. The licensee is also required to take measures for retaining a sufficient number of qualified personnel.

The licensing process is an ongoing dialogue between the applicant/licensee and the regulatory body, punctuated by specific licensing steps. Before moving from one stage to the next in the lifetime of the NPP, the licensee is required to prepare and formally submit a comprehensive application to the regulatory body that demonstrates: (i) that priority is given to safety and (ii) that the national safety requirements will be met at the facility during this and the succeeding stages in the lifetime of the NPP.

Following the review and assessment of the relevant submissions and the inspection of activities on-site, the regulatory body issues a licence for the specific stage of the lifetime of the NPP if it is satisfied that the NPP can be constructed, commissioned, operated and decommissioned safely. The licence sets out the activities that have been authorized and any attached conditions that need to be met to ensure safety. The objective of granting a licence is for the regulatory body to establish regulatory control over all activities where safety is concerned.

However, interactions between the licensee and the regulatory body are not limited to submitting and assessing licence applications. As soon as possible in the licensing process, regular meetings and correspondence have to be established between the staff of the applicant/licensee and the regulatory body at various levels from senior management to expert level. The purpose of these interactions is to establish mutual understanding, trust and respect between the regulatory body and the licensee to support a frank, open and yet formal relationship throughout the lifetime of the NPP. Such interactions provide a forum for the licensee to forewarn the regulatory body of potential upcoming issues and obtain early insight into the likely response of the regulatory body to the licensee's plans. The regulatory body can also forewarn the licensee of areas that it considers may need attention.

In the early phases, these interactions may consist of exchanges of information about the implementation of the NPP project. The licensee may present plans, including the proposed site, the choice of NPP design, the planned arrangements for operation and the proposed schedule for the project. The regulatory body will outline its requirements for the licensing process and provide guidance for the format and content of the necessary submissions, including the SAR.

In later phases of the NPP project, the ongoing interactions between the licensee and the regulatory body provide opportunities for the licensee to present status reports and updates, and for the regulatory body to raise issues related to its review and assessment of licensee documents and inspections of activities that may require the licensee's attention.

The main advantage of interactions between the regulator and licensee is that many issues can be addressed before they become critical. For example, the licensee's proposed or planned solutions to problems can be presented to obtain the regulator's view on their viability, subject to a fully developed safety argument and a satisfactory review and assessment by the regulatory body. Such an approach can streamline the implementation of an appropriate solution. Alternatively, the regulatory body can give advance warning in the event of a declining safety trend so that early corrective action can be taken. This safety trend may be in a conventional safety area but can still indicate the need to improve the situation in nuclear safety.

Both organizations have the same aim for the NPP, namely, to maintain safety throughout its lifetime. Licensing is a process in which open and honest communication is of great importance. Regulatory oversight is not a just a fault-finding exercise; nor should licensees hide faults or other issues from the regulator. Both organizations have to be open and honest about their views on the safety of the workers and the public in relation to the operation of the NPP.

2.2. RELEVANT IAEA SAFETY STANDARDS

The remainder of this publication draws upon the following IAEA Safety Standards Series publications and expands on the details of the topics covered to the extent that is necessary or appropriate:

— The main reference relevant to this Safety Report is SSG-12 [3]. It sets out the recommendations for licensing for the entire lifetime of nuclear installations, including NPPs. It covers the roles and responsibilities of both the regulatory body and the licensee, the nature of licence conditions and the types of document that are submitted by the licensee to the regulatory body.
— GSR Part 1 (Rev. 1) [2] sets out the main requirements regarding the authorization of facilities and activities by the regulatory body.
— IAEA Safety Standards Series No. SSR-1, Site Evaluation for Nuclear Installations [11] establishes requirements for defining the information to be used in the site evaluation process and for assessing site specific hazards and safety related site characteristics for the siting of nuclear installations. This Safety Report assumes that these requirements have been established by the regulatory body and will be incorporated as necessary into the NPP design.
— IAEA Safety Standards Series No. SSR-2/1 (Rev. 1), Safety of Nuclear Power Plants: Design [12], and IAEA Safety Standards Series No. SSR-2/2 (Rev. 1), Safety of Nuclear Power Plants: Commissioning and Operation [13], establish requirements for the proposed design, commissioning and operation of NPPs.
— SSG-38 [7] provides more detail on the regulation of the construction stage and how further design developments and modifications are regulated during this stage.
— SSG-28 [8] provides more detail on the commissioning stage and the role of the regulatory body.
— IAEA Safety Standards Series No. NS-G-2.4, The Operating Organization for Nuclear Power Plants [14], is one of several Specific Safety Guides that

deal with operational aspects. It also covers the interface with the regulatory body.

— IAEA Safety Standards Series No. GSR Part 4 (Rev. 1), Safety Assessment for Facilities and Activities [15], establishes the requirements and defines the responsibilities related to the safety assessment. The verification of compliance with these requirements is a primary objective of the licensing process.
— IAEA Safety Standards Series No. SSG-61, Format and Content of the Safety Analysis Report for Nuclear Power Plants [16], provides details on the content and format of the SAR, which is submitted by the licensee as part of the request for authorization at the various stages in the lifetime of the NPP.
— IAEA Safety Standards Series No. GSR Part 7, Preparedness and Response for a Nuclear or Radiological Emergency [17], addresses the requirements for preparedness and response for a nuclear or radiological emergency, including requirements for the transition to an existing exposure situation. This Safety Report will deal only with preparedness and response on the NPP site.
— IAEA Safety Standards Series No. GSR Part 2, Leadership and Management for Safety [18], establishes requirements in relation to establishing, sustaining and continuously improving leadership and management for safety, as well as an effective management system fostering a strong safety culture in an organization.
— GSG-13 [5] provides, inter alia, recommendations for the regulatory body to explicitly establish the regulatory framework for the licensing process for NPPs. It also details the review and assessment activities and inspection activities that support the licensing process.
— GSG-12 [4] provides a process description for the licensing process.
— SSG-16 (Rev. 1) [9] addresses all aspects of the safety infrastructure needed for the first three phases of the development of a nuclear power programme. Phase 2 and Phase 3 actions described in SSG-16 (Rev. 1) [9], which are related to the establishment of the regulatory framework and include a regulatory licensing and oversight process, were taken into consideration for the development of this Safety Report.
— Reference [6] outlines some of the key challenges that the regulatory body in a new entrant State will face throughout the lifetime of the first NPP, with suggestions on how the regulator and policy makers might address the requirements and take advantage of the opportunities from this experience for further development of nuclear power in the Member State.

2.3. NATIONAL LEGAL AND REGULATORY FRAMEWORK

GSR Part 1 (Rev. 1) [2] states (footnote omitted):

"**Requirement 2: Establishment of a framework for safety**

"**The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated.**

"2.5 The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following:

…….

(3) The type of authorization [footnote omitted] that is required for the operation of facilities and for the conduct of activities, in accordance with a graded approach;
(4) The rationale for the authorization of new facilities and activities, as well as the applicable decision making process".

Different Member States have different laws and regulations relating to the licensing process for NPPs. It is not the purpose of this publication to discuss the advantages and disadvantages of these different approaches, which in many cases have been developed over many years to suit the State's legal system. The fundamental aspects are, however, similar.

The government establishes the legal and regulatory framework and, through the legal system, establishes and maintains the regulatory body with the necessary legal powers to fulfil its statutory obligation for the regulatory control of facilities and activities to grant, amend, suspend or revoke licences and licence conditions, as appropriate [2]. Although this publication refers to only one authority covering all aspects of regulation, in some Member States the responsibilities are distributed among different authorities, which necessitates good liaison and communication between them.

The legal and regulatory framework clearly assigns the prime responsibility for the safety of the authorized NPP and the relevant activities to the authorized party, namely the licensee.

An important aspect of the regulatory framework is who has the legal responsibility to grant the licence. In some Member States, this responsibility lies with a high level member of the government, for instance a minister or even the

president or prime minister; in others, the responsibility is entrusted to the head of the regulatory body or a commission. In the former case, the regulatory body usually has the responsibility to provide information or a recommendation to the licensing authority. This is particularly important if senior government officials are involved, as they may not have the requisite technical knowledge to assess the adequacy of the safety of the NPP. In the latter case, consideration has to be given to how the head of the regulatory body or members of the commission are appointed.

GSR Part 1 (Rev. 1) [2] states:

> "**Requirement 18: Staffing and competence of the regulatory body**
>
> "**The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities.**"

The responsibility for granting authorization at a hold point during the licensing process is generally a responsibility at the regulatory body level.

Depending on the national legal system, the necessary requirements for safety are usually set out in mandatory regulations, which are issued by the regulatory body or are proposed by the regulatory body and issued by the government. The legal framework empowers the regulatory body to carry out the necessary activities, including issuing safety regulations, to ensure that the licensee is complying, and will continue to comply, with the State's safety requirements.

Paragraph 3.5 of SF-1 [1] states:

> "The licensee retains the prime responsibility for safety throughout the lifetime of facilities and activities, and this responsibility cannot be delegated. Other groups, such as designers, manufacturers and constructors, employers, contractors, and consignors and carriers, also have legal, professional or functional responsibilities with regard to safety."

Licensing principles are established in the regulatory and legal framework of the Member State. Paragraph 2.19 of SSG-12 [3] gives many examples of licensing principles. The regulatory framework for licensing applications is expected to be clear, especially the process for applying for a licence. A clear and explicit set of requirements, criteria and standards forming the licensing basis are defined in regulations set out by the regulatory body, and the licensee demonstrates that these have been met.

A licence for an NPP is granted to a suitable organization (the licensee — see Section 4.1), provided that it can demonstrate that the activities to be undertaken are adequately safe. The applicant/licensee organization provides evidence to demonstrate its resources, its organizational capability and the competence of its managers and staff (including the competence of contractors and subcontractors) to construct, commission, operate and decommission the NPP safely and comply with legal requirements, safety objectives, principles and criteria, and the conditions of the licence. The licence is granted after a satisfactory regulatory review and assessment of the information submitted, as well as inspection to verify its accuracy, where appropriate.

An activity on an NPP site may be licensed only when the regulatory body has confirmed that the NPP or activity will be conducted in a manner that does not pose an undue risk to workers, the public or the environment. It is essential that the regulatory body have the organizational capability to fulfil its responsibilities, which are described in GSG-12 [4].

Cooperation with the vendor State's regulatory body can be beneficial during the licensing process, particularly in the understanding of the safety standards and safety assessment of the proposed NPP. However, considering a potential conflict of interest in some cases, it would be better not to rely upon the vendor State's regulatory body as the sole source of advice. Hence, in performing its review and assessment and its inspection, the regulatory body may, if necessary, also seek assistance from an experienced third party regulatory body — particularly regulatory bodies having the same NPP technology and/or a suitable technical support organization — and utilize the peer review and expert services offered by the IAEA. The regulatory body is expected to maintain this approach throughout the lifetime of the NPP.

Paragraph 2.18 of GSR Part 1 (Rev. 1) [2] states:

> "Where several authorities have responsibilities for safety within the regulatory framework for safety, the responsibilities and functions of each authority shall be clearly specified in the relevant legislation. The government shall ensure that there is appropriate coordination of and liaison between the various authorities concerned in areas such as:
>
> (1) Safety of workers and the public;
> (2) Protection of the environment;
> (3) Applications of radiation in medicine, industry and research;
> (4) Emergency preparedness and response;
> (5) Management of radioactive waste (including government policy making and the strategy for the implementation of policy);
> (6) Liability for nuclear damage (including relevant conventions);

(7) Nuclear security;
(8) The State system of accounting for, and control of, nuclear material;
(9) Safety in relation to water use and the consumption of food;
(10) Land use, planning and construction;
(11) Safety in the transport of dangerous goods, including nuclear material and radioactive material;
(12) Mining and processing of radioactive ores;
(13) Controls on the import and export of nuclear material and radioactive material.

This coordination and liaison can be achieved by means of memoranda of understanding, appropriate communication and regular meetings. Such coordination assists in achieving consistency and in enabling authorities to benefit from each other's experience."

In relation to decommissioning, establishment of a specific legal framework is necessary for securing decommissioning funds and for protecting them from being depleted for other purposes.

In Sections 2.4 and 2.5, some of the primary responsibilities of both the regulatory body and the licensee are given.

2.4. PRIMARY RESPONSIBILITIES OF THE GOVERNMENT AND REGULATORY BODY

The most important responsibilities of the government are to define in law the role of the regulatory body and its powers and to make provisions to ensure that there are sufficient competent staff to carry out the functions of the regulatory body [4, 19]. These provisions will allow the regulatory body to recruit staff, carry out inspections (including entry into the site at any time), perform review and assessment, and make decisions regarding the licensing process.

The regulatory body has to be effectively independent of those parts of government and industry that have a role in promoting the use of nuclear energy so that it can make its decisions free of external influences, and the laws have to enforce this necessity, as emphasized by Requirements 2, 3 and 4 of GSR Part 1 (Rev.1) [2]. It has to guard its independence robustly so that it can gain and maintain the confidence of the public and other interested parties. If the public believes that the regulatory body is subject to influence, this could undermine public confidence in the regulatory body and weaken public support for regulatory decisions. Communication and consultation with interested parties, particularly

with the public, is an essential part of the legal structure and is also exercised by the regulatory body, as stated in Requirement 36 of GSR Part 1 (Rev.1) [2].

A major focus of regulatory oversight during the licensing process is on the review and assessment of the safety documentation submitted by the licensee to ensure that it complies with regulatory requirements. The regulatory body also conducts inspections to verify the reality of what is described in the licence application. Both the review and assessment process and the inspection process are conducted in accordance with a graded approach, taking into account the radiation risks associated with the relevant activities. GSG-13 [5] provides guidance on regulatory review and assessment topics and on inspection areas in appendices III and IV, respectively.

To provide clarity and transparency in the licensing process, the regulatory body develops regulations for the licensing process of NPPs and provides detailed guidelines for applicants (see Section 3.2). These have to be published at an early enough stage so that applicants/licensees can determine what is required when applying for a licence.

The regulatory body is empowered to include conditions in the licence that are appropriate to the licensing step. GSR Part 1 (Rev. 1) [2] states:

> "**Requirement 23: Authorization of facilities and activities by the regulatory body**
>
> "**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.**"

General aspects of licence conditions are expanded on in Section 3.1.3, and specific aspects for construction, commissioning and operational licences are discussed in the appropriate sections for these stages of the lifetime of an NPP. Throughout the licensing process, it is the responsibility of the regulatory body to ensure that the licensee is in full compliance with these conditions and has made appropriate arrangements to carry out all assigned responsibilities.

The regulatory body does not usually regulate licensees' contractors directly but ensures that licensees properly fulfil their responsibilities for oversight of their suppliers. The regulatory body may review, assess and inspect the review, audit and certification processes being conducted by licensees on their suppliers, contractors and subcontractors. Where the regulatory body does play a role in overseeing manufacturers, it may also directly grant certificates or licences to those suppliers and contractors, in accordance with the national regulatory framework.

The regulatory body may inspect and/or assess the work of contractors; in this case, the regulatory body has to contact them through the licensee. This may be an issue with non-domestic contractors. Where necessary and appropriate, it is important for the regulatory body and the licensee to make arrangements to visit international contractors. The regulator may also cooperate and share information with other national regulators who have a common interest in the supplier.

As the lifetime of the NPP project will exceed the working lifetimes of individuals, the regulatory body has to ensure that resource plans take into consideration long term needs and staff turnover rates.

