IAEA SAFETY STANDARDS SERIES

Documentation for Use in Regulating Nuclear Facilities

SAFETY GUIDE

No. GS-G-1.4

INTERNATIONAL
ATOMIC ENERGY AGENCY
VIENNA

IAEA SAFETY RELATED PUBLICATIONS

IAEA SAFETY STANDARDS

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DOCUMENTATION FOR
USE IN REGULATING
NUCLEAR FACILITIES

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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''.

Printed by the IAEA in Austria
August 2002
STI/PUB/1132

SAFETY STANDARDS SERIES No. GS-G-1.4

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INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2002

VIC Library Cataloguing in Publication Data

Documentation for use in regulating nuclear facilities : safety guide. — Vienna : International Atomic Energy Agency, 2002.
p. ; 24 cm. — (Safety standards series, ISSN 1020–525X ; no. GS-G-1.4)
STI/PUB/1132
ISBN 92–0–113702–8
Includes bibliographical references.

1. Nuclear facilities — Law and legislation. 2. Nuclear facilities — Safety regulations. I. International Atomic Energy Agency. II. Series.

VICL 02–00290

FOREWORD

by Mohamed ElBaradei
Director General

One of the statutory functions of the IAEA is to establish or adopt standards of safety for the protection of health, life and property in the development and application of nuclear energy for peaceful purposes, and to provide for the application of these standards to its own operations as well as to assisted operations and, at the request of the parties, to operations under any bilateral or multilateral arrangement, or, at the request of a State, to any of that State's activities in the field of nuclear energy.

The following bodies oversee the development of safety standards: the Commission on Safety Standards (CSS); the Nuclear Safety Standards Committee (NUSSC); the Radiation Safety Standards Committee (RASSC); the Transport Safety Standards Committee (TRANSSC); and the Waste Safety Standards Committee (WASSC). Member States are widely represented on these committees.

In order to ensure the broadest international consensus, safety standards are also submitted to all Member States for comment before approval by the IAEA Board of Governors (for Safety Fundamentals and Safety Requirements) or, on behalf of the Director General, by the Publications Committee (for Safety Guides).

The IAEA's safety standards are not legally binding on Member States but may be adopted by them, at their own discretion, for use in national regulations in respect of their own activities. The standards are binding on the IAEA in relation to its own operations and on States in relation to operations assisted by the IAEA. Any State wishing to enter into an agreement with the IAEA for its assistance in connection with site evaluation for or the design, construction, commissioning, operation or decommissioning of a nuclear facility or any other activities will be required to follow those parts of the safety standards that pertain to the activities to be covered by the agreement. However, it should be recalled that the final decisions and legal responsibilities in any licensing procedures rest with the States.

Although the safety standards establish an essential basis for safety, the incorporation of more detailed requirements, in accordance with national practice, may also be necessary. Moreover, there will generally be special aspects that need to be assessed on a case by case basis.

The physical protection of fissile and radioactive materials and of nuclear power plants as a whole is mentioned where appropriate but is not treated in detail; obligations of States in this respect should be addressed on the basis of the relevant instruments and publications developed under the auspices of the IAEA. Non-radiological aspects of industrial safety and environmental protection are also not explicitly considered; it is recognized that States should fulfil their international undertakings and obligations in relation to these.

The requirements and recommendations set forth in the IAEA safety standards might not be fully satisfied by some facilities built to earlier standards. Decisions on the way in which the safety standards are applied to such facilities will be taken by individual States.

The attention of States is drawn to the fact that the safety standards of the IAEA, while not legally binding, are developed with the aim of ensuring that the peaceful uses of nuclear energy and of radioactive materials are undertaken in a manner that enables States to meet their obligations under generally accepted principles of international law and rules such as those relating to environmental protection. According to one such general principle, the territory of a State must not be used in such a way as to cause damage in another State. States thus have an obligation of diligence and standard of care.

Civil nuclear activities conducted within the jurisdiction of States are, as any other activities, subject to obligations to which States may subscribe under international conventions, in addition to generally accepted principles of international law. States are expected to adopt within their national legal systems such legislation (including regulations) and other standards and measures as may be necessary to fulfil all of their international obligations effectively.

EDITORIAL NOTE

An appendix, when included, is considered to form an integral part of the standard and to have the same status as the main text. Annexes, footnotes and bibliographies, if included, are used to provide additional information or practical examples that might be helpful to the user.

The safety standards use the form 'shall' in making statements about requirements, responsibilities and obligations. Use of the form 'should' denotes recommendations of a desired option.

The English version of the text is the authoritative version.

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1. INTRODUCTION

BACKGROUND

1.1. The achievement and maintenance of a high level of safety in the siting, design, construction, commissioning, operation and decommissioning of nuclear facilities, and in the closure of waste disposal facilities, requires a sound legal and governmental infrastructure, including a regulatory body with clearly defined responsibilities and functions. The process of regulating a nuclear facility entails the preparation of a large amount of documentation, both by the operator of the facility and by the regulatory body.

1.2. The IAEA Safety Requirements publication on Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety [1] sets out the requirements for a regulatory infrastructure for nuclear facilities. These include requirements in respect of documentation to be produced by the operator or by the regulatory body at the various stages of the authorization process.

1.3. Four interrelated IAEA Safety Guides provide recommendations on satisfying the requirements concerning particular responsibilities and functions of the regulatory body in the regulation of nuclear facilities. The present Safety Guide addresses documentation relating to the regulatory process; three related Safety Guides cover, respectively, the organization and staffing of the regulatory body [2], regulatory review and assessment [3], and regulatory inspection and enforcement [4].

OBJECTIVE

1.4. The purpose of this Safety Guide is to provide recommendations for regulatory bodies and operators on the documentation to be prepared for regulatory processes for nuclear facilities, and on how to ensure that such documentation is of sufficient quality and provides correct information in an appropriate way to serve its intended purpose.

SCOPE

1.5. This Safety Guide covers the documentation required in the regulatory process for nuclear facilities such as enrichment plants and fuel manufacturing plants, nuclear

power plants, other reactors such as research reactors and critical assemblies, spent fuel reprocessing plants, and radioactive waste management facilities such as treatment, storage and disposal facilities. This Safety Guide also covers issues relating to the decommissioning (or closure) of nuclear facilities.

STRUCTURE

1.6. Section 2 presents an overview of documentation and Section 3 covers aspects of regulations and guides. Sections 4 and 5 cover documents to be produced by the operator and by the regulatory body, respectively. The appendix provides an outline of the authorization process.

2. OVERVIEW OF DOCUMENTATION

GENERAL

2.1. Certain formal documents will be required for the regulatory process by the laws and regulations of the State or by the rules of the regulatory body. Other formal documentation will be provided in response to specific requests from the regulatory body or at the initiative of the operator or other parties involved. The regulatory body itself will also produce and disseminate many documents, some of which will form the basis for its decisions. The records of official meetings and hearings could also constitute a means of formally exchanging information.

2.2. The regulatory body should maintain a record of all documents received or sent out, which should indicate from whom the documents were received or to whom they were sent, and should state what action was required and the result of that action.

2.3. The regulatory body should specify the purposes of the various regulatory documents necessary for it to perform its functions. The documents may be categorized as comprising:

— legislation;
— regulations, licences and other mandatory documents;
— guides and other advisory documents.

2.4. The regulatory body should also identify other documents that are required to be developed both by the regulatory body itself (see paras 2.27–2.29 and Section 5) and by the operator (see paras 2.25–2.26 and Section 4). In addition, industrial standards (see paras 2.23–2.24) developed by organizations working in various technological fields may be proposed by the operator in the authorization process, or may be referenced by the regulatory body in regulations and guides or in licence conditions (see paras 2.20–2.22).

