

# IAEA SAFETY STANDARDS SERIES

## Review and Assessment of Nuclear Facilities by the Regulatory Body

### SAFETY GUIDE

No. GS-G-1.2



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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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**Safety Requirements** (red lettering) establish the requirements that must be met to ensure safety. These requirements, which are expressed as 'shall' statements, are governed by the objectives and principles presented in the Safety Fundamentals.

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[www.iaea.org/ns/coordinet](http://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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# REVIEW AND ASSESSMENT OF NUCLEAR FACILITIES BY THE REGULATORY BODY

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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 the siting, 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.*

# CONTENTS

|    |                                                                                     |    |
|----|-------------------------------------------------------------------------------------|----|
| 1. | INTRODUCTION .....                                                                  | 1  |
|    | Background (1.1–1.3) .....                                                          | 1  |
|    | Objective (1.4) .....                                                               | 1  |
|    | Scope (1.5) .....                                                                   | 2  |
|    | Structure (1.6) .....                                                               | 2  |
| 2. | REVIEW AND ASSESSMENT PROCESS .....                                                 | 2  |
|    | Objectives of review and assessment (2.1–2.2) .....                                 | 2  |
|    | Management of review and assessment (2.3–2.5) .....                                 | 3  |
|    | Scheduling of submissions (2.6) .....                                               | 5  |
|    | Different stages of the authorization process (2.7–2.25) .....                      | 5  |
|    | Organization and technical resources for review<br>and assessment (2.26–2.29) ..... | 11 |
|    | External relationships (2.30–2.39) .....                                            | 12 |
| 3. | PERFORMANCE OF THE REVIEW AND ASSESSMENT<br>PROCESS .....                           | 14 |
|    | General (3.1) .....                                                                 | 14 |
|    | Internal guidance (3.2) .....                                                       | 15 |
|    | Review and assessment plan (3.3–3.8) .....                                          | 15 |
|    | Documentation to be submitted by the operator (3.9–3.14) .....                      | 17 |
|    | Bases for decisions (3.15–3.20) .....                                               | 18 |
|    | Bases for review and assessment (3.21–3.39) .....                                   | 19 |
|    | Verification of the safety analysis (3.40–3.62) .....                               | 24 |
|    | Regulatory inspection for review and assessment (3.63–3.64) .....                   | 32 |
|    | Records of the regulatory body’s review and assessment (3.65) .....                 | 32 |
|    | Documentation produced by the regulatory body (3.66) .....                          | 33 |
|    | Research and development initiated by the regulatory body (3.67–3.68) .             | 33 |
| 4. | MONITORING OF THE REVIEW AND ASSESSMENT<br>PROCESS (4.1–4.2) .....                  | 34 |
|    | APPENDIX: TOPICS TO BE COVERED BY REVIEW AND<br>ASSESSMENT .....                    | 35 |

REFERENCES ..... 42

GLOSSARY ..... 43

CONTRIBUTORS TO DRAFTING AND REVIEW ..... 45

BODIES FOR THE ENDORSEMENT OF SAFETY STANDARDS ..... 46

# 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 well defined responsibilities and functions. Review and assessment of submissions on safety from the operator of a nuclear facility are among the principal functions of such a 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 such an infrastructure. These include requirements in respect of the establishment of an independent regulatory body for nuclear facilities and the responsibilities and functions to be assigned to it.

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

## OBJECTIVE

1.4. The purpose of this Safety Guide is to provide recommendations for regulatory bodies on reviewing and assessing the various safety related submissions made by the operator of a nuclear facility at different stages (siting, design, construction, commissioning, operation and decommissioning or closure) in the facility's lifetime to determine whether the facility complies with the applicable safety objectives and requirements<sup>1</sup>.

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<sup>1</sup> Throughout this publication, the term 'safety objectives' is used to mean 'safety objectives, safety principles and safety criteria'.

## SCOPE

1.5. This Safety Guide covers the review and assessment of submissions in relation to the safety of nuclear facilities such as: enrichment and fuel manufacturing plants; nuclear power plants; other reactors such as research reactors and critical assemblies; spent fuel reprocessing plants; and facilities for radioactive waste management, such as treatment, storage and disposal facilities. This Safety Guide also covers issues relating to the decommissioning of nuclear facilities, the closure of waste disposal facilities and site rehabilitation.

## STRUCTURE

1.6. Objectives, management, planning and organizational matters relating to the review and assessment process are presented in Section 2. Section 3 deals with the bases for decision making and conduct of the review and assessment process. Section 4 covers aspects relating to the assessment of this process. The Appendix provides a generic list of topics to be covered in the review and assessment process.

# 2. REVIEW AND ASSESSMENT PROCESS

## OBJECTIVES OF REVIEW AND ASSESSMENT

2.1. The basic objective of review and assessment is to determine whether the operator's submissions demonstrate that the facility complies throughout its lifetime with the safety objectives stipulated or approved by the regulatory body.