2.5. PRIMARY RESPONSIBILITIES OF THE APPLICANT/LICENSEE

SF-1 [1] states:

"**Principle 1: Responsibility for safety**

"**The prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give rise to radiation risks.**"

Compliance with regulations and requirements imposed by the regulatory body does not relieve the licensee from the prime responsibility for safety. It is the responsibility of the licensee to demonstrate to the satisfaction of the regulatory body that this prime responsibility has been, and will continue to be, fulfilled.

The licensee and all the licensee's staff are required to comply with the terms of the licence, including all licence conditions and agreed codes and standards. All work done in relation to the NPP is also to be undertaken in compliance with any relevant national requirements and international legal instruments (treaties and conventions) that are effective in the Member State. In addition to the licence and any attached conditions, in almost all Member States requirements are set out in legal and regulatory documents. Throughout the lifetime of the NPP, the licensee may employ other organizations as contractors to carry out specific activities. The licensee is responsible for exercising control over the work of contractors and subcontractors, if any, and ensuring that they understand the

safety significance of this work and take responsibility for its implementation (intelligent customer capability[1]).

The applicant/licensee has to meet all obligations set out in paras 2.38 and 2.39 of SSG-12 [3]. These include the preparation, review and submission of an application for the activities in the specific stage of the lifetime of the NPP to the regulatory body, demonstrating that it will meet all legally binding safety requirements and standards. Applicants/licensees are required to have adequate financial resources to fulfil their obligations for safety throughout the lifetime of the NPP.

In addition, the applicant/licensee is obliged to have sufficient human resources within the applicant's/licensee's own organization (either on-site or within the organization as a whole) to safely manage the construction, operation, maintenance and decommissioning of the NPP and any contractors involved. There has to be a well structured and organized transition of staffing and competency, where appropriate, when moving from one stage of the lifetime of the NPP to the next. This may be particularly important in the move from construction to commissioning as SSCs are handed over to the operating staff of the licensee.

Another main obligation for the applicant/licensee is to establish, implement and maintain an integrated management system (IMS) fostering safety culture [18]. The IMS includes provisions for ensuring the continuing safety of the plant design, including the means for identifying and correcting design deficiencies, checking the adequacy of the design and controlling and recording design modifications. GSR Part 2 establishes requirements to be complied with by the licensee and the licensee's suppliers and subcontractors in relation to establishing, sustaining and continuously improving leadership and management for safety, as well as an effective management system.

The applicant/licensee is obliged to establish and implement a plant configuration management system in order to ensure consistency among the design requirements, physical configuration and plant documentation. This system aims to ensure that modifications made to the NPP and its safety related systems are properly identified, screened, designed, evaluated, qualified, tested, implemented and recorded. The procedures for the control of modifications are the same during the construction, commissioning and operation stages. Additional guidance is provided in IAEA Safety Standards Series No. NS-G-2.3, Modifications to Nuclear Power Plants [20].

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[1] Intelligent customer capability is the capability of the organization to have a clear understanding and knowledge of the product or service being supplied. The intelligent customer concept relates mainly to a capability required of organizations when using contractors or external expert support [4].

Before each licensing step, the applicant/licensee is responsible for developing and submitting documents that adequately demonstrate the safety of the NPP. The documents are required to have a scope and level of detail sufficient to support the conclusions reached and demonstrate this to the regulatory body when making a submission for authorization.

In accordance with Requirement 21 of GSR Part 4 [15], the SAR is either developed by the applicant/licensee or by a third party (e.g. by the NPP vendor) and is subject to independent verification either by the applicant/licensee or by another qualified organization acting on the applicant's/licensee's behalf. Irrespective of the process followed for the development and verification of the SAR, the licensee remains responsible for its content, comprehensiveness and quality, in accordance with Principle 1 of SF-1 [1]. Paragraph 4.71 of GSR Part 4 (Rev. 1) [15] states (footnote omitted):

> "In addition, the regulatory body shall carry out a separate independent verification to satisfy itself that the safety assessment is acceptable and to determine whether it provides an adequate demonstration of whether the legal and regulatory requirements are being met. The verification by the regulatory body is not part of the operating organization's process and it is not to be used or claimed by the operating organization as part of its independent verification."

3. STRUCTURE OF THE LICENSING PROCESS

3.1. GENERAL CONSIDERATIONS RELATED TO THE LICENSING PROCESS

3.1.1. Granting a licence

GSR Part 1 (Rev. 1) [2] states:

"**Requirement 24: Demonstration of safety for the authorization of facilities and activities**

"**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.**"

Therefore, when requesting a licence, the applicant is required to submit appropriate documentation to the regulatory body that demonstrates that the NPP will be designed, constructed, commissioned, operated, shut down and decommissioned, as appropriate, with an adequate level of safety.

Paragraph 4.34 of GSR Part 1 (Rev. 1) [2] states:

> "The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization. The applicant shall be required to submit or to make available to the regulatory body, in accordance with agreed timelines, all necessary safety related information as specified in advance or as requested in the authorization process."

The level of detail to be contained in those documents mainly depends on the regulatory approach being followed by the regulatory body. The regulatory body may also require additional information.

Paragraph 1.2 of SSG-61 [16] states:

> "The information to be submitted by the applicant should be presented mainly in the form of a report, hereinafter referred to as the 'safety analysis report'. Further requirements on the documentation of the safety assessment for a facility in the form of a safety analysis report; on the objectives, scope and level of detail of this report; and on updating the safety analysis report are established in Requirement 20 of…GSR Part 4 (Rev. 1)".

Further guidance regarding the content of the SAR is provided in para. 2.1 of SSG-61 [16]:

> "The safety analysis report, compiled either as a single document or as an integrated set of documents that collectively constitute the licensing basis of the plant, should provide an adequate demonstration that the nuclear power plant meets all applicable safety requirements."

The applicant progressively develops the SAR for successive licensing steps of the NPP as more information becomes available. Therefore, later versions of the SAR contain updated and/or more detailed information on the subjects outlined in the previous version(s). Consequently, it is expected that the same structure of the SAR will be maintained, as far as possible and appropriate, throughout its development process from construction up to the end of operation of the NPP.

Paragraph 2.24 of SSG-61 [16] states:

> "The information contained in the safety analysis report should be self-contained to a reasonable extent. Any important supporting material should be referenced in the safety analysis report. These supporting materials serve to enhance the review process and the subsequent usability of the safety analysis report, and should be easily accessible to the regulatory body, which will use the information for its review and assessment process."

Use of external references in the SAR is inevitable (e.g. detailed design documents, references to standards, detailed analysis reports, code validation reports, source material for probabilistic safety assessment). All external references are usually not required to be submitted to the regulatory body with the SAR, but they should be made available on request.

Paragraph 2.3 of SSG-61 [16] states:

> "While it might not be feasible to present all the relevant information in the safety analysis report itself, the information should be presented in such a way that the regulatory body can conduct the review and assessment process with only a limited need for additional documentation."

Licences are granted only to organizations that have adequate resources, both human and financial, and a management structure that comprehensively covers all aspects of the protection of workers, the public and the environment relevant to the particular stage of the lifetime of the NPP. The licensee is required to submit appropriate documentation covering all aspects of safety relevant to the particular stage of the lifetime of the NPP for which authorization is required. This documentation is subjected to regulatory review and assessment in conjunction with appropriate inspection of the licensee's premises, the site and the plant.

Regulatory review and assessment and regulatory inspection are expected to mainly cover the following three basic safety management aspects:

(a) Plant (including the site);
(b) Process or procedure;
(c) People.

Nuclear accidents, as all industrial accidents, have root causes that can be traced back to one or another of these safety management aspects. The documentation submitted by the licensee sets out the licensee's intentions. The regulatory review and assessment then determines if this appears to be adequate,

and the inspection checks whether what is meant to be in place is in fact in place and that the results of implementation meet the expected regulatory requirements.

In essence, the licensing process is simple. A submission is made by an applicant/licensee to the regulatory body for the relevant licence, which is supported by the necessary documentation. Once it is confirmed that the documentation is complete, it is subjected to review, assessment and verification on the NPP site. If the documentation demonstrates that the safety level is acceptable, which may require posing queries to the licensee to obtain further information, then the licence is granted. Appendix I gives an outline flow chart illustrating the typical process of granting a licence.

3.1.2. Content of a licence

The content of a licence document highly depends on the Member State's legal and regulatory system. Typical content of a licence is given in Appendix II [3].

3.1.3. Licence conditions

Licence conditions set out specific and generic safety requirements that the licensee must comply with. Guidance on the formulation of licence conditions is given in paras 3.112–3.114 of GSG-13 [5] and paras 2.14–2.17 of SSG-12 [3]. Appendix II of GSG-13 [5] provides detailed guidance on the licence conditions relevant to each stage in the lifetime of an NPP.

Accordingly, each licence issued by the regulatory body typically states the requirements determined by the regulatory body as conditions for granting the licence. Since the licence is the legal instrument that authorizes the licensee to conduct a specified activity, licence conditions also become legally binding requirements. Licence conditions thus supplement the regulations that apply to all licensees and/or add safety requirements specific to the circumstances of each licensee. The regulatory body, in formulating licence conditions, maintains consistency between the licence conditions and other regulations of general application.

The regulatory body may include any condition in the licence that it considers necessary for ensuring safety. Without restricting the generality of that statement, licence conditions usually fall into one of the following categories, as indicated in para. 3.114 of GSG-13 [5] and para. 2.16 of SSG-12 [3]:

(a) Conditions that set technical limits and thresholds;
(b) Conditions that specify procedures and modes of operation;
(c) Conditions pertaining to administrative matters;

(d) Conditions relating to inspection and enforcement;
(e) Conditions pertaining to the response to abnormal conditions.

Conditions that commonly appear in examples of NPP licences issued in different Member States include the following:

— A requirement for the licensee to conduct the authorized activity in accordance with the licensing basis (i.e. the relevant laws and regulations) and the licence application documents;
— A requirement for the establishment of a mechanism to control modifications (temporary or permanent), including obtaining prior approval from the regulatory body for modifications significant to safety;
— Reporting requirements, including periodic information reports and reports of events significant to safety and security, which the licensee is required to provide to the regulatory body;
— Hold points at which the licensee is required to obtain further authorization from the regulatory body to proceed with its activities.

The details of the content of licence conditions depend on the form of regulatory approach that the regulatory body employs.

Some licence conditions may be specific to the facility or to the activities that are authorized or may involve an issue that the licensee is required to resolve within a defined time period after the authorization is issued. The regulatory body needs to follow up on the licensee's activities regarding such licence conditions. These conditions may require revision of, or removal from, the licence conditions after the requirements are met by the licensee to the satisfaction of the regulatory body within the given time frame.

Some Member States have issued regulations that provide technical rules covering the construction, commissioning and operation of NPPs and that apply generally to all licensees. In some States, the regulations contain standard licence conditions. In such cases, a licence need only refer to the applicable regulations.

For example, the United States Nuclear Regulatory Commission (USNRC) has established detailed regulations and regulatory guides for NPPs, which are published in the Code of Federal Regulations. Licences issued by the USNRC typically include conditions that require compliance with the relevant laws and regulations, including the standard licence conditions, and additional conditions specific to the circumstances of the licensee. The operating licence granted to Watts Bar NPP Unit 2 is one such example [21].

In contrast, other Member States have chosen not to publish prescriptive regulations for the conduct of licensed activities. These States employ licence

conditions to set out the overall requirements with which the licensee is required to comply.

For example, in Canada, the regulations issued by the Canadian Nuclear Safety Commission (CNSC) for NPPs establish requirements for licence applications, but they do not otherwise set out comprehensive rules for the safe conduct of NPP construction, commissioning and operation [22]. In its licences for NPPs, the CNSC includes conditions that specify the rules and standards that the licensee is required to follow for safety, security and safeguards. The CNSC licence conditions are supplemented by a licence condition handbook, which elaborates on the requirements and provides compliance criteria and guidance for both the licensee and the regulatory staff.[2]

As a further example, the United Kingdom's Office for Nuclear Regulation (ONR) issues a single site licence that applies to the entire lifetime of a licensed nuclear site. In total, 36 standard licence conditions are attached to all site licences and provide the main basis for regulation by the ONR [23]. The licence conditions are generally non-prescriptive and set goals that the licensee is responsible for meeting. Most licence conditions require the licensee to make arrangements for, among other things, meeting the relevant safety standards and safe procedures at each stage in the lifetime of the facility [24].

Changes to licence conditions are not straightforward, as they are part of the licence and have to be consistent with the legal system. Care has to be taken in formulating them so that changes, if any, are not required frequently.

3.1.4. Regulatory hold points and witness points

In each stage of the lifetime of an NPP, there may be several 'hold points' or 'witness points' set by the regulatory body. These enable the regulatory body to ensure that the risks arising from the operation of the NPP and other relevant activities to workers, the public and the environment are being properly controlled by the licensee. To ensure that work is proceeding without risk to the licensee's organization from an engineering or financial perspective, licensees may set their own 'hold points' and 'witness points', which the regulatory body may also decide to include in its oversight activity on the basis of their safety significance.

Paragraph 3.1 of SSG-12 [3] states that: "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."

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[2] A copy of the Darlington Nuclear Generating Station licence and licence condition handbook is available to the public on request from the CNSC. See https://nuclearsafety.gc.ca/eng/reactors/power-plants/nuclear-facilities/darlington-nuclear-generating-station/index.cfm

Hold points and witness points specified by the regulatory body are communicated to the licensee as early as possible to allow them to be taken into account in planning and scheduling activities [7, 8]. These points may also be defined in the licence conditions. Regulatory hold points and witness points could be defined at the plant, process and system level, as well as the structural and equipment level.

A hold point is a regulatory tool to check the result of an activity — for example, during construction or commissioning — before progressing to the next stage. Hold points are used especially when subsequent activities are irreversible and/or make verification difficult. Hold points require some form of authorization or approval from the licensee's own organization and/or from the regulatory body before subsequent activities can commence.

If non-conformances significant to safety are identified, the regulatory body may require the licensee to establish an action plan to correct deficiencies. This may be defined as a further hold point, with progress requiring adequate implementation of the action plan agreed with the regulatory body.

From the point of view of licensees, the hold points that they establish allow them to ensure that the activities are proceeding as expected. When construction or commissioning activities are conducted by contractors, licensees make the necessary arrangements to review and approve these activities at all stages and may establish their own appropriate hold points and milestones [7, 8].

Witness points are activities that the regulatory body wants to observe to verify that they are being carried out correctly and safely but that do not require regulatory authorization or approval before moving to the next activity. However, they may lead to a requirement to stop activities if they are carried out in an unsatisfactory manner. A typical example of a witness point is an emergency exercise.

Generally, hold points and witness points at the plant, process and system level are defined in regulations or licence conditions. These hold points and witness points typically include the following activities:

(a) Start of the first nuclear concreting;
(b) Pressure tests of the primary circuit and the containment system;
(c) Functional test of the safety system and at plant level;
(d) Fuel loading;
(e) First criticality;
(f) Stepwise increase of reactor power.

Hold points and witness points at the structural and equipment level are usually described in the appropriate regulatory guides, technical directives and industrial codes and standards. Such hold points and witness points are usually

presented in the quality control plan and/or the construction plan for each major component or structure. The licensee and the regulatory body set these hold points and witness points when reviewing and approving the relevant quality control plan and/or construction plan. In some Member States, the regulatory body delegates part of the inspection and verification of hold points and witness points to recognized inspection organizations (or recognized persons).