2.5. The number of documents and their designations will vary substantially among States, depending on the legal system and on regulatory and industrial practices. This Safety Guide provides general guidance on the basis of a proposed system as described in this section, but it is recognized that other systems may also be effective in providing adequate control over nuclear safety. All documents prepared should be covered by the quality management system of the regulatory body.

LEGAL FRAMEWORK

2.6. "In order to fulfil its statutory obligations, the regulatory body shall define policies, safety principles and associated criteria as a basis for its regulatory actions." (Ref. [1], para. 3.l)

2.7. In accordance with para. 3.2 of Ref. [1], in fulfilling its statutory obligations the regulatory body is required to perform the following functions relating to documentation:

- developing or adopting regulations and guides upon which its regulatory actions are based;
- reviewing and assessing submissions relating to safety from the operators, both prior to authorization and in all phases of the facility's lifetime;
- issuing, amending, suspending, revoking or terminating authorizations or licences, as appropriate, and setting licence conditions which have the force of law and thus function in a similar way to regulations;
- carrying out regulatory inspections;
- taking necessary enforcement action in the event of a violation of safety requirements.

2.8. It is assumed in this Safety Guide that legislation is in force under which the regulatory body is granted sufficient authority and resources to carry out the authorization process (see the appendix). Depending on the legal system, the regulatory

body itself may participate in the preparation of additional legislation, or in the review and amendment of existing legislation.

SYSTEM OF REGULATIONS AND GUIDES

2.9. "The system of regulations and guides shall be chosen so as to suit the legal system of the State, and the nature and extent of the facilities and activities to be regulated. Where regulations are not issued by the regulatory body, the legislative and governmental mechanisms shall ensure that such regulations are developed and approved in accordance with appropriate time-scales." (Ref. [1], para. 5.25)

Regulations

2.10. "The main purpose of regulations is to establish requirements with which all operators must comply. Such regulations shall provide a framework for more detailed conditions and requirements to be incorporated into individual authorizations." (Ref. [1], para. 5.26)

2.11. Regulations which have the force of law are issued either by the government or by the regulatory body on behalf of the government. The principal purpose of establishing a system of regulations is to codify safety requirements of general applicability. The regulations should specify the requirements for authorization of nuclear facilities and for ensuring the protection of workers, the public and the environment. They should establish at least those requirements considered by the regulatory body to be necessary for achieving and maintaining safety, and should cover all the major aspects to be dealt with at all stages of the authorization process.

2.12. By providing orderly procedures and clear statements of safety requirements, a system of regulations serves as a basis for the authorization process. It helps the regulatory body to establish, maintain and enforce an acceptable level of safety and assists it in carrying out its regulatory functions in a consistent and orderly manner.

2.13. The system of regulations should provide advance information to the operator on the requirements for each major stage of authorization. This will assist the operator to make sound plans and decisions with respect to safety in the siting, design, construction, commissioning, operation and decommissioning or closure of a nuclear facility.

2.14. It should be recognized that a system of regulations is no substitute for good engineering and good management practices. Unduly detailed formal regulatory requirements can inhibit engineering innovation and good management initiatives, and may even be counterproductive if they have the effect of relieving or tending to relieve the operator of the responsibility for safety. Only a serious concern for safety on the part of all those concerned, not limited to the obligation to meet regulatory requirements, will engender a true safety culture and bring about lasting resolutions of safety issues.

2.15. The system of regulations adopted should provide an appropriate balance between regulatory provisions that are:

(a) numerous and detailed enough to achieve and maintain safety, and
(b) flexible enough to permit their application to developing technologies and in new circumstances.

The extent to which detailed provisions are made in licence conditions (see paras 5.11–5.21) will depend upon the legal system and the licensing philosophy of the State concerned.

2.16. "Guides, of a non-mandatory nature, on how to comply with the regulations shall be prepared, as necessary. These guides may also provide information on data and methods to be used in assessing the adequacy of the design and on analyses and documentation to be submitted to the regulatory body by the operator." (Ref. [1], para. 5.27)

2.17. Guides, which are advisory in nature, should be established by or under the authority of the regulatory body. Their purpose is to provide detailed and specific information on acceptable technical and administrative approaches to satisfying the regulatory requirements established in the regulations. In issuing guides, recent developments should be taken into account, including technological advances that have been proved by experience or shown by research results to be capable of providing effective and reliable means of satisfying regulatory requirements.

2.18. A system of guides will help the regulatory body to maintain consistent practices in implementing its requirements. However, the regulatory body should refrain from prescribing specific solutions. The advisory status of a guide carries the implication that alternative approaches would be acceptable provided that the operator can demonstrate that the required level of safety will be achieved.

2.19. Guides can assist the operator:

— by clarifying the regulatory body's interpretation of regulations;
— by explaining the basis or rationale for regulations, and their applicability;
— by providing guidelines for procedures, or approaches for implementing regulations;
— by providing information on data and methods to be used in assessing the adequacy of the design of a nuclear facility, and on results of analyses and documentation to be submitted to the regulatory body by the operator.

Relationships between regulations, licence conditions and guides

2.20. Safety requirements that are common to a particular type of nuclear facility should be established in the regulations. Other requirements, such as those applicable for only a short duration or relating to particular site characteristics, should be specified in the licence conditions.

2.21. In determining whether a particular topic should be made mandatory and thus be addressed in a regulation rather than a guide, consideration should be given to the regulatory requirements and the extent to which the topic in question can be considered as essential for implementing these requirements. Alternatively, a subject can be made mandatory by its inclusion in the licence conditions.

2.22. The regulatory body may facilitate its task if, instead of attempting to issue many detailed regulations, it establishes some of the provisions in the form of guides to advise the operators of ways of meeting more general regulatory requirements. Since guides are advisory, they allow the operator more flexibility in applying new technologies and developing new procedures which, in some cases, may enhance safety. They also allow the regulatory body to promote learning by modifying its guides to include innovative good practices and to revoke impractical or unnecessary features.

INDUSTRIAL STANDARDS

2.23. Industrial standards are developed by organizations working in various technological fields, generally independently of the regulatory body, although the regulatory body may be represented. Industrial standards describe technical solutions, products and services to a high level of detail. They may also be developed by specific operators and their suppliers. The industrial standards to be used by the operator and/or designer of a nuclear facility may require the approval or consent of the regulatory body.

2.24. Regulations and guides may incorporate, by reference, relevant industrial standards (in their entirety or in part) so as to provide an effective and reliable means of meeting the safety requirements. Compliance with industrial standards may also be made mandatory by specific references in the licence conditions. In all these cases the edition of the industrial standard to be used should be specified and consideration should be given to the question of whether to change the relevant regulations, licence conditions or guides if the standards are revised.

DOCUMENTS PRODUCED BY THE OPERATOR

2.25. Essential documents to be prepared by the operator in the authorization process should be identified in the regulations and guides issued by the regulatory body. Additional documents may be requested as needed, depending on the type of facility concerned as well as on the specific stage of the authorization process.

2.26. Documents of different types are required to be prepared by the operator in discharging its responsibilities with respect to the safety of the facility. Some of these documents are required to be submitted formally to the regulatory body for review and assessment in the course of the authorization process. Other documents are reports that should be submitted to the regulatory body periodically, or event, incident or accident reports to keep the regulatory body fully informed of the conditions prevailing at the facility. A third type of document is for internal use by the operator but should be made available upon request to the regulatory body to ensure its complete understanding of the design and operation of the facility, so that it can confirm that the requirements established in the regulations and licensing conditions have been fulfilled.

