

IAEA SAFETY STANDARDS SERIES

Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body

SAFETY GUIDE

No. GS-G-1.3



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**.

Safety Fundamentals (blue lettering) present basic objectives, concepts and principles of safety and protection in the development and application of nuclear energy for peaceful purposes.

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www.iaea.org/ns/coordinet

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REGULATORY INSPECTION
OF NUCLEAR FACILITIES
AND ENFORCEMENT
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.

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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 well defined responsibilities and functions. One of the key functions of the regulatory body is inspection for monitoring compliance with regulatory requirements and, in the event of non-compliance, taking enforcement action to bring about compliance.

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. 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 inspection and enforcement; three related Safety Guides cover, respectively, the organization and staffing of the regulatory body [2], regulatory review and assessment [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 the inspection of nuclear facilities, regulatory enforcement and related matters. The objective is to provide the regulatory body with a high level of confidence that operators have the processes in place to ensure compliance and that they do comply with legal requirements, including meeting the safety objectives and requirements of the regulatory body. However, in the event of non-compliance, the regulatory body should take appropriate enforcement action.

SCOPE

1.5. This Safety Guide covers regulatory inspection and enforcement in relation to 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. Section 2 sets out the objectives of regulatory inspection and enforcement. Section 3 covers the management of regulatory inspections. Section 4 covers the performance of regulatory inspections, including internal guidance, planning and preparation, methods of inspection and reports of inspections. Section 5 deals with regulatory enforcement actions. Section 6 covers the assessment of regulatory inspections and enforcement activities. The Appendix provides further details on inspection areas for nuclear facilities.

2. OBJECTIVES OF REGULATORY INSPECTION AND ENFORCEMENT

2.1. “Regulatory inspection and enforcement activities shall cover all areas of regulatory responsibility. The regulatory body shall conduct inspections to satisfy itself that the operator is in compliance with the conditions set out, for example, in the authorization or regulations. In addition, the regulatory body shall take into account, as necessary, the activities of suppliers of services and products to the operator. Enforcement actions shall be applied as necessary by the regulatory body in the event of deviations from, or non-compliance with, conditions and requirements.” (Ref. [1], para. 5.12.) Inspection by the regulatory body shall not relieve the operator of its responsibility for ensuring nuclear safety.

2.2. The principal objectives of regulatory inspection and enforcement are to provide a high level of assurance that all activities performed by the operator at all stages of the authorization process (see the Appendix in Ref. [4]) and all stages during the lifetime of a nuclear facility (siting, design, construction, commissioning, operation and decommissioning or closure) have been executed safely and meet the safety objectives and licence conditions.

2.3. Regulatory inspection is performed to make an independent check on the operator and the state of the facility, and to provide a high level of confidence that operators are in compliance with the safety objectives prescribed or approved by the regulatory body. This should be achieved by confirming that:

- (a) All applicable laws, regulations and licence conditions and all relevant codes, guides, specifications and practices are complied with;
- (b) The operator has a strong and effective management, good safety culture and self-assessment systems for ensuring the safety of the facility and the protection of workers, the public and the environment;
- (c) The required quality and performance are achieved and maintained in the safety related activities of the operator and in the structures, systems and components (SSCs) of the facility throughout its lifetime;
- (d) Sufficient numbers of personnel, who have the necessary competences for the efficient and safe performance of their duties, are available at all times and throughout all stages of the facility's lifetime;
- (e) Deficiencies and abnormal conditions are identified and promptly evaluated and remedied by the operator and duly reported to the regulatory body as required;
- (f) Any other safety issue that is neither specified in the authorization nor addressed in the regulation is identified and appropriately considered.

2.4. Regulatory inspection should include a range of planned and reactive inspections over the lifetime of a nuclear facility and inspections of other relevant parts of the operator's organization and contractors to ensure compliance with regulatory requirements. The methods of inspection should include examination and evaluation of the facility, procedures, records and documentation, and surveillance and interviewing of personnel, as well as tests and measurements. In addition to the regulatory body's staff, outside consultants may be used for inspection tasks. Regulatory inspections may be carried out by resident or non-resident inspectors, depending on the regulatory regime and the size of the State (Ref. [2], paras 3.20–3.22). The findings of regulatory inspections should be documented in inspection reports drawn up by the regulatory body. The technical bases for these reports — their scope, layout, content, timing and distribution — should be determined by the regulatory body. A programme to monitor and follow up inspection findings should also be in place.

2.5. Regulatory enforcement actions are actions taken to deal with non-compliance by the operator with specified conditions and requirements. These actions are intended to modify or correct any aspect of an operator's procedures and practices or of a facility's SSCs as necessary to ensure safety. Enforcement actions may also include the imposition or recommendation of civil penalties and other sanctions.

LEGAL AUTHORITY

2.6. In accordance with Ref. [1], the regulatory body shall be granted legal authority for conducting and co-ordinating inspection and enforcement actions during site

evaluation, design, construction, commissioning, operation and decommissioning or closure of nuclear facilities under its authority.

2.7. With regard to regulatory inspection, the regulatory body shall have the authority to:

- Establish regulations and issue guidance which, among other things, will serve as the basis for inspection;
- Enter the premises of any facility that is subject to any stage of the regulatory process or any related establishment at any time for the purposes of inspection;
- Require the preparation of, access to and submission of reports and documents from operators and their contractors when necessary;
- Seek the co-operation and support of other governmental bodies and consultants with competences or qualifications relevant to regulatory inspections;
- Communicate information, findings, recommendations and conclusions from regulatory inspections to other governmental bodies or interested parties, including high level officials, as appropriate in view of the significance of the issue.

2.8. The regulatory body shall have the authority and powers necessary to carry out its inspections. However, the co-operation of the operator should be forthcoming to ensure that the regulatory inspection can be carried out in an effective, informed and unhindered manner. The operator shall give inspection personnel free and prompt access to any area of the facility and its site for the purposes of regulatory inspection. The only necessary limitation to this requirement may arise when the operator can demonstrate that such access would give rise to a hazard. The operator should also provide regulatory inspectors with free and prompt access to all personnel at the nuclear facility and to all relevant documentation. The operator should additionally make appropriate arrangements to provide personnel conducting a regulatory inspection with access to its contractors and consultants where such access is deemed necessary by the regulatory body for the discharge of its responsibilities for inspection. Any findings from an inspection should be formally communicated to the operator.

2.9. With regard to enforcement, the regulatory body shall have the authority:

- to require the operator to take action to remedy deficiencies and prevent their recurrence, to curtail activities or to shut down the facility when the results of a regulatory inspection or another regulatory assessment indicate that the protection of workers, the public and the environment might be inadequate;

- to impose or recommend civil penalties or other sanctions for non-compliance with specified requirements.

2.10. The regulatory body shall be given adequate powers and authority to enforce compliance with its requirements and licence conditions, and should have available a number of methods of enforcement to provide the flexibility to use the method best suited to the seriousness of the violation and the urgency of corrective actions. The degree of authority of the regulatory inspectors should be clearly specified and clear administrative procedures should be adopted and implemented.

3. MANAGEMENT OF INSPECTION

3.1. The management within the regulatory body of inspection activities is an important element of the authorization process. Consideration should be given to assigning managerial responsibility to a single individual or organizational unit. These responsibilities should include:

- programming inspection activities;
- developing guidelines for inspection;
- determining the type of inspection;
- determining the resources to be used in an inspection;
- making the necessary arrangements for the co-ordination of inspection activities with the regulatory review and assessment process, particularly where there is a tentative agreement between the operator and regulatory body (if such an agreement exists);
- making arrangements for co-ordination with consultants or other organizations, as appropriate;
- maintaining a record of inspection activities;
- ensuring that follow-up actions from inspections, including dissemination of findings, are taken;
- ensuring that the findings from an inspection at a particular facility are fed back to inspectors involved in inspections at similar facilities;
- qualification and training of inspectors.