The regulatory body usually follows the manufacturing process, including inspection points of the manufacturer with relevant links to quality documentation, and uses this information to determine hold points and witness points. Annex II provides an example of the principles applied to safety class 1 pressure piping. The quality documentation of manufacturing companies is usually their intellectual property; however, if relevant and necessary, it is made available to the regulatory body upon request.

The licensee invites the regulatory body or the inspection organization to the manufacturing site when each hold point or witness point is ready for inspection. The licensee, vendor and manufacturer conduct their own oversight beforehand to ensure that prerequisites for an acceptable regulatory inspection are met.

The purpose of the regulatory inspection at the hold points and witness points is to verify that components are manufactured in accordance with the specifications of the construction plan and that all necessary inspections, examinations and tests, as specified in the quality control plan and construction plan, are successfully completed.

The commissioning programme includes a list and a description of the commissioning tests. The regulatory body determines its hold points and witness points from the information provided in the commissioning programme and communicates these points to the applicant. Each individual test has associated test plans and clearly defined test criteria.

Some additional information and guidance regarding hold points and witness points are available in SSG-38 [7] and SSG-28 [8].

3.2. RELEVANT REGULATIONS AND GUIDES TO BE DEVELOPED BY THE REGULATORY BODY

Depending on the legal system of the Member State and the scope of the facilities and activities, States need to develop mandatory regulations to lay out the requirements and related acceptance criteria to ensure the protection of people and the environment, focusing on continuous enhancement of safety.

Provisions of the regulations are expected to reflect, in an unambiguous manner, the safety goals and objectives of the State and to adequately address State specific issues, particularly siting related ones. Regulatory bodies may

implement a plan for developing these regulations in a timely manner, depending on the phase of development of the nuclear power programme and taking into account the legal system of the State, if appropriate.

A system of advisory safety guides may be established by the regulatory body, with the overall purpose to advise authorized parties on how to comply with laws and regulations, how to interpret and implement the regulatory requirements to ensure safety and how to demonstrate the safety of facilities and activities to the regulatory body. Guides provide detailed and specific information on acceptable technical and administrative approaches to satisfying the requirements established in the regulations. The guides may provide additional knowledge to authorized parties to demonstrate the achieved level of safety to the regulatory body.

The regulations describing the licensing process for NPPs are expected to be consistent with the legislative requirements of the State and usually address the following, as appropriate:

(a) A mechanism for organizations that are planning to build an NPP to make their intentions known to the relevant national authority as early as possible. This mechanism may also include demonstration of the competence and capability of the applicant at an initial stage to ensure that the applicant will be able to manage the later phases of the project. This may include an assessment of the applicant's financial capability and an evaluation of the applicant's staffing, including recruitment and training plans for various phases of the plant.
(b) Responsibilities assigned to the licensee for the safety of the licensed facilities and activities and the protection of workers, the public and the environment; compliance with regulations and licence conditions; and compliance with the documents approved by the regulatory body during the licensing process.
(c) Requirements for obtaining authorizations from other relevant governmental agencies and organizations as required under the legislative system of the State.
(d) Licensing steps, substeps and regulatory hold points.
(e) Identification of documents and information that are to be submitted during various licensing steps, along with the appropriate time for their submission.
(f) Provisions for generic terms and conditions of a licence.
(g) Provisions for granting, amending, modifying, suspending and revoking a licence.
(h) Validity period of a licence, if appropriate.
(i) Provisions and process for renewal and revalidation of a licence, as appropriate.

(j) Provisions for dispute resolution, if not already described in another legislation or regulation.
(k) Provisions for licensing fee and charges, if any.

The regulatory body develops internal guidance documents to standardize the licensing process, addressing activities such as the receipt, acceptance, review and assessment of applications; regulatory inspections to be conducted during the licensing; interactions with the applicant on matters related to the licensing; and reporting of the outcome of the review and assessment and the inspection. Publication of such guidance, which will usually be documented in the regulatory body's IMS, is also necessary for establishing and maintaining a reliable, predictable and consistent licensing process within the State and for building confidence with the public and other interested parties.

Additional guidance to the applicant may be provided regarding issues that determine the quality of the application. Such guidance may address issues such as the acceptability of electronic applications; the required number of copies of the submitted document; acceptable document languages; document quality issues, such as fonts and page numbers; authentication of documents; and means of inserting amendments to the submitted documents.

The regulatory body may establish dedicated secure IT channels for submitting licence applications and relevant licensing documentation. In this case, the regulatory body will issue guidance to the applicant on electronic submissions. Internally, the regulatory body may also establish electronic document handling systems, including an electronic workflow management system[3], for effective regulatory review and assessment. The necessary restrictions and control over the submitted licensing information are also defined and applied by the regulatory body. The regulatory workflow management system could be supported with a regulatory requirements management tool[4]. Also, common information servers and virtual reading rooms may be utilized to share additional information between the applicant and the regulatory body to support the official licensing submittals.

In addition to granting a licence for an NPP, the legislative and regulatory framework may also require granting authorization to specific personnel of NPPs, such as operating personnel or certain management personnel.

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[3] The workflow management system provides an infrastructure for the set-up, performance and monitoring of a defined sequence of tasks and can be arranged as an electronic workflow application.

[4] Regulatory requirements management is the process of documenting, analysing, tracing, prioritizing and agreeing on requirements, and then controlling changes and communicating with relevant interested parties. A regulatory requirements management tool helps to allocate regulatory requirements to each licensing application during regulatory review and assessment and facilitates traceability.

3.3. ALTERNATIVE REGULATORY PROCESSES

The licensing of NPPs typically involves several distinct steps, as described in SSG-12 [3] and in this publication. This process is especially important for States that are planning to construct their first NPP. In this publication, it is assumed that a series of licences are applied for and granted at each major stage of the lifetime of an NPP, as shown in Fig. 1. It is also assumed that the approval granted by the regulatory body at each stage is defined as a separate licensing step. However, there are alternative approaches, especially in States that have considerable experience in nuclear power over a long time and where several types of nuclear installation have already been built and operated (see Annex I).

The licensing process followed varies among States. Each step of the licensing process may be divided into several substeps or may be merged or combined as appropriate to facilitate the regulatory process. For example, in some States the regulatory body issues combined authorizations for construction and operation, whereas other States issue separate authorizations for siting, construction and operation. Some States, such as the United States of America and the United Kingdom, provide early approval of sites and certification of standardized plant designs in advance. Then, the applicant may apply for a licence referencing the early site permit and the certified standard design in its application. Depending on the national legislative regime, safety and environmental issues can be resolved before the site licence or design licence is granted, and the resolution of such issues can be considered final.

The elements of such an alternative licensing process may include the following steps, as explained in para. 3.2 of SSG-12 [3]:

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

(b) Certified standard designs. In such a licensing process, any qualified company may obtain certification of a standardized design for a nuclear installation, notwithstanding the fact that the application for a licence for construction and operation with the certified design has not been filed. The regulations should allow for approval to be granted for an essentially complete standard design for an entire nuclear installation [on a generic site, i.e. one that encompasses most of the site characteristics of potential sites in the State]. The regulations should require that the application for certification of a standardized design contain sufficient information to enable a final conclusion to be reached on all safety questions associated

with the design. Such a certification of a standardized design could help to ensure that two nuclear installations of the same design would not vary significantly from each other, except for variations required due to site requirements.

(c) Combined licence. In such a licensing process, an applicant can apply for a single licence to construct, commission and operate a nuclear installation. If the licence is issued, and if the installation is constructed in accordance with the requirements set forth in the licence, the regulatory body should then allow the plant to begin operation".

Some regulatory bodies issue licences that combine the authorizations for one or two stages in the lifetime of an NPP (Fig. 1). This approach can result in useful simplification of the licensing process for both the regulatory body and the licensee while retaining the advantages of the step by step approach. For instance, the construction licences issued by several regulatory bodies cover approval of the selected site, authorization of construction and pre-operational testing of the systems, structures and components of the NPP. An operating licence may authorize fresh fuel storage and handling, fuel loading and nuclear commissioning as preliminary activities before the commencement of full operation. Annex I shows examples of the licensing steps and submission requirements in several States.

In addition to the steps covered in SSG-12, there is a fourth step, as follows:

(d) Lifetime licence. In the case of a licensing process for a lifetime licence, the licence is granted to a suitable licensee for the operation of a specified NPP on a specified site on the basis of an SAR that supports the view that the NPP can be operated in a manner that meets regulatory requirements. Subsequent stages of the lifetime of the NPP require the licensee to obtain permissions from the regulatory body and require regular periodic safety reviews. In this approach, licence conditions are sufficient to cover the whole lifetime of the NPP and are not changed in the various stages. A variant of this approach is a licence that allows a long period of operation but requires a process for licence extension beyond the original licence validity period.

The combination of different stages into a single licence step requires a judicious approach, as it puts considerable pressure on the regulatory body to maintain control over all the licensee's activities.

4. BASELINE ASSUMPTIONS FOR CONSTRUCTION LICENCE APPLICATION

Several aspects, as set out in this section, are expected to be in place before a construction licence is applied for. However, this does not mean that interaction between the regulatory body and the applicant/licensee does not occur; nor does it mean that certain activities by the applicant/licensee cannot be approved and carried out during this time. It is important that the regulatory body clearly defines those activities that can be carried out before a construction licence is granted (e.g. detailed site investigations, ground clearing, flattening, excavation), as well as those activities that cannot be undertaken until the construction licence is granted (e.g. pouring nuclear safety concrete for foundations, starting manufacture of items important to safety).

This publication assumes that the completion of the formal EIA process and the site authorization (approval, permit or licence) process is a prerequisite for applying for a construction licence. Therefore, before the construction licence is applied for, it is expected that both processes have been successfully completed and all site related parameters given in the site evaluation report have been approved or accepted by the regulatory body as appropriate and then incorporated into the NPP design.

Additionally, there are programmes for radiological environmental monitoring and site parameter monitoring approved by the regulatory body as appropriate, subject to updates when necessary, that will be implemented at the pre-operational and operational stages of the NPP. Moreover, natural and human induced external hazards and site conditions, including possible changes in the conditions and assumptions used in the radiological EIA, will be reviewed at regular intervals as part of periodic safety reviews throughout the lifetime of the NPP using updated information mainly based on the outcomes of these two programmes. Detailed guidance and recommendations on the radiological EIA, site evaluation and relevant monitoring programmes mentioned above are provided in Refs [11, 25–37].

4.1. CHARACTERISTICS OF THE APPLICANT/LICENSEE

Depending on national laws, an organization that wishes to become a licensee needs to encompass certain characteristics, which are expected to be clearly defined in the national legislation and/or regulations. An early assessment of the capabilities of the applicant/licensee, to be carried out before the construction licence application, will prevent difficulties that may arise later if the

regulatory body is not satisfied with the existing organization at this stage. The following is a digest of the information presented in GSG-13 [5] in relation to the characteristics that are recommended to be maintained by the licensee through all subsequent stages of the lifetime of the NPP, until the facility is released from regulatory control by the regulatory body.

The national regulations require that the licensee maintains a sufficient number of qualified personnel to perform the licensee's activities, through recruitment, initial training, refresher training and succession planning, to ensure safety through all stages of the lifetime of the NPP until the release of the facility from regulatory control.

It is important that the licensee has a good, well documented IMS that fosters a strong safety culture [2, 18]. A strong safety culture is needed both at an individual and at an organizational level for the licensee, the licensee's contractors and subcontractors, and it is necessary to ensure that all contractors have been made aware of the need for an appropriate safety culture. Safety culture is subject to continual review and audit, and licensees have to put in place the necessary arrangements to audit and review their own safety culture and that of all their contractors. GSR Part 2 [18] sets out requirements in relation to establishing, sustaining and continuously improving leadership and management for safety and an effective management system fostering a strong safety culture in an organization, particularly in the licensee's organization.

Since the licensee is responsible for overseeing, auditing and (where appropriate) certifying suppliers and contractors with functions relating to safety, the licensee needs to be an 'intelligent customer'. To fulfil this responsibility, the licensee needs to employ sufficient suitable technically knowledgeable persons or organizations capable of fulfilling these functions in specific areas. The licensee is also responsible for providing and maintaining the financial resources necessary to fulfil obligations with respect to the safety of the NPP throughout its lifetime, including decommissioning and the management of spent fuel and radioactive waste.

4.2. CHOICE OF DESIGN BY THE APPLICANT/LICENSEE

At an early stage in a nuclear power programme, a decision is made about the design of the NPP to be built. The government may set out requirements related to the choice of design, and the regulatory body may also set out safety requirements that the design is required to comply with. Paragraphs 2.8, 2.31, 2.170, 2.283, 3.1, 3.8, 3.13, 3.22, 3.41, 3.47, 3.61–3.64, 3.67–3.72 and 3.75 of SSG-16 (Rev. 1) [9] set out the possible factors that need to be considered in more detail.

The design that is used to make the initial decision about the type of NPP to be built may be a 'conceptual' one, such as a pressurized water reactor with a specified thermal power. This will establish the requirements for the ultimate heat sink and the environmental effects on this sink.

Although the licensee/applicant will have chosen the design of a specific vendor's or designer's NPP, this will need to be reviewed in light of the site chosen and the State's specific requirements on the basis of national regulations. Discussion with the regulatory body will allow certain important aspects to be agreed upon before the application for a construction licence (see Section 2.1).

Before the construction licence is applied for, the NPP design is developed to a sufficient level of detail to demonstrate that the NPP will be able to operate at an adequate safety level at the proposed site in accordance with national safety requirements. The vendor, the designer or the applicant, as appropriate, may have already engaged with the regulatory body and agreed that the design concept is not unacceptable in terms of high level safety requirements. In some States, there is a pre-licensing step before a specific site is approved, and the regulatory body approves a 'generic design' based on the characteristics of a 'generic site'. This step may involve engagement between the regulatory body and the designer/vendor; it may also involve an organization that may decide to use this design in the future (see Section 3.3).

4.3. LOCAL ARRANGEMENTS

The nuclear regulatory body generally does not approve local issues such as visual amenity, access roads, accommodation for workers or utility requirements. Before a construction licence is granted, these local arrangements will be agreed upon between the applicant/licensee and the relevant national or local authorities. If some types of authorization are required from other authorities, the applicant/licensee needs to apply and obtain them in due time. In some States, the construction licence application to the nuclear regulatory body is submitted only after obtaining all the relevant authorizations from other authorities.

Detailed information and guidance regarding prerequisites for a safe and smooth construction stage are provided in SSG-38 [7].

4.4. DEVELOPMENT OF DESIGN INFORMATION

Some details of the design may not have been finalized when application is made for the construction licence. For example, details regarding the radiation protection system, the precise instrumentation, and so on may not have been

finalized, or the suppliers of some equipment may not have been chosen yet. However, the licensee/applicant needs to have a sufficient level of detailed design information in critical areas of the NPP to demonstrate that when operated, the NPP will comply with safety requirements. Information on all safety significant SSCs is necessary, and unresolved design issues that could lead to major plant or operational modifications during or after construction need to be avoided. In this context, 'significant' and 'major' mean that the safety justification will not fundamentally change. Therefore, review and assessment of outstanding design issues will continue throughout the construction process after the award of the construction licence. Before construction begins, the licensee sets up a configuration management programme for updating the design basis of the NPP while ensuring compliance with the original agreed or approved design basis.