2.2. The specific objectives of the review and assessment will depend on the stage of the lifetime of the facility. Examples of these specific objectives include the following:

- (a) To determine whether an operator has the ability and resources (in particular, the funding arrangements for decommissioning) to discharge its obligations associated with any authorization granted for any stage of the lifetime of the facility.
- (b) To determine whether the site chosen is suitable for the proposed facility, account being taken of the interaction between the site and the facility and of anticipated changes to the environment of the site during the proposed period of commissioning and operation; and to recommend to the appropriate authorities requirements in respect of the site surroundings that may be considered necessary by the regulatory body.

- (c) Before manufacture, construction, installation, commissioning, operation and decommissioning or closure: to determine whether proposals and commitments of the operator in respect of design, operation and decommissioning or post-closure meet the regulatory body's requirements, and to apply any further conditions or requirements that may be considered necessary by the regulatory body.
- (d) To determine whether the commissioning test programme is complete and contains a well defined set of operational limits, test acceptance criteria, conditions and procedures; whether the commissioning tests can be safely conducted; and whether the test results are adequate for confirming the adequacy of all safety related features of the facility.
- (e) To determine whether the operator uses an appropriate safety management system that meets the regulatory body's requirements.
- (f) To determine whether the operational limits and conditions are consistent with the regulatory body's requirements, the operational characteristics of the facility, and the state of knowledge and operational experience; and to determine whether an adequate level of safety is being maintained.
- (g) To determine whether the operator's personnel meet the regulatory requirements, in terms of both number and competence.
- (h) To determine whether proposed modifications to the facility, at whichever stage in its lifetime, have been conceived and their implementation planned so that safety is not compromised.
- (i) To evaluate safety reviews performed by the operator.
- (j) To determine whether the operator's plans and commitments in respect of decommissioning meet the requirements of the regulatory body.
- (k) To determine whether the operator's plans and commitments in respect of the closure and post-closure stages for a disposal facility meet the requirements of the regulatory body.
- (l) To determine, if relevant, whether the performance indicators proposed by the operator are appropriate.
- (m) To determine whether the programme proposed by the operator for confirmation of performance is acceptable (this is particularly important for waste disposal facilities).
- (n) To determine whether any additional requirements (or licence conditions) have been fulfilled by the operator.

## MANAGEMENT OF REVIEW AND ASSESSMENT

2.3. Management within the regulatory body of the review and assessment process is an important part of the process. Consideration should be given to assigning

managerial responsibility to a single individual or organizational unit. The management of review and assessment should include responsibility for:

- (a) Planning and directing the review and assessment process;
- (b) Preparing the procedures to be followed in accordance with the overall quality management programme;
- (c) Co-ordinating all information exchange between the regulatory body and the operator;
- (d) For all documents sent or received, keeping a log to record the name of the sender and that of the recipient, the follow-up action necessary and the outcome of this action;
- (e) Monitoring the progress of documents submitted by the operator and the progress of the review and assessment process against the tentative programme agreed by the operator and the regulatory body (if there is such a programme);
- (f) Making the necessary arrangements whenever different parts of the regulatory body need to combine their expertise to make a decision in a timely manner;
- (g) Making arrangements for co-ordination between review and assessment activities and inspection activities, as appropriate;
- (h) Making arrangements for liaison with consultants, advisory committees or any other relevant organizations as appropriate, whenever these are called upon;
- (i) Facilitating consultation nationally with other regulatory bodies and governmental departments, where appropriate;
- (j) Collating and disseminating the overall findings of the regulatory body following the completion of the review and assessment process;
- (k) Planning for public consultation during the review process, as appropriate;
- (l) Planning for any hearing process at the end of the review and assessment process, as appropriate;
- (m) Qualification and training of the personnel engaged in the review and assessment process.

2.4. The IAEA Safety Requirements publication on Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety [1] establishes the following requirements. "A primary basis for review and assessment is the information submitted by the operator. A thorough review and assessment of the operator's technical submission shall be performed by the regulatory body in order to determine whether the facility or activity complies with the relevant safety objectives, principles and criteria. In doing this, the regulatory body shall acquire an understanding of the design of the facility or equipment, the safety concepts on which the design is based and the operating principles proposed by the operator, to satisfy itself that:

- (1) The available information demonstrates the safety of the facility or proposed activity;
- (2) The information contained in the operator's submissions is accurate and sufficient to enable confirmation of compliance with regulatory requirements; and
- (3) The technical solutions, and in particular any novel ones, have been proven or qualified by experience or testing or both, and are capable of achieving the required level of safety" (Ref. [1], para. 5.9.)

2.5. The review and assessment of nuclear facilities necessitate considerable amounts of work and resources, and appropriate plans should be made for these. The regulatory body should develop a programme to review and assess information provided by the operator (see Ref. [4], paras 4.2–4.8) or collected during its own inspections [3]. The co-operation of the operator should be obtained to ensure that review and assessment can be carried out in an effective and informed manner. In addition, information from other sources (such as incident reports from other States) which have a bearing on the safety of facilities should be reviewed and assessed.