3.2. Specific responsibilities of the regulatory body in respect of inspection and enforcement include:

- conducting planned inspections at all stages of the authorization process;

- carrying out reactive inspections, if appropriate, in response to events, incidents or accidents;
- identifying and recommending necessary changes to the requirements approved by the regulatory body, specified in the authorization or contained in the regulations;
- preparing reports to document its inspection activities and their findings;
- verifying the operator's compliance with regulatory requirements and confirming adherence to safety objectives;
- ensuring that the operator has adequate, comprehensive and up to date information on the status of the facility and information for demonstrating its safety, and a procedure to maintain this information up to date;
- verifying that corrective actions have been undertaken by the operator to resolve safety issues identified previously;
- tracking recurrent problems and non-compliance;
- developing such procedures and directives as may be necessary for the effective conduct and administration of the inspection programme;
- determining and recommending suitable enforcement actions when non-conformance with requirements is encountered.

3.3. “Inspection by the regulatory body, both announced and unannounced, shall be a continuing activity.” (Ref. [1], para. 5.15.) The major activities of the inspection process are related to the stages of the authorization process. The regulatory body should organize and modify its inspection activities to conform to the stage of the facility's lifetime in order to make the most effective and efficient use of resources for inspections. Specifically, as a facility passes from one stage to another, the regulatory body will normally find it necessary:

- to adjust the levels of attention given to particular inspection areas and to redeploy its human resources accordingly;
- to alter the extent to which various inspection techniques and methods are employed;
- to modify the rigour and frequency of the inspections.

TYPES OF INSPECTION

3.4. The regulatory body should conduct two general types of inspection, namely planned inspections (including special inspections) and reactive inspections. Inspections may be conducted by individuals or teams and may be announced or unannounced, as part of a general programme or with specific aims.

Planned inspections

3.5. Planned inspections are carried out in fulfilment of, and in conformity with, a structured and largely prearranged or ‘baseline’ inspection programme developed by the regulatory body. They may be linked to operator schedules for the performance or completion of certain activities at all stages of the authorization process. Planned inspections differ from reactive inspections in that they are scheduled in advance by the regulatory body and are not initiated because of unusual or unexpected circumstances. Planned inspections provide an opportunity for the examination of the operator’s activities in order to confirm the operator’s performance and to identify potential problems at an early stage. Considerations in relation to performing planned inspections should include:

- the requirements of the authorization regime;
- the safety significance of the areas to be inspected;
- the operator’s overall performance in the areas to be inspected;
- operational experience and lessons learned from events or problems at other facilities or in other States.

3.6. In planned inspections, the observation and assessment of continuing safety activities are usually emphasized in order to assess the effectiveness of the operator’s performance. Less emphasis is usually placed on carrying out detailed ‘desktop’ reviews of programme descriptions and related procedures for reviewing paper-work.

3.7. Special inspections may be carried out to consider specific issues which may be of interest to the regulatory body, such as refurbishment, new findings from research and development work and experience from other facilities. Special inspections are usually in the category of planned inspections, since they are scheduled in advance; however, in certain circumstances they may be reactive inspections. This type of inspection may range from a single inspector reviewing a specific inspection area to a team of inspectors reviewing different inspection areas.

3.8. Team inspections, which may be multidisciplinary, provide an in-depth, independent and balanced assessment of the operator’s performance. This type of inspection may vary in both scope and complexity. Team inspections are of particular value once safety problems have been identified, since normal inspections cover only small samples of the operator’s activities in any particular area. Inspections of this type will identify underlying causes of problems in order to determine whether a safety concern represents isolated cases or may signify a broader, more serious problem.