Paragraph 2.10 of SSG-38 [7] states:

> "A design schedule, including verification of acceptance criteria and engineering work, commensurate with the authorization process, should be drawn up by the design organization and should be verified by the licensee prior to the start of construction, so that late procurement will not adversely affect the construction process. Before construction starts, a review of readiness should be carried out by the licensee or its construction organization to verify that the design is sufficiently complete and that all engineering documents are available, and to identify any areas where the design is incomplete. The design organization should develop an action plan covering any remaining design and engineering work, and the necessary resource requirements should be agreed with the licensee and monitored by the licensee as construction proceeds."

The design organization has specific responsibility for the preparation of the detailed design of the NPP to be built.

4.5. LONG LEAD ITEMS

The manufacturing process of some major structural items takes several years. These are known as long lead items, and their manufacturing needs to begin before the construction licence is granted, if undue delay is to be avoided. For this purpose, the licensee/applicant usually requests authorization or approval from the regulatory body to begin this manufacturing prior to applying for, or obtaining, the construction licence. Such an authorization or approval results in allowing regulatory control during the manufacture of these items by the regulatory body before the construction licence is granted.

To apply for this authorization or approval from the regulatory body, the licensee/applicant will provide information on the design basis and detailed design of the item, together with information on its manufacturing and assembly. This application needs to describe the item's role regarding safety within the overall safety case for the NPP. The regulatory body is responsible for carrying out review and assessment of the submitted information and, if approval for manufacturing is granted, carrying out inspections at the manufacturing site during the manufacturing process, in conjunction with the licensee/applicant. Such inspections are part of the regulatory body's oversight, which are in addition to, and independent of, the licensee's control and supervision of the manufacturing process.

No work related to structures affecting nuclear safety, other than that authorized by the regulatory body, is to be undertaken at the NPP site before the construction licence has been granted.

Furthermore, in some jurisdictions, the regulatory body may require the applicant/licensee to use only authorized manufacturers. In such a case, the regulatory body establishes the necessary process for the authorization of manufacturers even before the applicant/licensee initiates the procurement of these items, to prevent unnecessary delay.

5. REGULATORY PROCESS FOR LICENSING STEPS OF CONSTRUCTION, COMMISSIONING AND OPERATION

5.1. CONSTRUCTION

The IAEA Safety Glossary [10] defines the term 'construction' as: "The *process* of manufacturing and assembling the *components* of a *facility*, the carrying out of civil works, the installation of *components* and equipment, and the performance of associated tests".

Paragraph 1.4 of SSG-38 [7] states:

> "It is recognized that even if the design and commissioning are fully compliant with all safety requirements, a high level of safety can only be achieved when the construction is carried out with high quality and care, since commissioning cannot test all aspects of the design. Therefore, all

construction activities have a potential impact on safety, even though there may be no nuclear material present during the construction."

Construction of civil structures, including manufacturing, installation and post-installation commissioning, is important, as it is the first physical action(s) in developing an NPP (other than the long lead items discussed in Section 4.5). It is, therefore, the first opportunity for the applicant/licensee to demonstrate control and supervision of activities that have the potential to affect the safety of workers and the public. Once civil structures are erected and parts are made and installed, it is significantly more difficult to make any major changes.

Likewise, the regulatory body is able to apply its powers of review and assessment and of inspection to an actual plant, rather than to paper studies. Well in advance of the start of construction, the regulatory body will schedule allocation of its resources to ensure effective regulatory oversight in accordance with the schedule of the construction activities.

It is vitally important to check the actual situation on the site of the plant, and the best persons to do this are the regulatory body staff who have specific expertise and have reviewed and assessed the documentation submitted with the licence application (see Section 5.1.1). It is essential that these regulatory body staff visit the site, as the inspector on-site is unlikely to be experienced in a wide range of activities.

The granting of a construction licence is a major step and is the beginning of the process towards developing an NPP that is safe to operate and, eventually, be decommissioned. The design information submitted and reviewed for the construction licence is frozen; any subsequent additions or modifications are subject to a control process (see Section 5.1.5). It may be that certain SSCs and buildings, such as instrumentation and control (I&C) systems and facilities for spent fuel management, have not been designed in detail. At this stage, the licensee also has to take account of any security or safeguards requirements. Paragraph 2.1 of SSG-38 [7] states:

"Owing to differences in the construction schedule for each item, the commissioning and construction stages for the installation may take place concurrently. Hence, it is difficult to define a precise 'end of construction', but the licensee should ensure that items have been installed, inspected and tested and should obtain an authorization from the regulatory body before carrying out significant steps in the commissioning process".

For both the licensee and the regulatory body, further recommendations and guidance based on international good practices during the construction stage of an NPP are provided in SSG-38 [7].

5.1.1. Documents and information to be submitted by the applicant/licensee for authorization of construction

For a construction licence, the key parts of the application to be submitted by the applicant are the SAR and other supporting documents establishing that the NPP can be constructed, commissioned, operated and decommissioned safely and is fulfilling all applicable safety requirements. SSG-61 [16] provides detailed guidance on the format and content of the SAR (see Appendix III).

Additional guidance supporting the implementation of the relevant IAEA safety requirements regarding the licensing of the construction stage is contained in para. 3.128 of GSG-13 [5], in paras 3.36–3.43 of SSG-12 [3] and in SSG-61 [16]. Salient points from this guidance are discussed further below.

In many States, the regulatory body requires the applicant to submit the following documents or information when applying for a construction licence:

(a) The SAR, which contains the basis for authorization of construction.
(b) The description of the IMS of the applicant/licensee for the construction stage. At this stage, in particular, oversight of the procurement and supply chain will be described.
(c) A plan for the construction, including phases, anticipated schedule, construction manuals and instructions.
(d) Preliminary information regarding organizational and financial arrangements for decommissioning and for the management of radioactive waste and spent fuel.

Member States' experience has shown that it is better not to specify any time period for granting a construction licence in the regulations, because this time period depends on the quality and completeness of the information and the response of the applicant to queries from the regulatory body. An indicative time frame presented in figure 2 of SSG-16 (Rev. 1) [9] suggests a minimum of a year and a half from submission to the granting of a construction licence.

The information and documentation that needs to be submitted to the regulatory body by the applicant/licensee and the level of detail to be contained in those documents mainly depend on the regulatory approach being followed by the regulatory body. The regulatory body may also request additional information to that which has already been submitted.

5.1.2. Review and assessment and inspection for authorization of construction by the regulatory body

Once the formal submission of an application for a construction licence is made, the regulatory body's formal review and assessment and inspection can begin. These regulatory functions are not confined to the physical site and NPP, but also include the licensee's off-site activities, such as preparing procurement documentation and safety analysis. The regulatory body will also apply oversight to the contractors, if applicable, used to carry out these activities. The regulatory body may request further information that it needs to complete all aspects of its work.

The review and assessment of the information provided in the licence application documents, particularly in the SAR, is a significant task for the regulatory body. This work needs to be carried out in accordance with clearly specified procedures and requires appropriate planning, organization and resources. GSG-13 [5] and SSG-12 [3] set out in detail the areas to be reviewed before a licence for the construction of a nuclear installation is granted.

The regulatory body will develop a review plan that breaks down the application into different topical areas for review, identifies the relevant regulations, guides and standards applicable to each topic, describes the review methods to be employed and allocates responsibilities for each review area. Regulatory bodies are supported by either dedicated technical support organizations or contracted consultants to provide specialist expertise and to supplement their internal resources for the licensing review.

The design, which is part of the construction licence application and is reviewed by regulatory body, is 'frozen' — namely, it cannot be changed without going through a formal procedure (see Section 5.1.5). The need for a formal procedure also applies to any additional detail that is developed, as it is not necessary to have design detail for every structure, system and component. However, when the application to begin construction is made, the design has to be sufficiently developed so that any unresolved design issues will not require major plant or operational modifications during or after construction.

An important area for regulatory oversight is the IMS of the applicant or licensee, as it is necessary to ensure that the applicant/licensee is a suitable organization, with sufficient capacity and capability, unless this has already been considered (see Section 4.1). If the construction licence application is the first submission of the applicant/licensee, it is expected that this aspect will be given priority by the regulatory body, since — regardless of the quality of the SAR and other documents — the suitability of the applicant/licensee is a key aspect of the future safe operation of the NPP.

The licensee is required to apply control over the supply chain that supplies staff for many functions, including construction and the manufacture of SSCs important to safety. To be able to fulfil this function, the licensee usually identifies suitable technically knowledgeable persons capable of overseeing the contracts and the work of the contractors. Control of the supply chain will also be subject to review and assessment and to inspection, as appropriate, by the regulatory body.

An important aspect to be checked by the regulatory body is that the licensee, vendor and manufacturer have established an appropriate oversight mechanism regarding the manufacturing and construction activities, which will be appropriately described in the documentation of their IMS. In carrying out these activities, adequate record keeping, the quality of the SSCs delivered to the site or manufactured on-site, and the maintenance of equipment on-site before installation are significant issues. The guidance given in appendix I of GSG-12 [3] for the regulatory body is equally applicable to licensees in relation to control of the supply chain.

Regulatory inspection of the licensee's supply chain is an important input to the decision regarding granting a construction licence and will have an impact on later licensing steps. The licensee is responsible for making the necessary arrangements for the regulatory body to be able to carry out its inspections. There are advantages to the licensee being present during the inspections, as it has the primary responsibility. Particular issues may arise if part of the supply chain is in other States. In this case, the regulatory body ensures that there are legally binding arrangements in place that allow the necessary access to documents and to the premises of all organizations.

If a regulatory body intends to visit premises in another State, it is good practice for the visiting regulatory body to inform and, if possible, cooperate with the regulatory body of the State in which the premises are located. Regulatory inspections in other States may not be possible by the regulatory body on its own, but it may be possible for the regulatory body to visit the premises of vendors or manufacturers in other States jointly with the applicant/licensee and/or the regulatory body of that State. Wherever restrictions on regulatory oversight exist, it is necessary to ensure that services and goods supplied meet the safety requirements.

Depending on the national legislation, the regulatory body ensures that the appropriate national authorities have reviewed and assessed the licensee's risk assessment and risk management plans on hazards not directly related to ionizing radiation. Before applying for, or during, the construction, the licensee is required to conduct a risk assessment on various construction activities, such as dredging, digging, blasting, fall of cranes and load drops, as well as spillage of environmentally hazardous chemicals and substances. Specifically, during

construction, risks related to dust and dirt contamination to the buildings and equipment stored on the site need careful attention. The applicant/licensee is required to have sufficient processes, instructions, training and qualified staff to oversee, prevent and mitigate construction related risks that are not related to the nuclear authorizations.

5.1.3. Licence approval and licence conditions for construction

Granting of the licence depends on the regulatory body's assessment that the proposed facility complies with the relevant safety requirements and a sufficient basis exists for safe operation of the NPP. As described in Sections 5.1.1 and 5.1.2, the SAR forms a significant technical part of the construction licence application. The SAR typically does not present complete information on all aspects of the facility. Instead, it may give only preliminary information on the later commissioning, operational and decommissioning stages of the facility. Therefore, the regulatory body may determine that certain technical information that is not required for granting the construction licence can be deferred for review either before a specific construction activity takes place or at a later licensing phase.

However, the regulatory body decides to grant the construction licence based on whether the following key criteria are met:

(a) There is compatibility between the site and the design as described in the submitted SAR;
(b) The design will be safe to operate as described in the submitted SAR for the construction;
(c) The licensee's IMS is adequate to manage the construction.

The activities authorized by the construction licence typically start with the first placement of concrete for the safety related structures of the NPP and continue through construction, up to but excluding the introduction of nuclear material into the reactor core.

The regulatory body will normally attach conditions to the construction licence, such as those described in appendix II of GSG-13 [5]. Among the examples listed in GSG-13 [5], the following conditions are particularly important:

— Control of modifications. The licence conditions require the authorized party to construct the facility as described in the SAR and will prohibit changes significant to safety without the approval of the regulatory body (see Section 5.1.5). The licence conditions may also specify that the licensee

will update the SAR after construction to reflect any approved modifications and to accurately describe the as built plant.

— Reporting of deficiencies. During construction, it is important that the licensee's IMS records and appropriately resolves all deficiencies or non-conformances and implements corrective actions to prevent recurrence when necessary. The regulatory body needs to receive timely reports of deficiencies or non-conformances significant to safety and to respond in an appropriate manner; for instance, by conducting reactive inspections to verify the adequacy of the licensee's proposed actions, which then may have to be authorized or approved.
— Record keeping. Construction records need to be kept, including records of equipment design, manufacture and material, demonstrating to the regulatory body the continuing safety of the facility.
— Prohibiting bringing the fuel into the site. The construction licence will not allow the fuel to be brought into the site without further authorization (see Section 5.2.2).
— Deferral of commitments. The regulatory body, having accepted the deferral of some matters for later review, may set conditions requiring the applicant to take action or to provide additional information at specified points during construction or at a subsequent stage that is subject to licensing.

For example, the construction permit issued by the USNRC in 1973 for Watts Bar NPP Units 1 and 2 authorized the Tennessee Valley Authority as the licensee "to construct the facility described in the application and the hearing record in accordance with the principal architectural and engineering criteria set forth therein" [38]. The permit was subject to the conditions specified in the regulations and to all applicable provisions of the Atomic Energy Act of the United States of America, as well as the rules, regulations and orders of the USNRC, and to the further limitation that a licence authorizing operation of the facility would not be issued by the USNRC unless further stated conditions were met.

As a further example, the construction licences issued by the United Arab Emirates' Federal Authority for Nuclear Regulation (FANR) for the Barakah NPP authorized the Emirates Nuclear Energy Corporation to construct the facility and carry out other activities associated with the construction. The FANR licences also set out several other conditions. An example of those conditions can be found in Licence for the Construction of Units One and Two of the Barakah Nuclear Facility and Related Regulated Activities [39].

In the United Kingdom, the ONR needs to consent to the construction and any associated activities, including testing of adequate installation of SSCs by the licensee. A complete set of the details of the manufacture, construction and installation of SSCs is required, which must be retained for the entire lifetime of

the NPP. Any non-compliances are examined to show that they are still within the safety envelope, and these non-compliances are recorded together with any modifications made during construction.

Having obtained the construction licence, the licensee, as the organization with primary responsibility for safety, manages and controls its own activities and oversees the activities of its contractors and suppliers to ensure that construction is completed in accordance with the licensing basis and the licence conditions. These responsibilities include keeping appropriate records and maintaining traceability of components as part of the licensee's quality assurance programme. Further guidance on the topic of the licensee's responsibilities in construction may be found in SSG-38 [7].

5.1.4. Regulatory hold points and witness points during construction

During the construction stage, the regulatory hold points and witness points are related to the equipment manufacturing in several manufacturing locations and on-site in relation to civil construction, erection and installation, as well as initial component testing. The licensee will develop a plan for construction, which will set certain times when specific activities will take place so that the delivery of equipment and supplies and the availability of personnel can be controlled. Some of these activities are of special interest to the regulatory body and will, therefore, be designated as regulatory hold points or witness points (see Section 3.1.4).

In some States, regulatory approvals of the manufacturers, inspection organizations and testing organizations are required, and these approvals could be defined as hold points. During manufacturing, the goal is to verify that the manufacturer, vendor and licensee have implemented their oversight as presented in the licensee's manufacturing documents, and that the outcomes in terms of SSCs are acceptable (see Annex II). The manufacturing documentation will be inspected and verified during a construction inspection, and this off-site inspection is a hold point before equipment may be packed and shipped to the construction site. Alternatively, in some States, inspection and verification activities are carried out after delivery to the site and so become hold points before installation takes place.

