

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

Under the terms of Article III of its Statute, the IAEA is authorized to establish standards of safety for protection against ionizing radiation and to provide for the application of these standards to peaceful nuclear activities.

The regulatory related publications by means of which the IAEA establishes safety standards and measures are issued in the **IAEA Safety Standards Series**. This series covers nuclear safety, radiation safety, transport safety and waste safety, and also general safety (that is, of relevance in two or more of the four areas), and the categories within it are **Safety Fundamentals**, **Safety Requirements** and **Safety Guides**.

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www.iaea.org/ns/coordinet

or on request to the Safety Co-ordination Section, IAEA, P.O. Box 100, A-1400 Vienna, Austria.

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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".

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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. 3.1)

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 life-time;
- 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: