

IAEA Safety Standards

for protecting people and the environment

Licensing Process for Nuclear Installations

Specific Safety Guide

No. SSG-12



IAEA

International Atomic Energy Agency



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

The publications by means of which the IAEA establishes standards are issued in the **IAEA Safety Standards Series**. This series covers nuclear safety, radiation safety, transport safety and waste safety. The publication categories in the series are **Safety Fundamentals**, **Safety Requirements** and **Safety Guides**.

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

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LICENSING PROCESS FOR NUCLEAR INSTALLATIONS

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The Agency's Statute was approved on 23 October 1956 by the Conference on the Statute of the IAEA held at United Nations Headquarters, New York; it entered into force on 29 July 1957. The Headquarters of the Agency are situated in Vienna. Its principal objective is "to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity throughout the world".

IAEA SAFETY STANDARDS SERIES No. SSG-12

LICENSING PROCESS FOR NUCLEAR INSTALLATIONS

SPECIFIC SAFETY GUIDE

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2010

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PO Box 100
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email: sales.publications@iaea.org
<http://www.iaea.org/books>

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Printed by the IAEA in Austria
October 2010
STI/PUB/1468

IAEA Library Cataloguing in Publication Data

Licensing process for nuclear installations : specific safety guide. — Vienna : International Atomic Energy Agency, 2010.
p. ; 24 cm. — (IAEA safety standards series, ISSN 1020-525X ; no. SSG-12)
STI/PUB/1468
ISBN 978-92-0-107510-9
Includes bibliographical references.

1. Nuclear energy — Law and legislation – Standards. 2. Nuclear facilities — Licenses — Standards. 3. Nuclear facilities — Safety regulations — Standards. I. International Atomic Energy Agency. II. Series.

IAEAL

10-00653

FOREWORD

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

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

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

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

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

THE IAEA SAFETY STANDARDS

BACKGROUND

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

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

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

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

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

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

THE IAEA SAFETY STANDARDS

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

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

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

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

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

Safety Fundamentals

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

Safety Requirements

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

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

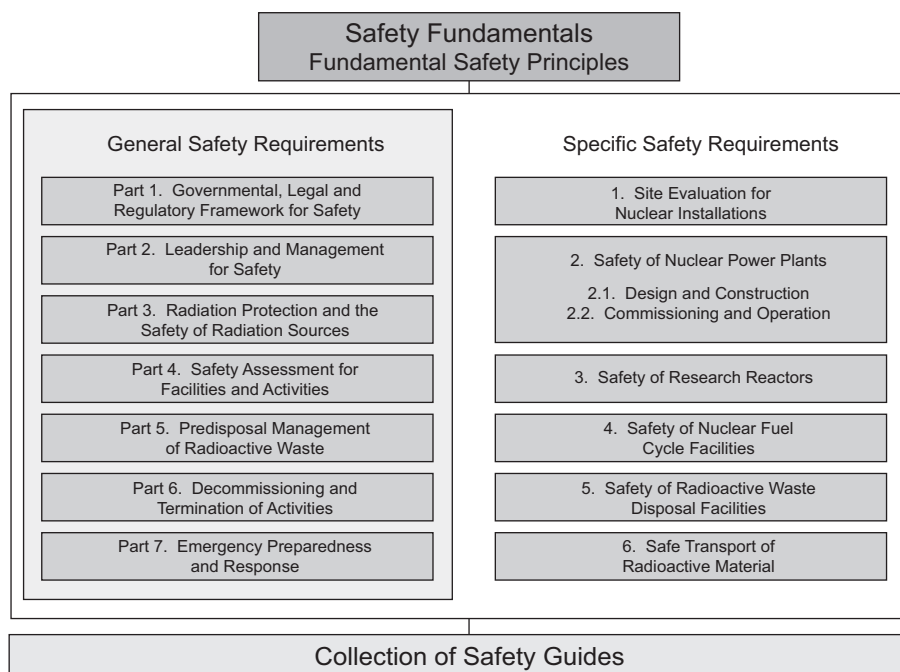


FIG. 1. The long term structure of the IAEA Safety Standards Series.