INTERNAL GUIDANCE AND PROCEDURES OF THE REGULATORY BODY

2.27. The regulatory body should establish its own set of internal guidance documents which describe its functions and the methods of performing them. For a regulatory body with responsibilities covering several facilities of the same type, it may be useful to develop written procedures that will make the authorization process consistent among its several technical groups, and among similar facilities. The internal guidance documents prepared should be covered by the regulatory body's quality assurance programme. This should include, among other things:

— review and assessment procedures;
— inspection procedures;

— general procedures for the development of regulations and guides;
— procedures for issuing, amending, suspending, revoking and terminating licences;
— enforcement procedures;
— procedures for issuing public information, with account taken of the confidential nature of some information and the security of the facility.

Documents produced by the regulatory body for a specific facility

2.28. A programme for the production of documents for specific facilities should be established by the regulatory body. This programme should include the development of:

— procedures describing the review and assessment process, documents to be generated in the course of this process, and the corresponding level of internal review and approval;
— procedures describing steps to be taken in the preparation of an inspection, the conduct of inspections, and the preparation of inspection reports as well as their review, approval and distribution;
— a system to control the status of identified deficiencies in order to ensure that corrective actions are taken in a timely manner, commensurate with the potential impact on the safety of the facility.

2.29. The licence is the principal document produced by the regulatory body that relates the legal framework of the regulatory system, (that is, laws and regulations) to the responsibilities of the operator of a facility at each stage of the authorization process. Licence conditions are incorporated into the licence, as necessary, in order to impose additional specific obligations with the force of law. Procedures for preparing a licence for each phase and type of facility should be prepared, in order to ensure that all necessary steps have been taken prior to the issue of a licence.

3. REGULATIONS AND GUIDES

GENERAL

3.1. A systematic approach should be adopted for the production of regulations and guides, and the regulatory body's quality management should cover these activities.

Procedures should be developed which establish the general method for the development and review of regulations and guides, in accordance with the State's legal system. These procedures should cover the composition of working groups and the drafting and review procedure, including the required legal support. The procedure for formal approval and promulgation of the regulations and guides should be established in accordance with the legal system of the State concerned.

3.2. The establishment and periodic review of a system of regulations and guides tailored to the specific needs of a State entail a continuing effort. They constitute an integral part of the activities of the regulatory body prior to the authorization process and in the preparation of a periodic safety review. The scope and content of a system of regulations and guides that is sufficient to fulfil the needs of the regulatory body and the operators will emerge gradually and will change over time.

3.3. "In developing regulations and guides, the regulatory body shall take into consideration comments from interested parties and the feedback of experience. Due account shall also be taken of internationally recognized standards and recommendations, such as IAEA safety standards." (Ref. [1], para. 5.28)

Extent and timing

3.4. The extent and detail of the system of regulations and guides established or adopted by the regulatory body will depend on several factors, including:

— the regulatory philosophy and the level of detail with which regulatory controls will be applied;
— the nature of the nuclear programme, including the types of facilities and the number of operators, and the extent of regulatory experience with the technologies utilized;
— the risks posed by the facilities.

3.5. Although the development effort may be lengthy, basic regulations should be established at an early stage. A range of engineering factors and also judgement or probabilistic safety assessments may contribute to setting priorities for topics to be covered by additional and more detailed regulations and guides. These should be sufficiently comprehensive and should be kept up to date to ensure that all essential safety requirements can be considered in a systematic and orderly manner in the authorization process.

3.6. Information to be included in the regulations needed for a nuclear programme, which may comprise different types of facility, may be divided into three categories:

Category 1: safety objectives, principles and criteria;
Category 2: requirements for structuring and conducting the authorization process;
Category 3: technical and managerial requirements relating to the stages of the authorization process.

3.7. In initiating a State's nuclear programme, priority should be given to the establishment of regulations dealing with safety objectives, principles and criteria, in particular those relating to radiation protection (including dose limits) (para. 3.6, Category 1).

3.8. The requirements covering applications for authorization and the related documents (para. 3.6, Category 2) should be clearly defined from the outset. Initially these requirements may be limited to a single design of facility and may be expressed in a letter to an operator, possibly with reference to international requirements or regulations of other States. As a nuclear programme matures, however, a more standard and uniform procedure will be beneficial and should be used.

3.9. As regards technical and managerial requirements (para. 3.6, Category 3), at an early stage the safety considerations relating to site evaluation have priority, and for the purposes of design these considerations should include interactions between the facility and the site.

3.10. Regulations establishing general design criteria such as defence in depth, use of multiple barriers, redundancy and diversity should be developed first (para. 3.6, Category 2). Later, more detailed regulations or guides should be developed which cover the details of design requirements for systems, components and equipment, their functional and testing requirements, and the requirements for the analysis of normal operation and fault conditions[1] (para. 3.6, Category 3).

3.11. Requirements relating to quality assurance should also be covered by regulations and guides and should be applied early enough to ensure that adequate quality assurance systems are put in place by the operator for all phases of a facility's lifetime.

[1] Throughout this publication, the term 'fault condition' is used to cover all situations in which there is a deviation from operational states or reference conditions that results from postulated initiating events.

3.12. Requirements for operation, decommissioning or closure will have an impact on the design and construction of a facility. For this reason, safety objectives, principles and criteria covering these stages should also be established at an early stage. At a later stage, detailed regulations and guides should be developed to cover aspects such as the conduct of operations, training of staff, reporting requirements and emergency preparedness.

Prescriptive versus performance based regulations

3.13. The principal purpose in establishing a system of regulations is to codify safety requirements of general applicability. The development of any particular regulation will involve a balance between the need for flexibility (to permit easy adaptation of the regulation to developing circumstances and technology) and the need to include detailed requirements (to facilitate determination of whether the requirements have been met).

3.14. Performance based regulations specify primarily the overall safety objectives. Performance based regulations can be comparatively easy to develop and are focused on what is to be achieved in terms of protection and safety. By setting objectives rather than prescribing specific requirements, performance based regulations have the advantage that they will not need to be changed so frequently to reflect changing technology or new knowledge. In addition, the use of objectives will tend to promote continual safety related improvements and the search for better approaches by the operator. Performance based regulations need greater involvement by the operator in determining how objectives are to be met. The regulatory body should assess whether the intent of the regulations has been fulfilled by judging how the operator has interpreted these regulations in each specific situation. The preparation of regulatory guides that set out acceptable ways of meeting performance based regulations should be considered.

3.15. A prescriptive regulation is more specific than a performance based one and states how to achieve safety. Prescriptive regulations have the advantage of providing both the regulatory body and the operator with clearly defined provisions for a particular activity or situation. They prescribe the means and methods to be used in order to comply with regulatory requirements for achieving an adequate level of protection and safety. Prescriptive regulations reduce the time and skills necessary to perform a licensing review or conduct an inspection. They enable the authorization and inspection process to focus on verification of compliance. However, they are more difficult to prepare, needing more detailed and expert knowledge of the specific practice in question on the part of the regulatory body. They are narrowly applicable to a specific activity or situation and need to be regularly reviewed and amended, as

necessary, to keep pace with technological changes. One difficulty with prescriptive regulations is that they tend to limit the flexibility of the operator in achieving safety; in addition, they may not be of help in the development of a safety culture.