During the installation on-site, the goal of the regulatory body's inspection of the installation is to check that the vendor and licensee have verified that accepted equipment has been installed according to approved installation documentation, that results of tests and inspections are acceptable and that prerequisites for commissioning are available. The regulatory body's installation inspection could be defined as a hold point necessary to proceed with installation activities.

Paragraph 3.10 of SSG-38 [7] recommends:

"Hold points should be carefully selected to:

— Enable observability or testability of the construction, especially before irreversible steps of safety significance are taken;
— Check preparations of the construction organization to progress to the next stage."

Typical examples of hold points or witness points during manufacturing and construction are the following:

— Excavation to rock head or formation level;
— First of a kind component qualification, such as recirculation sump filter testing, passive safety features, I&C systems factory acceptance tests and site acceptance tests;
— First phase concreting;
— Second phase concreting;
— Pressure tests;
— Factory functional tests and/or installation of major safety significant equipment.

The decision on which of the above activities is a hold point or a witness point is made by the regulatory body in accordance with its regulatory approach.

A typical example of a witness point during construction is the welding of the primary circuit and its components. On their own, witness points are similar to normal inspection practices, but developing a series of witness points to support the authorization or approval of a hold point is considered good practice. A good example of how a series of witness points could be combined is observing several different welds to develop the authorization or approval for a hold point, such as the reactor pressure vessel.

At each hold point set by the regulatory body or in the licensing process, an authorization by the regulatory body is required to proceed. Conditions may be attached to this authorization and may also require that the licensee obtain further, more specific, authorizations or approvals before carrying out further particular activities.

5.1.5. Control of modifications during construction

In practice, before an application for a construction licence, the design of the NPP is developed by a design organization considering the site specific

details, and any modifications to the design at this stage are handled by the design organization. However, the licensee, when submitting the application for the construction licence to the regulatory body, assumes the ownership and responsibility for the design.

Modifications to the design submitted and reviewed for authorization of construction are carried out through a defined procedure. The regulatory body will ensure that the licensee has a system (e.g. a configuration management system including management of modifications [40]) in place for retaining design information that includes provisions for controlling any subsequent additions, deletions and modifications to the design from the construction licence throughout the rest of the lifetime of the facility. Such a control system will include review of the proposed modifications, approval of changes at various levels according to their impact on the safety of the facility, and keeping of full records of modifications, as appropriate.

The applicant may establish and use a formally designated entity (e.g. a design authority [41]), usually within the licensee's organization, for assessing the safety significance of modifications and formally approving all design changes [12]. The licensee needs to ensure that the aggregation of several minor non-conformances does not lead to unforeseen consequential safety significant changes.

5.1.6. Regulatory review and assessment and regulatory inspection during construction

Granting a construction licence is only the start of regulatory oversight activities, which continue throughout the construction stage. Regulatory oversight activities, including controlling hold points and witnessing certain activities (see Section 5.1.4), are carried out to ensure that licensees meet their responsibilities for safety.

The licensee's evolving management systems for maintenance, inspection, testing and surveillance need to be assessed for adequacy in maintaining the basic safety measures that are required by the nuclear safety case to ensure satisfactory operations in future. The regulatory body's interaction with the supply chain and the licensee's control of it, as discussed in Section 5.1.2, will continue throughout the construction stage.

Other activities are continuous: for example, checking housekeeping so that SSCs are kept clean and no extraneous objects are inadvertently introduced during installation and construction. A regulatory inspection programme, including unannounced visits, will be developed by the regulatory body.

Arrangements for the radiation protection of workers and the public, covering radioactive sources used in the construction stage, are also required to

be in place. The regulatory body checks the adequacy of these arrangements and ensures that they will be capable of extension to future activities, including active commissioning (see Sections 5.2.2 and 5.2.3).

According to experience in States with operating NPPs, it is considered good practice for the regulatory body to start discussions on the applicant's/licensee's strategy for commissioning, including the training of operators, so that a smooth transition to commissioning is achieved.

5.2. COMMISSIONING

The IAEA Safety Glossary [10] defines the term 'commissioning' as: "The *process* by means of which *systems* and *components* of *facilities* and *activities*, having been constructed, are made operational and verified to be in accordance with the *design* and to have met the required performance criteria" as described in the SAR and relevant licence conditions. Commissioning is carried out to confirm that the performance of the NPP will be safe before commencing routine operation.

The nature of the activities conducted at this stage means that commissioning is a progressive transition from construction to operation. Therefore, it is necessary to plan, conduct and oversee the activities in a precise and careful manner and to establish good communication and coordination among all relevant parties (e.g. the regulatory body, the licensee, designers, constructors).

The top level management of the licensee needs to promulgate a clear policy that assigns responsibilities for the planning and implementation of the initial commissioning test programme. The commissioning programme has to include all the tests necessary to demonstrate that the NPP as constructed — which may differ from the NPP as designed — meets the requirements of the updated SAR and satisfies the design intent, and that the plant can therefore be safely operated in accordance with the licence conditions and complies with the operational limits and conditions (OLCs).

Commissioning starts with the testing and acceptance of installed components, continues with the testing of individual systems, then with integrated system tests and nuclear tests, until the safe operation of the NPP as a whole is finally demonstrated. The test programme is established during the design stage, with detailed test procedures developed and approved some months prior to their use.

Since the commissioning process provides more insight into the design and operational characteristics of the systems and components of the facility, the operating personnel of the licensee receive training so that they can participate

in the commissioning activities. The test programme is under the control of the licensee and may be jointly implemented by commissioning and operating groups drawn from the licensee or from contractors. The licensee may also use personnel from construction organizations, as well as equipment suppliers and their teams in engineering and procurement, during commissioning.

Commissioning provides the opportunity for the operating personnel to become familiar with the operating characteristics, the proposed operating and maintenance procedures, and periodic tests. The collection of baseline data is one of the main outcomes of the commissioning stage. The commissioning programme will also validate the draft operating and maintenance procedures, to the extent practicable, with the participation of future operating personnel.

Owing to differences in the construction schedule for each item, the commissioning and construction stages for the NPP may take place concurrently. Hence, it is difficult to define a precise end of construction, but the licensee ensures that items have been installed, inspected and tested and obtains authorization from the regulatory body before carrying out significant stages in the commissioning process. Systems that have been partially installed, and hence only partially commissioned, are given special attention, and commissioning tests are developed and conducted to allow for appropriate and sufficient commissioning of the full system. Although most of the commissioning takes place on-site, account will be taken, to the fullest extent possible, of tests performed off the site.

Generally, commissioning is divided into two main stages: non-nuclear testing and nuclear testing. Non-nuclear testing is performed before loading nuclear material, whereas nuclear testing is performed after loading nuclear material into the reactor. These two stages are further divided into substages.

Paragraph 2.30 of SSG-28 [8] states that "[t]he main role of the regulatory body in the commissioning process (including the preparations for commissioning) is the oversight of commissioning activities, including, where appropriate, issuing (or not) relevant authorizations."

SSR-2/2 (Rev. 1) [13] establishes the requirements that must be satisfied to ensure the safe commissioning and operation of NPPs, according to experience and the present state of technology. SSG-28 [8] provides detailed guidance, based on SSR-2/2 (Rev. 1) [13], for both the licensee and the regulatory body for the commissioning stage.

SSG-28 [8] makes recommendations on the commissioning programme, the organization and management of the commissioning, the commissioning test and review procedures, and the interfaces between organizations involved in the commissioning activities, including the regulatory body. The annex to SSG-28 [8] provides a list of typical commissioning tests. Sections 5.2.1 to 5.2.9 give a brief description of the various substages of the commissioning stage.

States can benefit from inviting an IAEA Pre-Operational Safety Review Team[5] (Pre-OSART) mission at the beginning of the commissioning stage. The Pre-OSART mission aims to assist the licensee in achieving high standards of commissioning and readiness for safe operations.

5.2.1. Non-nuclear testing

The purpose of non-nuclear testing as part of the commissioning is to verify, to the extent possible, that SSCs are constructed in accordance with the design bases set out in the safety case and they perform their intended functions. Non-nuclear commissioning usually includes two sets of tests, namely cold and hot performance tests.

Cold performance tests aim to verify the functional performance of the systems. They include tests such as pressure tests of circuits, flow rates, pump heads, motor operations, valve opening and closing times, I&C tests and electrical system tests.

Hot performance tests aim to verify the conformance of SSCs with regulatory requirements under simulated conditions to those expected during operation, in terms of temperature, pressure and flow rate, for example, including conditions for steady state operation and anticipated operational occurrences. These tests follow the cold performance tests. The hot performance tests cover mainly the following:

— Integrity and effectiveness of the heat removal systems;
— Ability to sustain flow rates;
— Thermal expansion of the systems;
— Operation of instruments at operating conditions;
— Operation of systems according to specifications.

Other tests may include tests of the moderator, reactor control and protection systems and are performed as early as possible prior to fuel loading. During these tests, the relevant operating procedures are confirmed, and the operation of instruments and other equipment at operational temperatures is verified.

If deviations from design specifications are identified during the non-nuclear commissioning, they are recorded, and their impact on safety is analysed to ensure that safety has not been compromised. If the deviations are not acceptable, corrective actions are necessary to achieve the design intent and performance

[5] https://www.iaea.org/services/review-missions/operational-safety-review-team-osart/types

of the SSCs. Detailed guidance regarding non-nuclear commissioning testing is provided in SSG-28 [8].

The regulatory body may require the licensee to establish an approval mechanism for the test results, demonstrating that they are in compliance with the design specification, to ensure that the licensee takes over the responsibility for the as built SSCs. The results of the tests are also used for developing or updating detailed operational instructions for the relevant systems and the plant and are subject to verification during the nuclear testing stage by the licensee and approval by the regulatory body.

In authorizing commissioning, the regulatory body may consider establishing hold points and/or witness points to some selected tests or require additional authorizations for some important substeps, such as bringing nuclear fuel into the site or commencing loading fuel into the reactor core.

5.2.2. Bringing nuclear fuel into the site

Before the fuel is brought into the NPP site, the radiation risks are limited; therefore, the delivery of fresh fuel to the site means a significant change in risk. Consequently, this substep is treated as a major hold point, and the regulatory body allows fuel to be brought onto the site only if the licensee demonstrates that the arrangements for safe handling and storage of the fresh fuel are adequate and emergency preparedness arrangements are in place in accordance with national regulations.

It is vital that, before this activity is permitted, the necessary infrastructure and agreements with other bodies, both national and international, are in place and functioning to ensure that the nuclear material is controlled under the IAEA's safeguards regime and its security is ensured. Before the fuel is brought into the NPP site, the nuclear regulatory body, along with relevant co-authorities, may set a hold point to confirm that the licensee has fulfilled the security and safeguards arrangements and obligations as well as emergency preparedness arrangements.

5.2.3. Initial fuel loading

Initial fuel loading into the reactor core is another major milestone that usually requires authorization from the regulatory body. In order to commence with fuel loading, the non-nuclear testing stage has to be completed, particularly for the systems that are essential for the operation of the NPP, such as fuel loading systems, heat removal systems, reactor control and instrumentation systems, safety and auxiliary systems. According to SSG-28 [8], nuclear testing starts with the initial loading of nuclear fuel and then proceeds with subcritical

tests. A comprehensive list of prerequisites for initial fuel loading can be found in the appendix of SSG-28 [8].

Nuclear fuel is loaded by suitably trained personnel in accordance with a predefined loading pattern and a written procedure. It is essential to keep the reactor subcritical during the fuel loading, and adequate means for maintaining the subcriticality need to be available to avoid any inadvertent criticality. In addition, it is important to keep periodic or continuous records of important core parameters to identify any deviations from the predicted behaviour and to take corrective actions if deviations are observed.

5.2.4. Nuclear testing

Nuclear testing is the second major substage of commissioning and aims to confirm the safe performance of the plant before commencing routine operations. Once nuclear testing begins, it will not be possible to reverse the process as some material will have been irradiated. Before the start of nuclear tests, the operational staff of the licensee — suitably trained, qualified and licensed — need to be ready to participate in nuclear commissioning.

The regulatory body may establish the requirements on the commencement of this substage, such as satisfactory completion of all previous commissioning activities demonstrating satisfactory performance of plant systems and clear documentation of the results. The regulatory body may also establish additional hold points and/or witness points on certain tests, on beginning to approach criticality or increasing power, as deemed necessary.

After the fuel loading is completed, subcritical tests are performed. These may include the verification of the characteristics of coolant flow and the effects on components, mechanical operability and the functioning of core instrumentation and any reactor control systems, as well as other important features of the primary circuit.

Satisfactory completion of the subcritical tests then allows actions to begin the first approach to criticality. Before any reactivity increase, systems important to safety, in-core instrumentation and automatic shutdown systems are confirmed to be operational, monitoring systems are calibrated and the detailed procedures for startup are ready, in order to ensure that the first startup proceeds safely.

Because achieving initial criticality poses some risks, a cautious approach and continuous checks are needed to monitor the increase in reactivity and the estimated point of criticality. Further guidance regarding a safe approach to initial criticality is provided in SSG-28 [8].

After initial criticality is achieved, a set of low power tests are performed to verify that the reactor performance and characteristics are in conformance with the design and that systems are ready for higher power levels. In particular,

reactor physics parameters are checked for conformance with the design values at this stage, prior to power ascension. This stage comprises a stepwise approach to full power, with tests at various power levels to confirm safe operation of the plant within the design intent. Power levels and tests at each level are to be specified in the relevant procedures of the licensee.

Paragraph 4.59 of SSG-28 [8] states:

> "Tests should be made to demonstrate to the extent practicable that the plant operates in accordance with the design both in steady state conditions and during and after anticipated operational occurrences, including reactor trips and load rejections initiated at appropriate power levels."

As in the case of non-nuclear commissioning, the results of the nuclear testing are subject to verification by the licensee and the regulatory body for final confirmation of the adequacy of safety related features and readiness for safe and reliable operation. If there are deviations from design parameters, they are analysed by the licensee and reported to the regulatory body, which will carry out the necessary review and assessment and may approve the proposed manner of dealing with the deviations, as appropriate.

The results of the nuclear commissioning tests are also used for finalizing operational procedures and OLCs, both of which are reviewed and assessed by the regulatory body before authorization of the routine operation. A further test of the emergency procedures may be considered at this stage to confirm the adequacy of procedures and emergency preparedness.

Further details regarding this commissioning stage are provided in SSG-28 [8].

5.2.5. Documents and information to be submitted by the applicant/licensee for authorization of commissioning

SSG-16 (Rev. 1) [9] states:

> "**Action 186. The operating organization should establish a comprehensive commissioning programme, should prepare the corresponding chapter of the safety analysis report, as appropriate, and should ensure that there are a sufficient number of competent operating staff to be involved in commissioning activities.**"

Additional guidance supporting the implementation of the above action in the licensing of commissioning is contained in para. 3.129 and appendix II of GSG-13 [5], paras 3.44–3.55 of SSG-12 [3] and in SSG-28 [8]. Salient points from this guidance are discussed further below.