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

Safety Guides

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

APPLICATION OF THE IAEA SAFETY STANDARDS

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

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

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

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

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

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

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

DEVELOPMENT PROCESS FOR THE IAEA SAFETY STANDARDS

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

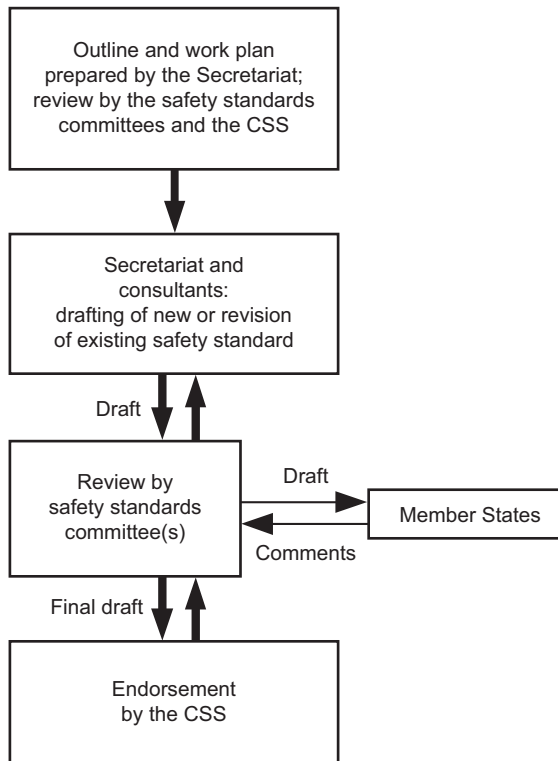


FIG. 2. The process for developing a new safety standard or revising an existing standard.

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

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

INTERACTION WITH OTHER INTERNATIONAL ORGANIZATIONS

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

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

INTERPRETATION OF THE TEXT

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

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

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

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

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1. INTRODUCTION

BACKGROUND

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

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

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

OBJECTIVE

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

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

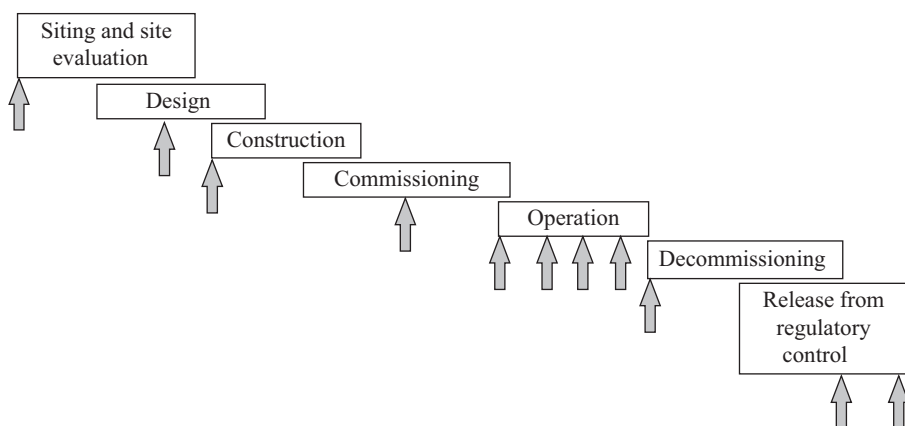


FIG. 1. Stages in the lifetime of a nuclear installation; the arrows indicate where hold points may be imposed.

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

SCOPE

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

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

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

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

STRUCTURE

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

2. GENERAL RECOMMENDATIONS ON THE LICENSING PROCESS

DEFINITIONS

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

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

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

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

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

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

BASIC LICENSING PRINCIPLES

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

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

2.7. Licences may be granted:

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

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

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

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

2.11. Reference [1] states that:

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

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

Furthermore, Ref. [1] states that:

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

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

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

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

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

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

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

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

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

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

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

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