3.16. A regulatory system should include both types of regulations, striking an appropriate balance between performance based and prescriptive regulations (or guides) to match the anticipated workload and the skills of the regulatory body's staff.

PROCESS FOR DEVELOPING REGULATIONS AND GUIDES

3.17. In order to develop regulations and guides, the regulatory body should have two basic resources: qualified staff and information. The staffing requirements, the organization, the resources and the necessary liaison with other organizations for the development of regulations and guides are covered in Ref. [2].

Sources of information

3.18. The regulatory body should base its regulations and guides on national legislation and should utilize existing national regulations or industrial standards in areas relating to or adaptable to nuclear facilities as its initial sources of information. Other sources of information that should be considered in the development of regulations include:

- standards and recommendations prepared by international organizations such as the IAEA, the International Commission on Radiological Protection (ICRP), the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC);
- regulations, guides and other relevant information produced by regulatory bodies in other States;
- industrial standards developed in other States;
- experience in the nuclear industry;
- results of research in nuclear safety.

3.19. States embarking on a nuclear programme should consider adapting the IAEA's safety standards or regulations developed by other States, or a combination of these. The IAEA's safety standards are issued in the form of specific requirements and recommendations so as to facilitate their incorporation into regulations. The IAEA standards may be adopted individually or collectively. However, adaptation and rewording may be necessary, depending on the national legal system. IAEA safety

standards that are expressed in a general way may be implemented in a State by introducing appropriate requirements into regulations or by adapting the standards as national guides.

3.20. If regulations of other States, usually those of the State supplying a nuclear facility, are to be adapted, particular attention should be paid to the legal framework of that State. Owing to differences between States in legal and governmental infrastructures, and in the structure of industry and available resources, it is unlikely that the regulatory body will be able to adopt without revision regulations issued in another State. In adapting regulations and guides issued in other States, the regulatory body should ensure that it understands the regulations in terms of their technical background and significance, and the legal and regulatory framework in the State that issued them.

3.21. In adapting IAEA safety standards or regulations of other States, the regulatory body should:

— make its regulations compatible with its national legal and regulatory framework;
— include appropriate requirements specific to national conditions such as special site characteristics and electrical grid conditions;
— promptly evaluate amendments made to the reference regulations or standards and issue amendments to its own regulations as appropriate.

3.22. It should be noted that the nature of the national legal framework, more than any other single factor, will determine the form and content of the regulations and guides. Advice and support may be obtained from the IAEA and from other States. When the design of a nuclear facility originates in another State, it may be particularly useful to seek advice and support from the regulatory body of that State. The IAEA can, as appropriate, provide assistance to States on request.

3.23. The regulatory body may find it useful to set up advisory committees to advise on the need for regulations and on their technical content. A well founded committee can provide a valuable service to the regulatory body by helping to ensure that policies and regulations are clear, practicable and complete. For more details on the composition of advisory committees see Ref. [2], paras 3.30–3.32.

Legal support

3.24. The development and review of regulations and guides will, by its very nature, require professional legal support. This legal support can be provided by staff of the

regulatory body or by another governmental body, or it can be obtained by means of a contract. The regulatory body should be structured in such a way as to facilitate the interaction between legal functions and its technical and management functions. Functions that typically require professional legal assistance include:

— development of the basic nuclear legislation;
— development and review of regulations;
— checking of the compatibility of regulations;
— review of drafts of legislative documents.

3.25. The purpose of the review by legal staff is to ensure that regulations do not contain provisions that are beyond the jurisdiction and authority of the regulatory body, prohibited by or inconsistent with laws or other regulations, unclear or ambiguous, or otherwise unenforceable.

Procedures for the development of regulations and guides

3.26. The regulatory body should follow a consistent procedure for establishing, revising and revoking regulations and guides.[2] A general procedure should be prepared that details the general format and style of language to be used in developing the regulations and guides. This procedure should be distributed to members of drafting working groups and should be adhered to by all parties involved. Procedures should be efficient and flexible enough to permit revisions to be made so as to adapt to changing conditions or as justified by technological advances. Because of differences between States' legal systems and practices, it is impossible to provide detailed procedural guidance for establishing regulations that can be followed by all States. However, certain basic steps for establishing regulations can be specified. The procedure followed by the regulatory body for establishing regulations should include the following steps:

(1) Determination of the need for the regulation. The need for a regulation may arise from the regulatory body's activities in relation to its sets of responsibilties and functions as specified in Ref. [1]. Alternatively, the need may be identified as a result of a request or enquiry by an operator or its contractors. Additionally, regulations may be needed as a result of national debates or to meet international obligations.

[2] In some States a cost–benefit analysis is performed in connection with the development of regulations and guides.

(2) Setting the priority for development of the regulation. The regulatory body should consider the advantages and disadvantages of the proposed regulation, including such matters as risks associated with the type of facility, the need for improvements in safety, the number of operators to be affected, and the effect on the efficiency of the authorization process.
(3) Determination of the scope of the proposed regulation. This includes identification of the type of facility and the stage of the authorization process to be covered, as well as the technical topic to be addressed.
(4) Determination of the resources to be employed. This will depend on the resources available and on the time-scale for the preparation and establishment of the regulation.

These four steps should form the basis for a decision on whether or not to prepare the proposed regulation, including adoption or adaptation of regulations issued by others. A positive decision should be followed by these additional steps:

(5) Collection of information. The information necessary to prepare the proposed regulation should be collected.
(6) Drafting of the proposed regulation. The initial version of the proposed regulation may be drafted either by staff of the regulatory body, or by consultants or advisory committees.
(7) Review of the proposed regulation. Although practices vary widely, the initial version of the proposed regulation is usually reviewed by other staff of the regulatory body, including legal staff and special advisory committees, as appropriate. In some States, operators, nuclear industry organizations and other organizations participate in such reviews. The draft version may also be published with an invitation for comment from the public. Comments received as a result of the review should be analysed, evaluated and resolved as appropriate. Which-ever review process is adopted, a formal procedure should be established to ensure that advice on the proposed regulations is obtained from all parties concerned. A final decision with regard to the advice obtained should be made by the regulatory body before the regulation is finalized. At this stage, consideration should also be given to the implications of the regulation for existing facilities.
(8) Establishing and issuing the regulation. The regulation should be established and promulgated in a manner which makes it legally binding under the national legal system, thereby ensuring that its provisions can be enforced by the regulatory body.

3.27. The procedures for issuing safety guides should follow steps similar to those for regulations. However, a guide can be formally issued with a lower level of approval, since its contents are only advisory in nature.

REVIEW AND REVISION OF REGULATIONS AND GUIDES

Review procedures for regulations and guides

3.28. The regulatory body should ensure that regulations and guides are kept up to date, and procedures should be established for their periodic review. Experience in implementing the regulations should be examined, and any problems or difficulties which may have arisen should be duly considered. The status of applicable requirements should also be examined in the light of new developments in relation to nuclear safety. The effect of too frequent changes on the stability of the regulatory system should be taken into account. However, events may occur which necessitate more frequent revisions. The reasons for revising regulations may include:

— changes in legislation;
— changes in the organization, responsibilities, policies or procedures of the regulatory body;
— experience gained by the regulatory body in the authorization process;
— feedback from events, incidents and accidents;
— major modification or refurbishment of a facility;
— results from research and development in fields relevant to safety;
— technological advances;
— the need to improve or revoke impracticable, misleading, unenforceable or otherwise inadequate regulations.