States that grant a separate authorization for commissioning will require the applicant to submit the following:

(a) A safety analysis report[6] that builds upon the SAR submitted for the construction licence by providing updated information on the as built site and the NPP, as well as additional information on the proposed arrangements for commissioning, including details of the organization, staffing, programmes and procedures for commissioning, OLCs and emergency management arrangements. Further guidance regarding the content of the SAR is provided in SSG-61 [16].
(b) The commissioning programme for the NPP. In some States, the commissioning programme is a stand-alone document and only its summary is provided in the SAR.
(c) The description of the IMS of the applicant/licensee for the commissioning stage. At this stage, the arrangements to deal with non-conformances are particularly important.
(d) Specific programmes and plans that are usually required to be in place to support the commissioning, such as the following (if they are not part of the SAR):
    (i) Radiation protection programme;
    (ii) Emergency preparedness and response plans;
    (iii) Staff training programme (operational and non-operational);
    (iv) Fire protection programme;
    (v) Maintenance programme;
    (vi) Surveillance programme;
    (vii) In-service inspection programme;
    (viii) Programme for monitoring and sampling of effluents;
    (ix) Programme for management of inspection and testing;
    (x) Programme for monitoring and sampling of radioactive waste;
    (xi) Ageing management programme;
    (xii) Programme for environmental surveillance around the site.

The regulatory body usually does not formally approve all of the specific programmes and plans listed in (d); however, these programmes and plans facilitate the regulatory review process and are also required during regulatory inspections. If they are not submitted, the regulatory body will request them.

In States that have licensed NPPs, experience has shown that it is better not to specify any time period for granting a commissioning licence in the regulations, because this time period depends on the quality and completeness of

[6] This is called a 'commissioning safety analysis report' in some States.

the information and the response of the applicant to queries of the regulatory body. The indicative timeline shown in figure 2 of SSG-16 (Rev. 1) [9] suggests that it will take at least one year from submission to granting a commissioning licence.

If the commissioning activities are performed by the supplier or other groups, the licensee needs to make proper arrangements to participate in, review and approve these activities and submit all the necessary documents to the regulatory body according to the schedule agreed with the regulatory body.

For authorization of initial fuel loading and nuclear testing as a separate licensing substep or a hold point, in addition to the results of the non-nuclear tests, the licensee is required to provide the regulatory body with a preliminary decommissioning plan and a waste management plan.

5.2.6. Review and assessment and inspection by the regulatory body for authorization of commissioning

SSG-16 (Rev. 1) [9] states:

"**Action 188. The regulatory body should review and assess the commissioning programme, should verify compliance with requirements and should prepare a programme to oversee the commissioning of systems important to safety in the next phase.**"

Regulatory control at this stage is required to ensure that commissioning activities are performed safely and to ensure that the actual characteristics of the installation meet the safety criteria and objectives as previously approved by the regulatory body. Another aspect of commissioning from the regulatory point of view is that it provides an integrated demonstration to the regulatory body that the safety margins as presented in the SAR of the NPP are adequate.

Commissioning is a staged process and is checked at each stage to ensure that safety of operation will not be compromised. In fact, nuclear commissioning is the first operational stage in the lifetime of the NPP. To grant a commissioning licence, the regulatory body needs to ensure that the NPP has in place all the safety requirements that are set by the legislation to ensure safe operation. Prior to granting such a licence, the regulatory body's review and assessment process and inspection process are intended to determine, inter alia, that the following apply:

(a) All the outstanding issues at the construction stage have been addressed or, at least, that there is an adequate programme to resolve them;
(b) The SAR has addressed all the elements to be submitted for the commissioning licence;

(c) Draft operating instructions — including emergency procedures, radiation protection protocols and routines for maintenance, inspection, testing and surveillance — are sufficiently developed, in accordance with the commissioning stage (see Section 5.2.10);
(d) The commissioning programme is complete, including a set of well defined operational limits, test acceptance criteria, conditions and procedures, in accordance with the commissioning stage (see Section 5.2.10);
(e) The commissioning programme includes the testing of all the SSCs important to safety to demonstrate that the NPP can be operated safely in all modes for which it has been designed to operate;
(f) The licensee's safety management system is capable of managing the commissioning programme;
(g) The training programme for operational staff, including the use of simulators, has been implemented;
(h) Sufficient trained staff have been allocated to carry out the commissioning programme.

The regulatory body needs to consider its staffing, as different skills and knowledge are required for commissioning and operation compared with those needed during construction.

5.2.7. Licence approval and licence conditions for commissioning

As elaborated in Section 5.2.6, the regulatory body will decide whether a sufficient basis exists for the granting of a commissioning licence after it has satisfactorily completed its regulatory oversight activities and has determined that the proposed facility complies with the relevant requirements. Several IAEA safety guides provide guidance on regulatory oversight of commissioning, including GSG-13 [5], SSG-12 [3] and SSG-38 [7]. Further guidance on licence conditions for commissioning is given in GSG-13 [13]; see para. 3.129 and para. II.5 in appendix II. The main points from this guidance are discussed below, supported with examples drawn from State practices.

As noted in Section 5.2.6, some overlaps exist between commissioning and the construction and operational stages. In some States, the regulatory bodies issue authorizations covering all of commissioning, whereas other States have chosen to authorize pre-operational tests as part of the construction licence and nuclear commissioning as part of the operating licence (see Annex I). For example, for many of the NPPs operating in the United States of America, the Nuclear Regulatory Commission authorized non-nuclear pre-operational testing

as part of construction and subsequently authorized fuel loading and nuclear commissioning tests through the operating licence[7].

The United Arab Emirates' FANR followed similar practices to the USNRC for licensing the commissioning of the Barakah NPP. FANR's construction licences permit the licensee to conduct 'parts and stages of commissioning' comprising pre-operational testing but prohibit the possession of nuclear material or the loading of nuclear fuel into any reactor. FANR authorized startup testing and power ascension testing for Unit 1 of the Barakah NPP through the operating licence [39]. All licences approved by FANR are available on the FANR web site.[8]

In the United Kingdom, the ONR usually consents to inactive and active[9] commissioning separately. An authorization to bring fuel into the site is also issued.

Some of the licence conditions suggested in appendix II, para. II.5, of GSG-13 [5] apply to all phases of commissioning, as follows:

"(a) Commissioning should be carried out in accordance with a programme approved by the regulatory body.
(b) Completed structures, systems and components important to safety should be put into service only once they have been inspected, tested and approved as being in accordance with the terms of the authorization.
(c) Commissioning records, including records of equipment and system tests, test procedures and test results should be kept to demonstrate to the regulatory body the continuing safety of the facility."

The following licence conditions described in appendix II, para. II.5, of GSG-13 [5] apply to commissioning once nuclear fuel is on-site:

"(d) The authorized party[10] should provide approved storage facilities for nuclear or radioactive materials.…
(e) Fissile material or other radioactive material should not be brought onto the site without a regulatory authorization.
(f) From the introduction of radioactive material into the facility, the authorized party should operate the facility only under the control and supervision of authorized personnel using written procedures, in accordance with the

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[7] https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML19176A134

[8] https://www.fanr.gov.ae/en/rules-regulations/licenses-regulatory-approval

[9] 'Inactive commissioning' and 'active commissioning' are general terms; in the case of NPPs, they refer to non-nuclear testing and nuclear testing, respectively.

[10] Referred to as 'the licensee' in this publication.

operational limits and conditions approved by the regulatory body. Any changes made to the operational limits and conditions should be approved by the regulatory body prior to their implementation.

(g) The authorized party should have an approved emergency plan, coordinated with the other authorities involved in emergency preparedness and response."

The regulatory body also includes conditions that require the licensee to make available the results of commissioning tests for its review and assessment.

5.2.8. Regulatory hold points and witness points during commissioning

The purpose of setting regulatory hold points and/or witness points during the commissioning process is to verify that commissioning has been done according to approved documentation and that the results are in accordance with the design bases of the plant, systems and equipment and fulfil the acceptance criteria. Therefore, the necessary regulatory oversight during commissioning is conducted mainly at the hold points, before proceeding further with commissioning activities.

There are several substeps in the commissioning process for which the regulatory body may require the licensee to obtain prior authorization or approval and at which regulatory decisions may be made. Two significant substeps have been noted above: bringing fuel into the site and loading fuel into the reactor core. These require specific authorizations in most States. Hence, the regulatory body introduces hold points at these key substeps.

Typical hold points and witness points during commissioning are organizational readiness inspection(s) to verify that the licensee: (i) has developed an IMS in order to start the plant commissioning activities and (ii) has sufficient qualified staff for the plant commissioning, operation and maintenance. The regulatory body may observe the plant operator's training on the plant simulator and review the qualifications of personnel, including witnessing operator oral examinations and in situ demonstration of skills. Some regulatory bodies authorize the plant operational staff, whereas others just oversee the training, qualification and authorization programmes implemented by the licensee. Authorized, qualified operating staff are a prerequisite for nuclear fuel loading, which is one of the major regulatory hold points during the commissioning stage.

The regulatory body may also impose the following hold points and/or witness points during the commissioning stage:

— Primary circuit initial filling and integrity pressure test;
— Containment tightness test and containment pressure test;
— Pre-operational tests of active safety systems and passive safety features;

— Fuel loading system tests;
— Radiation protection system tests;
— Emergency diesel generator site acceptance tests.

After the nuclear fuel loading, the regulatory body will check particular activities relating to safety and witness particular tests. The process of achieving initial criticality and then raising the power to the maximum allowed during commissioning is an obvious area of regulatory interest. This process will take several days, while the power is increased in steps and checks on core stability and so on are carried out. Therefore, the first criticality and power increases by several steps may be set as individual hold points or witness points. During this process, some of the plant level tests may be set as hold points or witness points. Such plant level tests could be load drop tests to different load levels and island operation, as well as load following tests.

5.2.9. Control of modifications during commissioning

The management of modifications during commissioning is similar to the management of modifications during construction. However, the focus of modifications during commissioning, particularly after the fuel has been introduced into the reactor core and initial criticality has been achieved, usually moves from design to documents and procedures previously reviewed and approved, if appropriate, by the regulatory body. It would be expected that design changes at the commissioning stage would be minor; however, there may be updates to operational procedures and OLCs. All these updates are subject to modification management, and the licensee needs to follow the same procedures to record, assess and approve, if appropriate, the modifications made. Since such modifications may have an impact on the safe operation of the plant, often they are also reviewed, assessed and approved, if necessary, by the regulatory body.

5.2.10. Regulatory review and assessment and regulatory inspection during commissioning

The main role of the regulatory body during the commissioning process (including the preparations for commissioning) is the oversight of commissioning activities, including, where appropriate, issuing (or not) the relevant authorizations. Regulatory control is required to ensure that commissioning activities are performed safely.

The purpose of regulatory oversight of commissioning is to ensure the following:

— The plant has been constructed in accordance with the design intent and its licensing basis;
— The functionality of SSCs demonstrates compliance with the design intent and the requirements in the SAR;
— The behaviour of the NPP as a whole meets the safety requirements, and it can be operated safely;
— The safety management system and all operating rules are in place and are adequate;
— The commissioning has been carried out in accordance with the programme and completed.

During licence approval, a number of hold points and witness points may have been identified (see Section 5.2.8). The regulatory body carries out appropriate inspections and assessments at these points and, where required, gives approval to proceed with commissioning.

It is good practice to organize the increase in power in agreement with the regulatory body so that sufficient confidence in the stability of the reactor core and the adequacy of reactor protection systems can be obtained, which will allow a submission to move to operation to be made in a timely manner. This will avoid having to shut down the reactor while waiting for the regulatory body to grant the operating licence.

SSG-28 [8] and SSG-12 [3] provide further guidance on the responsibilities of the regulatory body with respect to the commissioning process.

5.3. OPERATION

After successful completion of commissioning, the NPP enters the operation stage and starts commercial electricity generation. Operation includes all activities that are necessary to generate electricity safely, such as maintenance, refuelling, in-service inspection, surveillance and other associated activities. Operation of an NPP is most significant from the point of view of public and environmental safety and accordingly calls for appropriate regulatory control and oversight.

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

SSR-2/2 (Rev. 1) [13] establishes the requirements that must be satisfied to ensure the safe commissioning and operation of NPPs according to experience and the present state of technology. Interfaces between commissioning activities and operating activities are explained in a detailed manner in SSG-28 [8].

The operation stage may be divided into various substages, such as authorization for operation for a certain period of time, revalidation of authorization periodically up to the design life and authorization for operation beyond the design life. The licence will set out the conditions under which the licence is valid and/or state the time period for which the licence is valid. Regardless of the conditions of validity of the licence, the regulatory body has the power to order shutdown or otherwise restrict the operation of the NPP at any time if it feels that safety is compromised [2].

The national regulatory framework is expected to describe clear requirements for the authorization of operation, as discussed in Section 5.3.1.

5.3.1. Documents and information to be submitted by the applicant/licensee for operation

Paragraph 3.56 of SSG-12 [3] states:

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

Additional guidance supporting the implementation of the above actions in the licensing of operation is provided in para. 3.130 and appendix II of GSG-13 [5], paras 3.56–3.65 of SSG-12 [3], paras 3.94 and 3.95 of SSG-16 (Rev. 1) [9] and SSG-61 [16]. Salient points from this guidance are further discussed below.

Prior to authorization of operation, the licensee needs to submit at least the following documents to the regulatory body:

(a) Reports of the results of commissioning tests, along with evaluation of these by the licensee.
(b) An updated version of the SAR that takes into account information from commissioning, other relevant sources and queries raised by the regulator during the regulatory review of the SAR.
(c) The description of the IMS of the applicant/licensee for the operation stage. At this stage, the arrangements to deal with modifications, recruitment and training are particularly important.

(d) Updated and confirmed versions of the specific programmes and plans that are necessary for operation, which are set out in Section 5.2.5.
(e) The as built design of the NPP.

It is good practice to organize the submission of the above information to the regulatory body in a stagewise manner as it becomes available. As with organizing the increase in power in agreement with the regulatory body, this will allow the move to operation to be made in a timely manner and will avoid having to shut down while awaiting the regulatory body's granting of the operating licence. The timescale for granting the operating licence will depend on the delivery of the information from the licensee during commissioning and its adequacy.

5.3.2. Review and assessment and inspection by the regulatory body for authorization of operation

At this stage, the NPP moves into a stable phase, with the regulatory body's activities becoming more regular accordingly. The key documents for consideration by the regulatory body before authorizing routine operation are the reports of the results of commissioning tests. The regulatory body needs to review, assess and inspect the results of the commissioning tests for consistency with the expected results. If there are inconsistencies in the results of the commissioning tests, the regulatory body will assess any corrections of non-conformances and modifications to the design and to operating procedures that were made as a result of the commissioning tests.

The SAR submitted in the application for the operating licence is not expected to differ greatly from that submitted with the application for the commissioning licence. In the case of significant changes in the SAR, changes concerning SSCs important to safety and operational rules are expected to be given special consideration and are to be investigated carefully. This situation indicates that the initial design and expected operational activities were not sufficiently analysed by the licensee and were also not recognized by the regulatory body during its assessment.

While the SAR describes many safety and management processes, which can be subject to review and assessment in accordance with the regulatory approach followed, regulatory inspections verify that these processes have been implemented and provide what is needed. The regulatory oversight activities mentioned in Section 5.2.10 have the same purpose regarding decision making for granting the licence for operation. SSG-12 [3] and GSG-13 [5] give details on the issues that the regulatory body has to consider.

5.3.3. Licence approval and licence conditions for operation

As elaborated in Section 5.3.2, before granting a licence for the operation of an NPP, the regulatory body has to be satisfied that the information and documentation made available by the applicant demonstrates the safety of the facility and its compliance with regulatory requirements. Further guidance on the authorization of NPP operation is discussed in paras 3.130–3.134 of GSG-13 [5] and in paras 3.56–3.65 of SSG-12 [3]. Guidance on licence conditions for operation is provided in appendix II, para. II.6, of GSG-13 [5]. The discussion below elaborates on the main points of this guidance and provides examples.