## SCHEDULING OF SUBMISSIONS

2.6. The regulatory body should indicate to the operator the period of time that is considered necessary for the review and assessment process so as to facilitate the process and to minimize delays in the granting of any necessary authorizations. It is appropriate to reach agreement on an indicative schedule. In scheduling a review and assessment programme, the regulatory body should allow for the fact that the information initially submitted by the operator may be incomplete. In such cases, it will take time to obtain adequate information so that review and assessment in full can be initiated. In addition, important issues may arise, necessitating additional studies and leading to delays. Such factors may lead to large variations in the time necessary for review and assessment in a given stage of the lifetime of the facility. The operator should submit any additional information sought by the regulatory body within the stipulated time. The regulatory body should expend its best efforts to complete its review and assessment process in accordance with the agreed schedule, but this objective should in no way compromise the regulatory body's responsibilities.

## DIFFERENT STAGES OF THE AUTHORIZATION PROCESS

2.7. The authorization process (see Ref. [4], Appendix) is a continuing process which may start before the planning and feasibility study for the site and continue

through decommissioning or closure of the nuclear facilities until release from regulatory control. This section outlines the areas in which review and assessment should be concentrated. It is not sufficient to review and assess these areas in isolation; all relevant areas from previous decision points should be considered at each stage in the authorization process in order to ensure that the acceptability of the operator's submissions has not been compromised. A listing of the topics that should be considered in the review and assessment process throughout the lifetime of a facility is given in the Appendix.

2.8. As a practical matter, review and assessment of each area may start at an earlier stage and continue into subsequent stages. Also, depending on the arrangements made at the national level and the nature of the facility, review and assessment of some areas may be combined. Since this Safety Guide covers a wide range of types of facility, it is not possible to provide details of specific areas that should be subject to review and assessment at each stage of the lifetime of facilities of each type. However, this section provides a general overview of major areas for review and assessment; the degree to which the respective areas should be considered will depend on the nature of the facility and the risks associated with it.

## Site evaluation

2.9. In considering an application for siting, the regulatory body will tend to concentrate on the characteristics of the site and, as appropriate, the interaction between the proposed facility and the site. Site evaluation for many facilities is initially determined by processes not greatly influenced by highly prescriptive criteria. However, general requirements concerning remoteness, local population density and transport arrangements will apply. For waste disposal sites, geological and hydrogeological considerations will be major factors in site evaluation. It is likely that for such sites the regulatory body may be involved in the formulation of site selection criteria and in the process of determining the suitability of a site (see Refs [5–7]).

2.10. In all cases, the site of the facility should be qualified by review and assessment to determine the potential interaction between the proposed facility and the site and to assess the suitability of the site from the point of view of safety. This site review and assessment may be performed in parallel with the design review and assessment or may, as in some States, be performed at an earlier stage. Areas of review and assessment which are of particular significance are the implications of the local environment, natural and human made, for the facility's safety and the demands that the facility would make on the local infrastructure.

2.11. For waste disposal facilities, the geological barrier is an important element of the very long term assurance necessary. The arguments to be made will depend on an understanding of the natural environment. Such an understanding is unlikely to be complete at this stage and should be reinforced and confirmed in the construction and operational stages to provide the technical basis and gain the public confidence necessary. The process of review and assessment of the site qualification could take many decades and indeed may last into a period of institutional control following closure of the facility.

### **Design, construction, manufacture and installation**

2.12. Before authorization of construction of the facility, review and assessment will be concentrated on the operator's approach to safety and safety standards, and how these have been applied in developing the design. Features such as the physical layout and the construction of the facility and the key process elements should be carefully considered, and their effects on the safety of the facility throughout its lifetime should be assessed at the design stage. In addition, before authorizing construction, the regulatory body should review and assess the operator's arrangements for the control of activities in construction, manufacture and installation. Once construction has started, many features of the design can be changed only with great difficulty. An outline plan for decommissioning, covering issues such as strategies to be used, radiation doses to be expected and amounts of waste to be produced, should be prepared by the operator at the design stage. The plan should be subject to review and assessment by the regulatory body.

2.13. Review and assessment of the design should continue during construction, manufacture and installation as the details become finalized. Changes to the authorized design at this stage should be analysed by the operator and reported to the regulatory body, which should carry out the necessary review and assessment.

### **Commissioning**

2.14. Commissioning can be considered in two stages: inactive, before fissile and radioactive material is introduced, and active, after fissile and radioactive material has been introduced. Clearly, radiological risks arise only after the second stage has been started. Commissioning should be carried out in accordance with programmes which have been reviewed and assessed by the regulatory body, which should determine whether the as-built facility meets its requirements.

2.15. The inactive stage of commissioning is aimed at ensuring that the facility has been constructed, manufactured and installed correctly and in accordance with the