Procedures for the revision of regulations and guides

3.29. The procedures applicable in the establishment of regulations may also be followed for making any necessary revisions. Advice should be obtained from all parties concerned. Operators and others who may be affected by the revised regulation should be given adequate time to complete any preparations that may be necessary to enable them to comply with newly established requirements. A general procedure should be prepared that details the general format and style of language to be used in revising regulations and guides. This procedure should be distributed to members of drafting working groups and should be adhered to by all parties involved. A review of the final draft for quality control should be carried out before formal approval. One way in which the regulatory body can do this is to publish the regulation in its revised form for comment in advance of the effective date.

3.30. The process and procedures established for the revision of regulations and guides should not diminish the authority of the regulatory body to take immediate action if required for reasons of safety.

Impact of the revision of regulations

3.31. In revising regulations, special care should be taken to ensure that no contradictions or inconsistencies arise between the retained and the revised parts of a regulation. The extent to which the proposed changes should be applicable to nuclear facilities that have already been authorized and the degree of backfitting to be required should also be considered.

4. DOCUMENTS TO BE PRODUCED BY THE OPERATOR

GENERAL

4.1. As discussed in paras 2.25–2.26, documents of different types have to be prepared by the operator in carrying out its responsibilities in respect of the safety of a facility. Where a contractor is used to prepare these documents, the operator is still responsible for their content and for ensuring that they are adequate and are covered by the quality assurance system. There are three categories of documents:

— documents required to be submitted to the regulatory body for formal approval at the various stages of the authorization process (paras 4.2–4.8);
— reports which should be submitted to the regulatory body periodically or, for events, incidents or accidents, should be specified in the regulations (paras 4.9–4.16);
— documents which should be prepared for the conduct of activities relating to the facility and which should be made available to the regulatory body upon request (paras 4.17–4.23).

DOCUMENTS TO BE SUBMITTED FOR THE AUTHORIZATION PROCESS

4.2. In applying for a licence, the operator should provide all relevant information describing the approach to safety in order to demonstrate that the facility will not present undue radiological risks to workers, the public and the environment. This should include proposed objectives, principles, criteria, standards and analyses in relation to nuclear safety for all stages of the authorization process. The aim should be to present the relevant information in such a way that the regulatory body can conduct the review and assessment process without needing to seek further information or clarification [3].

4.3. The basic information to be provided should cover each stage of the authorization process, including:

— a description of the site in terms of geography, demography, topography, meteorology, hydrology, geology and seismology;
— a description of the facility, including the layout of buildings and equipment;
— applicable safety regulations, guides and industrial standards;
— the safety concepts and criteria used in the design of the facility, including the classification of equipment, systems and components, the application of the defence in depth principle, the use of multiple barriers to prevent radioactive releases and the approach to issues relating to the human–machine interface;
— a description of the facility's systems and components, including their design criteria, the processes involved in their design, and the modes of operation and testing.

4.4. The results of an analysis of the normal operation of the facility and, for a waste disposal facility, of the long term period after closure should be provided to demonstrate the acceptability of the design, including a demonstration that radiation protection criteria, waste management requirements and effluent limits are met by the design.

4.5. The results of a safety analysis should be provided to demonstrate how the design of the facility and related operational procedures will contribute to the prevention of accidents and to the mitigation of the consequences of accidents if they do occur. The analysis should describe and evaluate the predicted response of the facility to postulated initiating events, both internal and external, which could lead to fault conditions. The analysis should be extended to relevant combinations of such disturbances, malfunctions, failures, errors and events. Consideration should be given to aspects such as the initial conditions assumed, the physical or mathematical models used and their correlation with experiments, and the method of presenting the results.

4.6. Such analyses should show the extent to which the operator can control or accommodate situations at the facility relating to various events and fault conditions. The limits and conditions for safe operation should be defined. If any part of the analysis has been independently reviewed by another organization, the results of this review should also be presented to the regulatory body. Additional recommendations and guidance on safety analysis are provided in Ref. [5].

4.7. Information regarding organizational matters should be formally presented for review and assessment by the regulatory body. It should include a description of the quality assurance system established to ensure that all items are designed, manufactured,

constructed, assembled, tested, qualified, operated, maintained and replaced in compliance with the relevant safety requirements. The information should cover topics such as:

— management structure and resources;
— quality assurance arrangements, including internal and external audits;
— the organizational structure for each stage of authorization;
— qualification and training of personnel;
— development of procedures;
— documents and records control.

4.8. Information on other plans and programmes that are established by the operator in support of its safety activities should also be submitted to the regulatory body for review and assessment. This includes areas such as:

— the radiation protection programme (including how to apply the 'as low as reasonably achievable' (ALARA) principle);
— the environmental monitoring programme;
— emergency preparedness;
— physical protection;
— fire protection;
— radioactive waste management;
— research and development in relation to the safe design, operation, decommissioning or closure of the facility;
— feedback of operating experience;
— the decommissioning (or closure) strategy.

REPORTING BY THE OPERATOR

4.9. The requirements for periodic reporting and progress reporting and the general criteria for notifying the regulatory body of events, incidents or accidents should be specified in regulations or licence conditions.

Periodic reporting and progress reporting

4.10. Reports should be required from the operator at set times or upon the completion of specific activities over the lifetime of the facility.

4.11. During the stage of site evaluation and construction, reports should be prepared to keep the regulatory body informed of the progress of the project. The reports should cover:

— the progress of site studies;
— the progress of construction;
— results of the pre-operational environmental monitoring programme.

4.12. During commissioning and operation, reports should be prepared to demonstrate to the regulatory body the continuing safety of the facility. The reports should cover:

— the results of commissioning tests;
— operational data, including data on the facility's output and performance;
— modifications;
— results of the radiation protection programme;
— results of the environmental monitoring programme;
— radioactive waste management.

4.13. In order to enable the regulatory body to consider the release of any facility from regulatory control, or to require institutional controls for the post-closure phase, reports should include details of:

— the amounts and destinations of radioactive waste resulting from the decontamination and dismantling programme;
— levels of residual activity in the facility;
— results of environmental monitoring and other performance confirmation programmes.

Where necessary owing to the nature of the facility (for example, for a waste disposal site), reports should also include details of:

— the overall waste inventory;
— the sealing arrangements;
— any institutional controls intended for the post-closure phase.

Notification and reporting of events, incidents and accidents

4.14. The operator should notify the regulatory body of any event considered significant to safety. The time limit for and type of notification should be established in regulations and should be commensurate with the severity of the event. Events that require notification may be specified in regulations or licence conditions.

4.15. Depending on the severity of the event or fault, an investigation should be carried out by the operator and a report prepared and submitted to the regulatory body

within a specified period of time. The report should cover details of the event, the findings of the investigation and proposals for corrective action.

Reporting of changes and modifications

4.16. During site evaluation and construction, any changes in the design or major non-conformances that may affect safety should be reported to the regulatory body prior to their implementation. Any major design deficiencies identified during commissioning or operation should also be analysed and reported.

RECORDS TO BE KEPT BY THE OPERATOR

4.17. The operator, having responsibility for the safety of the facility, should be required to keep records of all activities that are considered to be safety related. These records, although not formally submitted to the regulatory body for review and approval, should be made available upon request. Regulations or licence conditions should establish the types of records that should be kept and the periods for which they should be retained. In specifying the retention period, account should be taken of the possible future need to refer to these records and of the difficulties of regenerating the information.

Records of site evaluation and construction

4.18. The results of site evaluation studies (geological, meteorological and hydrological data, as well as results of the pre-operational environmental monitoring programme), construction design records, manufacturing records (including shop quality control results) and erection records (including quality control results and as-built design records) should be kept in accordance with established regulations or licence conditions. They may be useful later in the investigation of events or generic problems and in decommissioning.