The regulatory findings needed to support granting the operating licence include the following aspects:

(a) The facility has been constructed in accordance with the design specifications, according to submissions made by the applicant relating to the completion of construction and pre-operational testing. These submissions have been reviewed and assessed by the regulatory body to determine that they meet regulatory requirements and the real situation on-site has been checked by regulatory inspections.
(b) The facility will be operated safely and in accordance with the requirements, according to regulatory review and assessment of the commitments made in the licence application.
(c) The applicant is ready to commence operation, according to submissions made by the applicant and regulatory inspections to verify that the arrangements described in the application are in place, including the necessary trained personnel, procedures for normal operation, anticipated operational occurrences and design basis accidents, and safety equipment.

The operating licence that the regulatory body grants will typically authorize the licensee to operate the facility and to conduct other activities associated with the operation of the facility, including possession and handling of the nuclear materials necessary for, and arising from, operation.

The licence will include conditions with which the licensee is required to comply. The licence conditions for operation typically include the following requirements, if not otherwise stated in the regulations (see Annex II):

(a) The licensee operates the facility in compliance with the licensing basis, that is, the applicable laws and regulations and the licence application documents, including any OLCs approved by the regulatory body.

(b) The licensee does not modify any equipment, management arrangements, staffing or procedures that are important to safety without the prior approval of the regulatory body.
(c) The licensee provides reports to the regulatory body on the operation of the NPP and on any events significant to safety and security.
(d) The licensee ensures that the facility is subject to in-service inspection and testing, to be carried out as specified for SSCs important to safety, in accordance with a schedule approved by the regulatory body.
(e) The licensee ensures that the maintenance of equipment and systems important to safety is carried out in accordance with a schedule notified to or approved by, as appropriate, the regulatory body.
(f) The licensee reviews the safety of the NPP on a regular basis and, if necessary, makes safety improvements. Typically, periodic safety reviews are carried out at ten year intervals. Further guidance on the periodic safety review of NPPs is given in IAEA Safety Standards Series No. SSG-25, Periodic Safety Review for Nuclear Power Plants [42].
(g) The licensee keeps operational records, which are available for inspection by the regulatory body.

Some regulatory bodies include other conditions in the operating licences that address matters related to the operation of the facility, including nuclear security and safeguards requirements and/or financial guarantees, such as nuclear liability insurance and fees for nuclear waste management and decommissioning.

As an example, the current licence issued by the CNSC for the Darlington NPP authorizes Ontario Power Generation: "(i) to operate the facility and to (ii) possess, transfer, use, package, manage and store the nuclear substances that are required for, associated with, or arise from the activities described in (i)".

The CNSC licence thereafter sets out numerous conditions specifying standards and requirements for safety, security and safeguards that the licensee is required to meet when operating the facility.[11]

As a second example, in 2015 the USNRC issued an operating licence for Watts Bar NPP Unit 2, which authorizes the Tennessee Valley Authority as the licensee to "possess, use and operate" the facility and "to receive, possess and use at any time" the nuclear materials necessary for and produced by the operation of the facility. The licence is issued subject to all applicable provisions of the relevant laws and to the rules, regulations and orders of the USNRC, now or hereafter in effect, as well as to additional conditions specified in the licence [43].

[11] See footnote 2 on p. 22.

5.3.4. Regulatory review and assessment and regulatory inspection during operation

Once the operating licence has been granted, the licensee, having the primary responsibility for safety, operates the NPP in accordance with the terms and conditions of the licence, the regulations and the licence application documents, which establish the basis for the licence.

Independently of the licensee, the regulatory body carries out a programme of work to verify safety throughout the operational lifetime of the NPP. This will include regulatory oversight of the following:

— Ongoing NPP operation;
— Monitoring and maintenance work performed by the licensee on the NPP, especially during planned outages;
— Restart of operations after planned and unplanned shutdowns;
— Modifications to the NPP;
— Periodic safety reviews;
— Radiation measures both on-site and off-site.

During operation, the regulatory body will develop and implement a programme of inspection covering all areas of operation to verify the licensee's compliance with the requirements. Examples of such inspection areas include, but are not limited to, the following:

— The licensee's activities related to operating the facility within the approved OLCs;
— Operating procedures;
— Staffing and training;
— Availability and maintenance of safety equipment;
— Radiation protection;
— Environmental monitoring.

Regulatory inspections may be both planned and reactive in nature. To enable regulatory inspections, the licensee is expected to give the regulatory body all necessary assistance and access to the NPP, the relevant personnel and documents [5].

The licensee establishes a programme to analyse operating experience at the NPP and at similar facilities elsewhere to ensure that lessons are learned and acted upon. The regulatory body conducts inspections to verify the effectiveness of this programme. The licensee also submits to the regulatory body reports of incidents and events that are significant to safety and security in accordance with

criteria established in the regulations or licence conditions. Such experience may be shared with relevant national and international bodies. It is important to emphasize that data can be collected from both the State and other Member States for similar NPPs, as well as from other nuclear facilities and major industrial activities.

Paragraph 3.4 of GSR Part 1 (Rev. 1) [2] states:

> "The regulatory body shall establish and maintain a means for receiving information from other States, regulatory bodies of other States, international organizations and authorized parties, as well as a means for making available to others lessons learned from operating experience and regulatory experience. The regulatory body shall require appropriate corrective actions to be carried out to prevent the recurrence of safety significant events. This process involves acquisition of the necessary information and its analysis to facilitate the effective utilization of international networks for learning from operating experience and regulatory experience."

All relevant operational lessons learned are valuable for the regulatory body and are expected to be used in revising the relevant regulations and guides, as appropriate.

The results of inspections, event reports and other licensee submittals are subject to review and assessment by the regulatory body on an ongoing basis. Further information on the role of the regulatory body during the operation stage can be found in GSR Part 1 (Rev. 1) [2], SSG-12 [3] and GSG-13 [5]. GSG-13 [5] gives advice on review and assessment topics in appendix III and on inspection areas in appendix IV. These appendices provide a comprehensive basis for the regulatory body's programme.

5.3.5. Authorization for restart of operation

There are several reasons why an NPP may have shut down temporarily or for an extended period of time. These include the following:

— Refuelling outage;
— Major maintenance, modernization or refurbishment activities;
— Anticipated operational occurrences;
— Radiation or nuclear incidents;
— Other significant activities or events.

Before an NPP is brought back into operation following such shutdowns, the licensee is required to demonstrate to the regulatory body that the NPP will be able to continue to operate in compliance within its safety justification.

The licensee submits a written application to the regulatory body for restart of operation. In appendix IV, para. IV.23, of GSG-13 [5], it is noted that "Before returning the facility to normal operation, it is usual for the regulatory body to perform a special inspection."

The degree of regulatory review and inspection will be dependent on the reason for the shutdown. The results of the regulatory body's review and inspection activities are part of the process of approval or authorization for restarting operation. The regulatory body has processes and internal instructions described in its IMS to define the necessary review and assessment, inspection, as well as authorization actions, regarding the restart of operation. Special attention needs to be paid to covering all necessary regulatory disciplines and their tasks for authorization. If necessary, the regulatory body will also liaise with relevant national security, safeguards and emergency preparedness authorities to confirm that there are no hindrances to authorizing restart of operation.

For a planned maintenance outage in the United Kingdom, which happens every three years, the ONR holds a meeting on-site to agree on the activities that will be undertaken. Before restart, a further meeting (the startup meeting) is held, where the results of the maintenance inspections are discussed and any changes to the SAR are considered. For example, the Trawsfynydd NPP presented three versions of the SAR that the Nuclear Installations Inspectorate (the ONR's predecessor) did not accept, so the operator decided to shut the NPP down. Several advanced gas cooled reactor stations are currently running with requirements of obtaining evidence in order to put in a safety submission to request consent from the ONR for further operation after fixed periods shorter than the normal three years, because of progressive problems with their core structures.

5.3.6. Authorization of modifications during operation

Some modifications to the design of the plant hardware, the processes and procedures being used and the management structures will eventually be needed at all NPPs. These modifications may be required by failures that have occurred, by ageing or by the need to make improvements and are based on operational experience at the plant itself, at other similar plants or even at non-nuclear facilities. NS-G-2.3 [20] provides detailed guidance on modifications to NPPs.

All modifications are subject to a process of scrutiny that depends on their potential adverse effects on safety, either when completed or during the process of modification. There has to be a written procedure, which will be a part of the IMS of the licensee, that deals with changes and modifications.

Paragraph 2.5 of NS-G-2.3 [20] states that "Proposed modifications should be categorized according to their safety significance and proposals for modifications should be submitted to the regulatory body for prior approval if required."

Further, para. 2.6 of NS-G-2.3 [20] states:

"Modifications which may affect safety can be divided into:

(a) Modifications directly relating to plant configuration, i.e.:
   — Modifications to structures, systems and components or process software;
   — Modifications to the operational limits and conditions;
   — Modifications to operating procedures; or
   — A combination of these; and
(b) Modifications to management systems:
   — Changes in organizational structures or resources;
   — Modification of operational management programmes; and
   — Modifications relating to safety reassessment tools and processes, including improved knowledge of physical phenomena (from the results of research and development)."

If required, the licensee submits a written application and its safety justification to the regulatory body to request approval for the proposed modifications. The application first describes the purpose of the modification and then specifies the affected operations and documentation. The proposed modification could influence the validity of some parts of the safety case; therefore, specific justifications and/or results of revised parts of the safety case are presented in the application for regulatory review and assessment. On the basis of the safety significance and scope of the proposed modification, the regulatory body may also plan its inspection activities to check that the licensee is following the licensee's plans and carrying out its activities in accordance with the instructions and procedures specified in the licensee's IMS. A graded approach may be used when planning the regulatory review and inspection activities to authorize the planned modifications.

In cases where an operating plant was designed and constructed several years before, it is vital to check the requirements and specification of new SSCs against the design substantiation in accordance with the modification procedure, where the 'formally designated entity' (see Section 5.1.5) takes the lead. Similar considerations apply to changes in management organization, processes or procedures.

In the case of changes to management structures, it is necessary for a process to be established by the licensee for determining whether the change will affect safety provisions, including the time available to carry out necessary audits and inspections. It is useful for the licensee to set out the experience and qualifications necessary for all roles associated with the protection of workers and the public.

It is also important to recognize that, even when replacing an existing SSC with a new one of the same type, certain risks need to be considered. For example, the specifications of an SSC that is to replace an existing SSC may have been subtly changed by a supplier who is unaware of the full requirements for that equipment.

APPENDIX I

TYPICAL PROCESS FOR GRANTING A LICENCE

The typical process for granting a licence is shown schematically in Fig. 2.

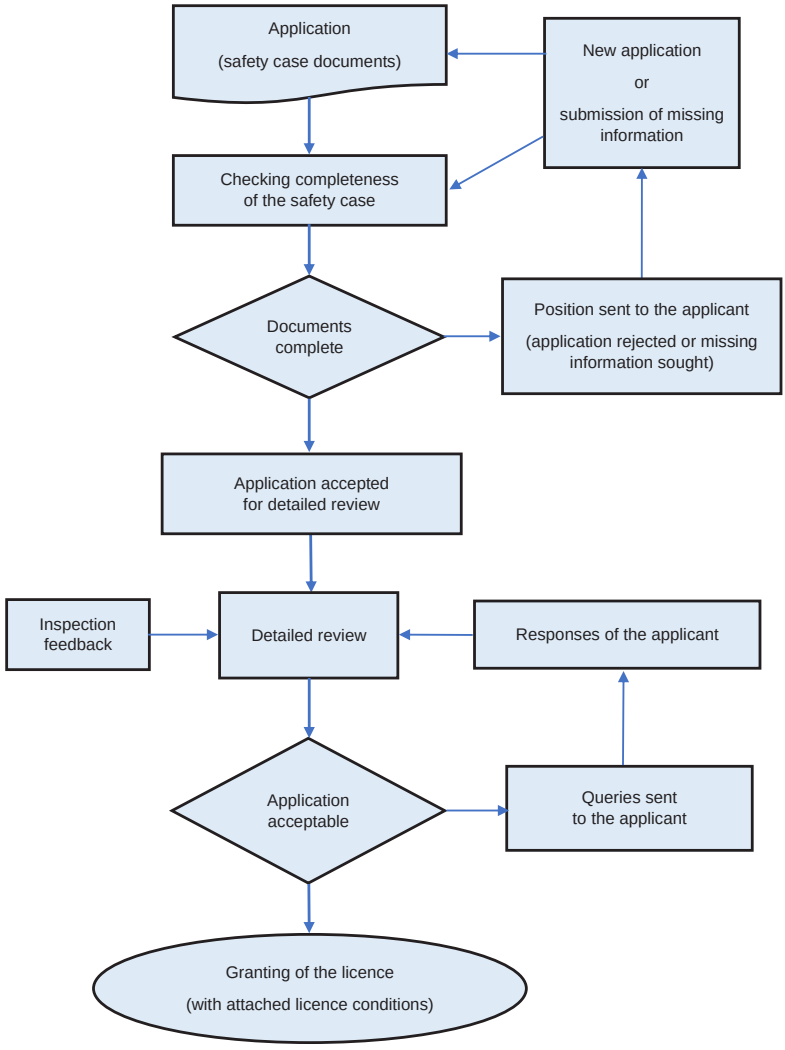

FIG. 2. Flowchart of a typical process for granting a licence.

APPENDIX II

TYPICAL CONTENT OF A LICENCE

The licence may include the following (unless specified elsewhere in the national legislation or in national regulations) [3][12]:

(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 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 NPP or activity.
(d) A sufficiently detailed description of the NPP, its maximum allowable thermal power, its location and its activities, including a clear depiction and description of the site boundaries and other drawings as appropriate.
(e) The maximum allowable inventories of sources covered by authorizations.
(f) The requirements for notifying the regulatory body of any modifications that are significant to safety.
(g) The obligations of the licensee with respect to both safety at the NPP and the safety of its equipment, its radiation source(s), its personnel, the public and the environment.
(h) Any limits on operation and use (e.g. dose limits, discharge limits, action levels or limits on the duration of the authorization, permit or licence).
(i) Any separate additional authorizations that the licensee is required to obtain from the regulatory body.
(j) The requirements for reporting events and incidents at the NPP.
(k) The requirements for providing routine reports to the regulatory body (see para. 3.61 of SSG-12 [3]).
(l) The requirements for retention of records by the person or organization responsible for the NPP and its activities, including the time periods for which records are retained.
(m) The requirements for arrangements for emergency preparedness.
(n) The means and procedures for changing any information stated in the licence.

[12] This list is adapted from para. 2.40 of SSG-12 [3].

(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 are 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) Time bound licensing conditions.
(s) Licence conditions dealing with safety aspects of the NPP and its activities.

APPENDIX III

DEVELOPMENT OF THE SAFETY ANALYSIS REPORT IN DIFFERENT LICENSING STEPS

Table 1 lists information that needs to be included in the SAR at different stages of the licensing process of an NPP [16].

TABLE 1. INFORMATION TO BE INCLUDED IN THE SAFETY ANALYSIS REPORT ISSUED FOR DIFFERENT LICENSING STAGES OF THE NPP [16][a]

	Chapter of a typical SAR	SAR for construction	SAR for commissioning	SAR for operation
1	Introduction and general description of the plant	Final information on plant description and layout	Updated only if changed[b]	Updated only if changed
2	Site characteristics	Final and verified information on site characteristics	Updated only if changed	Updated only if changed
3	Safety objectives and design rules of SSCs	Final design requirements specific to the reactor type and site	Updated only if changed	Updated only if changed
4	Reactor	Preliminary description[c] of reactor SSCs	Final description[d] of SSCs as manufactured	Updated only if changed
5	Reactor coolant and associated systems	Preliminary description of primary circuit SSCs	Final description of SSCs as manufactured	Updated only if changed
6	Engineered safety features	Preliminary description of engineered safety features of SSCs	Final description of SSCs as manufactured	Updated only if changed

TABLE 1. INFORMATION TO BE INCLUDED IN THE SAFETY ANALYSIS REPORT ISSUED FOR DIFFERENT LICENSING STAGES OF THE NPP [16][a] (cont.)