Commissioning records

4.19. Records made during commissioning should include records of equipment and system tests, test procedures and test results. The results should be thoroughly evaluated by the operator, and the results of this evaluation should also be retained together with the test results. It is common practice for the regulatory body, which would normally closely monitor the commissioning of a facility, to review commissioning test results at each phase of the commissioning process before proceeding to

the next phase. The retention of documentation relating to commissioning tests should also be required by regulations.

Operational records

4.20. Operational records form the main documentation to be used in the routine monitoring of nuclear safety by the regulatory body. This monitoring is conducted through the system of regulatory inspections [4]. The documents to be retained by the operator for possible examination by the regulatory body should include:

— output and performance records of the facility;
— operating log books;
— inventories of fissile and radioactive materials;
— records of periodic calibration of equipment;
— records of periodic testing of equipment and systems;
— records of in-service inspections;
— records of preventive maintenance and repairs;
— records of personnel training;
— records of personnel radiation monitoring;
— records of radiation monitoring and contamination records for the facility;
— records of radioactive waste management;
— records of effluent discharges and of the environmental monitoring programme;
— records of fault conditions.

Records of modifications to the facility

4.21. All modifications relevant to safety and their evaluations should be recorded for possible re-examination. The regulatory body should periodically examine the complete set of modifications made to the facility in order to evaluate the effectiveness of the operator's control process and to ensure that all modifications relevant to safety have been submitted for approval, in accordance with applicable regulations.

Records and evaluation of events

4.22. The event evaluation process and its results should be recorded for all events above an established threshold of significance. Recorded events should be periodically reviewed by the operator to identify trends and possible deterioration of safety levels. The regulatory body should periodically examine the complete set of events in order to evaluate the effectiveness of the evaluation process, to ensure that

procedures for notification have been properly followed, and to review trends in the events recorded at the facility.

Decommissioning and licence termination records

4.23. The operator should maintain, for an agreed period of time, records of decommissioning actions and licence termination to provide a basis for examining safety related issues. These records should include records of any decisions taken with regard to the release of parts of the site before the initial site licence is terminated.

5. DOCUMENTS PRODUCED FOR A PARTICULAR FACILITY BY THE REGULATORY BODY

GENERAL

5.1. The regulatory body should treat the authorization process for each facility as a specific task which should generate specific documentation. This documentation may be similar to the documentation for similar facilities, but it should remain specific to the facility concerned. The documentation may be categorized according to the main continuous functions of the regulatory body, including review and assessment, inspection and enforcement.

RESULTS OF REVIEW AND ASSESSMENT

5.2. The review and assessment performed by the regulatory body are discussed in Ref. [3]. The documentation submitted by the operator as described in paras 4.2–4.8 should be evaluated for the review and assessment.

Records of information exchange between the regulatory body and the operator

5.3. The process of review and assessment is conducted by means of exchanges between the regulatory body and the operator, which should be formally recorded. The records will concern mainly:

— requests for additional information by the regulatory body;
— questions formulated by the regulatory body;

— responses by the operator (including those provided by its contractors);
— records of meetings between regulatory body staff and operator personnel.

5.4. These records should be kept in an organized way that permits retrieval according to different criteria such as subject, type, date or originator.

Documentation of review and assessment

5.5. At several stages of the authorization process a decision will have to be made on whether a licence should be granted. The regulatory body should record in the form of a report the basis for such a decision. This report should summarize the review and assessment performed by or for the regulatory body and should provide a clear conclusion about the safety of the authorized activity. Typically, the report should cover the following points:

— reference to the documentation submitted by the operator;
— the basis for the evaluation;
— the evaluations performed;
— conformance with regulatory requirements and guides;
— comparison with similar (reference) facilities;
— independent analysis performed by the staff of the regulatory body or by consultants on its behalf;
— conclusions with respect to nuclear safety;
— reasons for the decisions made;
— any additional conditions to be fulfilled by the operator.

RECORDS OF INSPECTION ACTIVITIES

5.6. The primary purpose of inspection reports is to record the results of all inspection activities in order to provide the basis for notification of the inspection findings to the operator. The format, content and distribution of inspection reports are discussed in Ref. [4], paras 4.29–4.39. Inspection findings should be forwarded to the operator so that the necessary corrective actions can be taken. In some States, the full inspection report is forwarded to the operator. Care should be taken not to identify individuals by their name or their post.

5.7. From time to time the regulatory body may find it useful to produce a composite report covering a type of facility or a specific aspect of inspection, drawing together findings from a number of relevant inspection reports.

RECORDS OF ENFORCEMENT ACTIONS

5.8. Enforcement actions should be taken in the event of non-compliance with the regulations. All enforcement actions should be recorded in accordance with an established procedure and with legal and regulatory practices. Whenever an enforcement action has to be taken urgently to ensure the protection of workers, the public and the environment, the action should be confirmed in writing as soon as possible (see Ref. [4], Section 5).

LICENCE DOCUMENT

5.9. The authorization process (see the appendix) is the principal mechanism connecting the legal framework of the regulatory system (laws and regulations) with the responsibilities of the principal parties concerned with the regulatory system (the regulatory body and the operator). As already mentioned, the principal purpose of regulation for a nuclear facility is to establish requirements, both technical and administrative, that apply to persons, activities and facilities involved in a nuclear power programme. Such regulations provide a basis for the more detailed requirements incorporated into licences. The licence may also refer to non-mandatory technical guides or industrial standards, in their entirety or in part, thus making them mandatory. The licence establishes, directly or by reference, conditions governing the safe performance of activities.

Format of licences

5.10. The format of a licence will depend upon the content of the authorization and the conditions deemed necessary by the regulatory body for a given stage of the authorization process in accordance with national legal procedures. For example, the licence may incorporate by reference the underlying documents and provide only the material necessary to define the basic terms not previously defined elsewhere. Thus, the format of a licence will vary not only among States, but also within a State, from stage to stage, and from licence to licence for a given stage. Consequently, this Safety Guide provides only general considerations for use by a State in determining which licence formats best meet its needs. However, the licence should contain information such as:

— Statutory authority. The licence should explicitly refer to the laws and regulations on which it is based.
— Issuing authority. The licence should identify the official designations of those who are empowered by law or regulation to issue the licence, whose signature

and stamp will appear on the licence, and to whom the operator will be accountable under the terms of the licence.

— Fulfilment of requirements. The licence should include a summary statement that all legal and technical requirements in respect of safety have been fulfilled and that the proposed activities can be carried out without undue radiological risk to workers, the public or the environment.
— Documentary basis. The licence should identify the documents provided by the operator in support of the application and those prepared by staff of the regulatory body in the review and assessment process, which together form the basis for issuing the licence.
— Relationship to other licences. The licence should indicate whether it is contingent upon a prior authorization or is a prerequisite for a future authorization.
— The operator. The licence should contain a precise identification of the individual or organization both legally responsible for the licensed activity and in day to day control of the facility.
— Period of authorization. The licence should state an effective date of authorization. It may also include a termination date, which may be based on a fixed term such as one or two years. Alternatively a period may be stated over which the assumptions underlying the licensing decision will remain valid and at the end of which the basis for licensing will be re-examined.
— Licensed activity. The licence should clearly describe in sufficient detail the nuclear facility, its location and the activities authorized.
— The operator's responsibility for compliance. The licence should contain an appropriate declaration that the operator has the responsibility for compliance with the legal requirements, regulations and conditions referenced or contained in the licence or in other references, if applicable. The licence should also state that this responsibility is not transferable.