	Chapter of a typical SAR	SAR for construction	SAR for commissioning	SAR for operation
7	I&C	Preliminary description of I&C SSCs	Final description of SSCs as manufactured	Updated only if changed
8	Electric power	Preliminary description of electrical SSCs	Final description of SSCs as manufactured	Updated only if changed
9	Auxiliary systems and civil structures	Preliminary description of auxiliary SSCs and final information on civil structures	Final description of SSCs as manufactured and constructed	Updated only if changed
10	Steam and power conversion system	Preliminary description of steam and power conversion SSCs	Final description of SSCs as manufactured	Updated only if changed
11	Management of radioactive waste	Preliminary description of source terms, waste management policies and relevant SSCs	Final description of source terms, waste management policies and SSCs as manufactured	Updated only if changed
12	Radiation protection	Preliminary information on demonstration of compliance with the requirements	Final demonstration of compliance with the requirements	Updated only if changed
13	Conduct of operations	Preliminary information on demonstration of compliance with the requirements	Final demonstration of compliance with the requirements	Verified and updated information on conduct of operations

TABLE 1. INFORMATION TO BE INCLUDED IN THE SAFETY ANALYSIS REPORT ISSUED FOR DIFFERENT LICENSING STAGES OF THE NPP [16][a] (cont.)

	Chapter of a typical SAR	SAR for construction	SAR for commissioning	SAR for operation
14	Plant construction and commissioning	Demonstration of compliance with the requirements, final information for construction and preliminary information for commissioning	Final information on demonstration of compliance with the requirements for construction and commissioning	Updated only if changed
15	Safety analysis	Final information on demonstration of safety of site specific design	Verified and updated information on safety analysis if changed	Updated only if changed
16	OLCs	Preliminary information on description and specification of OLCs	Final information on description and specification of OLCs	Verified and updated information
17	Management systems	Final information on description of management system for construction	Updated for the commissioning and future operation phase	Updated for operation phase
18	Human factors engineering	Preliminary information on description of the scope, methodology and results of human factors engineering	Final information on description of human factors engineering	Updated only if changed
19	Emergency preparedness	Preliminary information on description of emergency facilities and emergency plans	Final information on description of emergency facilities and emergency plans	Updated only if changed

TABLE 1. INFORMATION TO BE INCLUDED IN THE SAFETY ANALYSIS REPORT ISSUED FOR DIFFERENT LICENSING STAGES OF THE NPP [16][a] (cont.)

	Chapter of a typical SAR	SAR for construction	SAR for commissioning	SAR for operation
20	Environmental aspects	Final information on environmental aspects	Updated only if changed	Updated only if changed
21	Decommissioning and end-of-life aspects	Preliminary information on decommissioning and end-of-life aspects	Updated information on decommissioning and end-of-life aspects	Updated information on decommissioning and end-of-life aspects

[a] This table is based on the annex of SSG-61 [16].

[b] This type of change is to be communicated to the regulatory body.

[c] Preliminary description involves preliminary design and operational information on systems and components, sufficiently detailed to allow understanding and evaluating the accident analyses.

[d] Final description involves final design information, sufficiently detailed to verify that the system and/or components can operate in accordance with the design intent and perform their operational and safety functions.

Note: SAR: safety analysis report; SSCs: structures, systems and components; I&C: instrumentation and control; OLCs: operational limits and conditions.

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Annex I

EXAMPLES FROM MEMBER STATES

Table I–1 presents examples of the authorization steps and submission requirements used in some Member States.

TABLE I−1. AUTHORIZATION STEPS AND SUBMISSION REQUIREMENTS IN SOME MEMBER STATES

Member State	Authorization step[a]	Submission requirement
Finland	Construction licence	— The preliminary SAR, which shall include the general design and safety principles of the nuclear facility, a detailed description of the site and the nuclear facility, a description of the operation of the facility, a description of the behaviour of the facility during accidents, a detailed description of the effects that the operation of the facility has on the environment and any other information considered necessary by the authorities — A probabilistic risk assessment of the design stage — A proposal for a classification document, showing the classification of SSCs important to the safety of the nuclear facility on the basis of their significance with respect to safety — A description of quality management during the construction of the nuclear facility, showing the systematic measures applied by the organizations that take part in the design and construction of the nuclear facility in their operations affecting quality — Preliminary plans for the arrangements for security and emergencies — A plan for arranging the safeguards control that is necessary to prevent the proliferation of nuclear weapons — A description of the arrangements referred to in section 19, para. 7, of the Nuclear Energy Act (nuclear safeguards arrangements) An applicant for a licence shall also provide the Finnish Radiation and Nuclear Safety Authority (STUK) with any other reports that STUK considers necessary

TABLE I–1. AUTHORIZATION STEPS AND SUBMISSION REQUIREMENTS IN SOME MEMBER STATES (cont.)

Member State	Authorization step[a]	Submission requirement
Finland	Operating licence	— The final SAR — A probabilistic risk assessment — A classification document showing the classification of SSCs important to the safety of the nuclear facility on the basis of their significance with respect to safety — A quality management programme for the operation of the nuclear facility — The technical specifications, which shall at least define limits for the process quantities that affect the safety of the facility in various operating states, provide regulations on operating restrictions that result from component failures and set forth requirements for the testing of components important to safety — A summary programme for periodic inspections — Plans for the arrangements for security and emergencies — A description of how to arrange the safeguards that are necessary to prevent the proliferation of nuclear weapons — Administrative rules for the nuclear facility — A programme for radiation monitoring in the environment of the nuclear facility — A description of how safety requirements are met — A programme for the management of ageing
France	Creation authorization of a basic nuclear installation	— Description of the installation and the site — Preliminary SAR (PSAR) — Environmental Impact Assessment — Decommissioning plan — Report and results of public hearings

TABLE I–1. AUTHORIZATION STEPS AND SUBMISSION REQUIREMENTS IN SOME MEMBER STATES (cont.)

Member State	Authorization step[a]	Submission requirement
France	Commissioning authorization of a basic nuclear installation	— Updated PSAR including the data provided for the assessment of installation conformity with the requirements of the authorization decree and the construction requirements — General operating rules — Study of installation waste management — On-site emergency plan — Updated dismantling plan of the installation — Updated environmental impact study
India	Consent for construction	— PSAR — Construction site quality assurance manual — Construction schedule — Construction methodology — Design basis report and design reports as supplement to PSAR
	Consent for commissioning (period for power operation is normally 100 days)	— Quality assurance manual for commissioning and operation — Schedule for commissioning programme — Organization for commissioning and operation — Technical specifications for operation — Training and qualification programme — Approved emergency preparedness plans for plant, site and off-site — Complete set of flowsheets and logic diagrams — Commissioning related submissions covering system status and test results

TABLE I–1. AUTHORIZATION STEPS AND SUBMISSION REQUIREMENTS IN SOME MEMBER STATES (cont.)

Member State	Authorization step[a]	Submission requirement
India		— Waste management operation manual — Radiation protection procedure — Fire order with available provisions — In-service inspection manual — Operating manuals — Maintenance procedures — Emergency operating procedure — Level 1 probabilistic safety analysis studies for internal and external events — Manual on nuclear security measures — Fire hazard analysis
	Licence to operate (maximum 5 years)	— Final SAR — Report on performance of the plant operation within the commissioning consenting period — Report on pending issues — Report on performance of the fuel handling system — Report on the status of documentation
Republic of Korea	Construction permit	— Radiation environmental report — PSAR — Quality assurance programme description for construction — Initial decommissioning plan — Site survey report and detailed geological survey report are also required for early site approval when the applicant wishes to start civil work prior to the construction permit
	Operating licence	— Technical specifications for operation — Final SAR — Accident management plan (including severe accident management plan) — Description of quality assurance programme for operation — Radiation environmental report (update on the previous report) — Decommissioning plan (update on the previous report) — Discharge plan

TABLE I–1. AUTHORIZATION STEPS AND SUBMISSION REQUIREMENTS IN SOME MEMBER STATES (cont.)

Member State	Authorization step[a]	Submission requirement
Pakistan	Construction licence	— PSAR — Design probabilistic safety assessment of full power internal initiating events — Quality assurance programme for design and construction phases (for reference and record)
	Permission for commissioning	— Commissioning programme — Quality assurance programme for the commissioning phase
	Permit for introducing nuclear material (fuel load permit)	— Final SAR — Level 1 probabilistic safety analysis — Physical protection programme — Emergency preparedness plans — Radiation protection programme — Environmental monitoring programme — Radioactive waste management programme — Initial decommissioning plan — Pre-service inspection/in-service inspection programme — Quality assurance programme for operation — Programmes for maintenance, testing, surveillance and inspection of SSCs important to safety (for reference and record) — Fire protection programme (for reference and record) As the cold and hot commissioning (without introducing nuclear material into the systems) proceeds, the licensee shall regularly submit commissioning reports up to the introduction of nuclear material to the Pakistan Nuclear Regulatory Authority (PNRA) for information, reference and record
	Operating licence (up to 10 years)	— Results of first startup and full capacity tests (low power tests, power ascension tests and full power tests) — Updates of all documents required at the stage of fuel load permit

TABLE I–1. AUTHORIZATION STEPS AND SUBMISSION REQUIREMENTS IN SOME MEMBER STATES (cont.)

Member State	Authorization step[a]	Submission requirement
United Kingdom	Major stage of facility life cycle and associated safety case	Particular purpose of safety case
	Pre-construction and safety case or pre-commencement safety case	Information on the quality management arrangements for the design, including (but not limited to): — Standards and design codes to be applied and demonstration of how they are met — Design controls, control of standards, validation and verification, and interface between design and safety — Safety case development processes, including peer review arrangements and nuclear safety assurance — Quality management system for development of the safety case and design — Information on radioactive waste management and decommissioning strategies
	Pre-operation: commissioning safety cases[b]	The purpose of these safety cases is to demonstrate: — That the facility as built meets relevant safety criteria and is capable of safe operation — That the active commissioning activities can and will be carried out safely and that the operating procedures for commissioning are supported by the safety case — That a programme of safety commissioning activities has been produced that will, as far as practicable: • Demonstrate the safe functioning of all systems and equipment • Prove that all safety claims on equipment will be delivered • Confirm the effectiveness of safety related procedures • Ensure that there are no aspects of nuclear or radiological safety that remain to be demonstrated after active commissioning

TABLE I−1. AUTHORIZATION STEPS AND SUBMISSION REQUIREMENTS IN SOME MEMBER STATES (cont.)

Member State	Authorization step[a]	Submission requirement
United Kingdom		Particularly in the active commissioning mode, many of the aspects of the operational safety case (see below) will need to be in place. In particular, operating procedures will need to have been developed, and these also need to be compatible with the limits and conditions necessary in the interest of safety
	Operation[c]	The purpose of the operational safety case is to demonstrate: — That the facility as built meets relevant safety criteria and is capable of safe operation — That the operating procedures provide sufficient control that operations will remain within the limits and conditions of safe operation — Compliance with the legal duty to reduce risks to workers and the public 'so far as is reasonably practicable'
	Site wide safety case	For sites containing multiple facilities, the licensee may choose to produce separate safety cases for specific facilities, activities, functions or parts of a site, together with a site wide safety case The purpose of a site wide safety case is to demonstrate that the site as a whole is safe and to substantiate dependencies and claims using individual facility safety cases (e.g. facility interfaces, common services, emergency arrangements)

[a] Licensing stages, if defined, before the construction licence and after the operation licence (e.g. site licence) are excluded from this table.

[b] Also called pre-inactive commissioning safety report, pre-active commissioning report or pre-operational safety report.

[c] Also called facility safety case or station safety case; updated as necessary.

Note: SAR: safety analysis report.

Annex II

PRINCIPLES OF A FOLLOW-UP DOCUMENT

Tables II–1 and II–2 show examples of follow-up documents for Safety Class 1 pressure piping.

TABLE II−1. SUPERVISION BEFORE MANUFACTURING

Step no.	Step	Reference document	Manufacturer/vendor	Third party	Licensee	Regulatory body
1	Auditing manufacturer's quality management system	Quality management documentation	H[a]		H	H
2	Approvals — Manufacturer — Construction plan (including use of third party) — Testing organizations (NDT[b], DT[c])	Applications via licensee to the Finnish Radiation and Nuclear Safety Authority (STUK)	H		H	H
3	Qualification of manufacturing procedures — Permanent joints — Forming — Heat treatment	Qualification documents	H	H	W[d]	W (in cases when the regulatory body approves qualification plans)
4	Qualification of personnel — Permanent joints — NDT testing	Qualification test and proof	H	H	W	

TABLE II−1. SUPERVISION BEFORE MANUFACTURING (cont.)

Step no.	Step	Reference document	Manufacturer/vendor	Third party	Licensee	Regulatory body
5	Oversight of material testing (scope according to approved plans)					
	— Destructive testing		H	H	H	H
	— Filler material testing		H	H	W	W
	— NDT		H	H	W	W

[a] H: hold point.
[b] NDT: non-destructive testing.
[c] DT: destructive testing.
[d] W: witness point.

TABLE II−2. SUPERVISION DURING AND AFTER MANUFACTURING

Step no.	Step	Reference document	Manufacturer/vendor	Third party	Licensee	Regulatory body
1	Control of manufacturing Scope according to approved plans	Inspection and testing plan with welding procedures and NDT instructions				
	— Welding and NDT[a] of main parts		H[b]	H	W[c]	W
	— Heat treatments			H	W	W
	— Production tests			H	W	W
2	Construction inspection	Inspection and testing plan with necessary technical guidelines				
	— For component and its manufacturing documentation		H		H	H
	— Pressure test and inspection of component afterwards				H	H
	— Final approval of component after manufacturing				H	H
3	Packing		H		W	
4	Shipping		H		W	

[a] NDT: non-destructive testing.
[b] H: hold point.
[c] W: witness point.

ABBREVIATIONS

CNSC	Canadian Nuclear Safety Commission
EIA	environmental impact assessment
FANR	Federal Authority for Nuclear Regulation
I&C	instrumentation and control
IMS	integrated management system
NPP	nuclear power plant
OLCs	operational limits and conditions
ONR	Office for Nuclear Regulation, United Kingdom
PSAR	preliminary safety analysis report
SAR	safety analysis report
SSCs	structures, systems and components
USNRC	United States Nuclear Regulatory Commission

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Consultants Meetings

Vienna, Austria: 10–12 July 2019, 5–9 October 2020, 10–14 December 2020, 22–26 February 2021, 16–20 August 2021

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This Safety Report provides guidance, targeted towards Member States embarking upon a nuclear power plant programme, on the licensing process and associated procedures needed for the construction, commissioning and operation stages of a nuclear power plant, so that the applicant complies with national regulations, in line with the internationally recognized safety principles and requirements, throughout these stages. The publication elaborates on the generic guidance provided in IAEA Safety Standards Series No. SSG-12, Licensing Process for Nuclear Installations, and gives supplementary practical guidance for nuclear power plants.

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