Licence conditions

5.11. Licences should state explicitly, or should impose by reference or attachment, all conditions as determined by the regulatory body, which are obligations with which the operator is required to comply. Laws and practices relating to licensing vary between States. In some States, conditions are specified in the law and in regulations of the regulatory body, and are merely referenced in the licence, while in other States some or all conditions are stated explicitly in the licence.

5.12. Licence conditions should cover as appropriate all safety related requirements affecting the siting, construction, commissioning, operation and decommissioning or closure of the nuclear facility, so as to enable effective regulatory control. These

requirements should cover such important aspects as design, radiological protection, emergency procedures, modifications, quality assurance, operational limits and conditions, procedures, and authorization of operating personnel.

5.13. While the conditions may vary in format, there are certain basic qualities that should characterize the set of conditions so as to make them understandable and effective. Each condition should be consistent with all other conditions in that the fulfilment of one should not conflict with the fulfilment of another or with any other legal requirement. It may be useful to group the conditions into logical types, such as conditions which set technical limits and thresholds, conditions which specify procedures and modes of operation, conditions pertaining to administrative matters, conditions relating to inspection and enforcement requirements, and conditions pertaining to the response to abnormal circumstances.

General licence conditions

5.14. General licence conditions should include the following provisions:

(a) The operator shall provide the authorized representatives of the regulatory body with full access to personnel, facilities and records that are under the operator's control, when such access is deemed necessary by the regulatory body to verify compliance and to assess safety.
(b) The operator shall keep the regulatory body fully and continuously informed of any significant or potentially significant events or changes in the considerations, information, assumptions and expectations upon which the issue of the licence was based.
(c) The operator shall take such corrective actions or measures as the regulatory body may require in the interests of safety.
(d) The operator shall not extend its activities beyond those specifically authorized in the licence without the prior approval of the regulatory body.
(e) The operator shall develop, preserve, update and maintain a complete set of records relating to the safety of the facility, including those referenced in the applications and those required by law, regulations and the licence, and shall dispose of them only as authorized by the regulatory body.
(f) The operator shall carry out its activities in accordance with an approved quality assurance programme covering all stages of the authorization process, so as to provide a basic framework for ensuring that all activities are carried out with due regard for safety.
(g) The operator shall report on modifications to the facility in accordance with the requirements established by the regulatory body.

(h) The operator shall report on all accidents, incidents and events relating to safety as required by the regulatory body.

Licence conditions relevant to certain stages of the authorization process

5.15. In addition to those general licence conditions which are applicable to all licences, there are some conditions that are relevant only to licences issued at certain stages of the authorization process. The following listing is not all-inclusive, nor is it the only possible arrangement of such conditions, but it may be helpful in determining which conditions are relevant.

5.16. Site preparation. The regulatory body should specify the controls that the operator is required to exercise over the use of the site and the degree to which the operator may prepare the site without conducting activities which, under the laws and regulations of the State, require a construction licence.

5.17. Construction. When authorizing construction, there are several conditions which should be fulfilled to ensure that this stage can proceed in a manner that ensures safe operation of the nuclear facility. These conditions should include the following:

— The nuclear facility shall be designed and constructed in accordance with the relevant site parameters approved by the regulatory body.
— The nuclear facility shall be constructed in accordance with the design that has been approved by the regulatory body. The operator shall not deviate from the approved design in any way that might affect safety without the prior approval of the regulatory body.
— The operator shall initiate a radiological study of the region, including an appropriate baseline survey, prior to the start of operation.

Furthermore, at the time of authorizing construction, conditions may be imposed on the operator requiring that it obtain from the regulatory body additional approvals relating to the design of certain parts of the facility.

5.18. Commissioning. In authorizing the commissioning of a nuclear facility, the regulatory body should specify a number of conditions, including the following:

— Commissioning shall be carried out in accordance with a programme approved by the regulatory body.
— Completed structures, systems and components important to safety shall only be put into service once they have been inspected, tested and approved as being in accordance with the terms of the licence.

— The operator shall provide approved storage facilities for nuclear materials. The regulatory body may require that appropriate physical security measures be in effect before nuclear material is brought into the facility.
— Fissile or radioactive material shall only be brought onto the site with regulatory authorization.
— Beginning with the introduction of fissile and radioactive material into the facility, the operator shall operate the facility only under the control and supervision of authorized personnel using written procedures, in accordance with the operational limits and conditions approved by the regulatory body. Any changes made to these limits and conditions shall be approved by the regulatory body prior to their implementation.
— The operator shall have an approved emergency plan, co-ordinated with the other authorities involved in emergency preparedness.

5.19. Operation. In authorizing routine operation, the conditions imposed for commissioning (para. 5.18) should be appropriately amended in the light of commissioning results. The regulatory body should add conditions such as the following to the licence, as necessary:

— The operator shall not operate the facility outside the design limits authorized by the regulatory body.
— The operator shall have a procedure for modifications to be approved by the regulatory body in order to ensure that no part of the approved facility that is important to safety will be modified without the prior approval of the regulatory body.
— The operator shall ensure that the facility is subjected to in-service inspection and testing, to be carried out as specified for structures, systems and components important to safety, to a time schedule approved by the regulatory body.
— The operator shall ensure that the maintenance of safety related equipment and systems is carried out in accordance with a schedule approved by the regulatory body.
— Only changes given prior approval by the regulatory body shall be made to the approved arrangements, schedules, procedures and rules.
— The operator shall ensure that the facility is operated only under the control and supervision of authorized personnel in adequate numbers, that are acceptable to the regulatory body.

Other possible licence conditions relating to such matters as the liability of the operator in the event of accidents are not covered in this Safety Guide.

5.20. Decommissioning. In authorizing decommissioning of a facility, the regulatory body should take particular care in specifying requirements to ensure compliance, since the sanction of shutting down the facility or revoking the licence is unlikely to be effective at this stage. The regulatory body should examine a final radiological survey conducted by the operator. The radiological survey should be conducted after the completion of decommissioning activities to ensure that regulatory requirements are met prior to terminating the licence and releasing the site.

5.21. Closure. Following the closure of a waste disposal facility, continuing control, including environmental monitoring, may be necessary. Depending on national legislation, requirements may be specified in a post-closure licence held by the operator or responsibilities may be taken by a relevant national authority prior to agreeing to closure of the facility.

DOCUMENT CONTROL

5.22. The regulatory body should establish a system to control the preparation, review, approval, issuance, revision, distribution and storage of documents.

5.23. The document control system should be such as to ensure that regulatory staff are provided with up to date regulatory requirements and policies and are issued with the appropriate revisions of documents for use in their work. External documents that are products of the regulatory staff's work, such as regulations and guides or reports, should also be controlled and should be kept available. For further details, see Ref. [6].

REVIEW OF THE DOCUMENTATION SYSTEM

5.24 The effectiveness of the regulatory body's activities in relation to the documentation system should be assessed regularly by different methods such as management overview, internal audits and the use of quality indicators. Management should ensure that a suitable document approval process is established and adhered to.

5.25. Internal audits should be conducted to review the use of up to date versions of internal procedures and regulations as well as the use of controlled copies of documents that have been submitted to the regulatory body by the operator.

5.26. The effectiveness of the document control system should be evaluated on the basis of the capability of retrieving documentation under different conditions and for

different search criteria (such as by date, source, type or subject). Numerical indicators relating to the time necessary for retrieving the documentation may be established and monitored, and deviations may be recorded and corrected. Systems and conditions for the storage of records should also be reviewed periodically. Guidance on quality assurance for document control and records is provided in Ref. [6].

Appendix

THE AUTHORIZATION PROCESS

GENERAL

A.1. Authorization is the principal mechanism connecting the legal framework of the regulatory system (the laws and regulations) with the responsibilities of the principal parties that are affected by the regulatory system (the regulatory body and the operator).

A.2. An authorization is a written permission for an operator to perform a specified activity or a set of activities dealing with the siting, design, construction, commissioning, operation, decommissioning or closure of a facility. It also establishes, directly or by reference, conditions governing the safe performance of these activities. Authorization could consist of, for example, a licence, certification or registration.

A.3. An important task of the regulatory body is the approval or rejection of applications for authorization on the basis of its review and assessment. To obtain an authorization for a facility, the operator submits adequate information to the regulatory body for its review and assessment. Approval of an application by the regulatory body is formalized by granting an authorization to the operator in accordance with the laws and regulations of the State concerned.

A.4. The granting of an authorization does not restrict or preclude subsequent amendment, suspension or revocation of that authorization by the regulatory body within the period of its validity. Once it has been issued, however, the terms of the authorization, including any conditions attached thereto, are binding on the operator unless and until amended, suspended or revoked by the regulatory body. A request for an amendment may be initiated by the operator, or an amendment may be imposed by the regulatory body in the interest of safety. A modification of the authorization may be desirable or necessary as a result of proposed changes relating to the facility, experience from the facility itself or elsewhere, or technological advances, or as a consequence of research and development relating to nuclear safety.

SIGNIFICANT REGULATORY DECISIONS

A.5. Review and assessment by the regulatory body give rise to a series of decisions in the authorization process. Not all of these decisions necessarily result in the

granting of a formal authorization to the operator. However, at the conclusion of one or more stages, the regulatory body takes an official action which may result in the granting of an authorization.

A.6. The types and number of authorizations to be issued in connection with a particular facility vary between States. Some States, for example, issue only one authorization, followed by various amendments, additions and modifications, while others issue several authorizations at a number of intermediate points from site evaluation to decommissioning. Practices vary widely in terms of the number of authorizations issued and the points in time at which they are issued. Despite these differences in practice, several points can be identified, corresponding to the major stages of the authorization process, at which significant regulatory decisions are usually made and documents issued. It should be noted that some of these stages may be combined, depending on the nature of the facility and the laws and regulations of the State concerned.

APPROVAL OF THE SITE

A.7. For a facility that is to be installed at a permanent site, at some point a decision has to be reached on the acceptability of the site from the safety point of view, after information on the site itself and preliminary information on the facility and its interaction with the site has been reviewed and assessed.

AUTHORIZING CONSTRUCTION, MANUFACTURE AND INSTALLATION

A.8. Construction, manufacture or installation of the facility shall not be authorized until the basic design has been reviewed and assessed, including verification of the compatibility of the design with the site, as appropriate.

AUTHORIZING COMMISSIONING

A.9. There is some overlap between the construction and commissioning stages in that individual structures, systems and components may be commissioned before completion of the entire facility. There are several steps in the commissioning process for which the regulatory body may require the operator to obtain prior approval and at which regulatory decisions may be made. However, the introduction of fissile and radioactive material into the facility marks a significant step in the commissioning procedure and is often considered the main point at which regulatory decisions are

made at this stage. Introduction of fissile and radioactive material shall not be authorized until the proposed commissioning programme has been reviewed and assessed, preliminary operational limits and conditions have been established, the final design has been assessed and conformity of the construction with the design of related systems has been verified.

AUTHORIZING OPERATION

Initial routine operation

A.10. Commencement of routine operation shall only be authorized once commissioning tests have been completed and their results assessed, and operational limits and conditions have been reviewed and assessed by the regulatory body.

Routine operation

A.11. The regulatory body shall require the operator to provide evidence that in routine operation the facility is being operated in accordance with the safety requirements, in particular the operational limits and conditions. This evidence may be provided by means of reporting on operational parameters and occurrences relevant to safety. The regulatory body shall review and assess the reports, and shall perform inspections to ensure that the facility complies with the safety requirements and is fit to continue in operation.

Return to operation after an outage

A.12. Before bringing a facility back into operation following a major outage, the operator should demonstrate to the satisfaction of the regulatory body that the facility will be able to continue to operate in compliance with the safety requirements.

Periodic safety review

A.13. Over the full operational lifetime of a nuclear facility, the regulatory body shall require the operator to provide evidence at appropriate intervals, in the form of a safety reassessment termed a periodic safety review, that the facility is still fit to continue in operation. In many States, this reassessment period is around ten years for nuclear power plants. In the periodic safety review, account should be taken of the potential nature and magnitude of the associated hazards, operating experience, significant changes to safety standards, technical developments, and new safety related information from relevant sources. Depending on the national laws and

regulations and the outcome of the periodic safety review, the regulatory body may renew the authorization of the operator at this stage.

AUTHORIZING MODIFICATIONS

A.14. In any phase of the lifetime of a facility, the operator may wish to modify the existing design and operations. Any modification proposed that may have a significant effect on safety related aspects should be implemented only if it has been authorized. The proposal shall be subject to appropriate regulatory review and assessment.

AUTHORIZING DECOMMISSIONING OR CLOSURE

A.15. Decommissioning or closure shall only be authorized once the detailed plans and procedures to be used, the conditions to be observed during decommissioning or closure, and the proposed final state of the facility, including the radiological status, have been inspected, reviewed and assessed by the regulatory body.

A.16. Before the release of a facility from regulatory control, the regulatory body should review and assess the evidence for the following:

— that all responsibilities and liabilities have been discharged, particularly for waste disposal facilities;
— that any necessary institutional controls, including continuing environmental monitoring programmes, are in place;
— that the final radiological status of the facility is fully documented;
— that such documentation is made publicly available.

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GLOSSARY

assessment. The process, and the result, of analysing systematically the hazards associated with sources and practices, and associated protection and safety measures, aimed at quantifying performance measures for comparison with criteria.

authorization. The granting by a regulatory body or other governmental body of written permission for an operator to perform specified activities. Authorization could include, for example, licensing, certification and registration.

closure. Administrative and technical actions directed at a repository at the end of its operating lifetime — e.g. covering of the disposed waste (for a near surface repository) or backfilling and/or sealing (for a geological repository and the passages leading to it) — and termination and completion of activities in any associated structures.

commissioning. The process during 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.

decommissioning. Administrative and technical actions taken to allow the removal of some or all of the regulatory controls from a facility (except for a repository which is closed and not decommissioned).

enforcement. The application by a regulatory body of sanctions against an operator intended to correct and, as appropriate, penalize non-compliance with conditions of an authorization.

inspection. An examination, observation, measurement or test undertaken to assess structures, systems, components and materials, as well as operational activities, processes, procedures and personnel competence.

licence. A legal document issued by the regulatory body granting authorization to perform specified activities related to a facility or activity.

operator (operating organization). Any organization or person applying for authorization or authorized and/or responsible for nuclear, radiation, radioactive waste or transport safety when undertaking activities or in relation to any nuclear facilities or sources of ionizing radiation. This includes, inter alia,

private individuals, governmental bodies, consignors or carriers, licensees, hospitals, self-employed persons, etc.

regulatory body. 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, radiation, radioactive waste and transport safety.

repository. A nuclear facility where waste is emplaced for disposal.

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