

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.

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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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Printed by the IAEA in Austria
August 2002
STI/PUB/1130

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INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2002

VIC Library Cataloguing in Publication Data

Regulatory inspection of nuclear facilities and enforcement by the regulatory body : safety guide. — Vienna : International Atomic Energy Agency, 2002.

p. ; 24 cm. — (Safety standards series, ISSN 1020-525X ; no. GS-G-1.3)

STI/PUB/1130

ISBN 92-0-114102-5

Includes bibliographical references.

1. Nuclear power plants — Inspection. 2. Nuclear facilities — Safety measures. I. International Atomic Energy Agency. II. Series.

VICL

02-00291

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.

3.9. Different approaches may be used in planning team inspections, some of which may be broad in focus and cover a wide subject area ('horizontal slice') in the programme area of interest. For example, during operation a team of inspectors may assess the performance of facility operations, or a team of maintenance and engineering inspectors may assess activities during an outage of the facility. Other team inspections may be narrow in focus and cover a smaller subject area ('vertical slice'). For example, a number of specialist inspectors may review in depth a single safety system in order to confirm that the system is in full compliance with the regulatory requirements or a team may inspect the same aspect at similar nuclear facilities in the State.

Reactive inspections

3.10. Reactive inspections, by individuals or teams, are usually initiated by the regulatory body in response to an unexpected, unplanned situation or incident in order to assess its significance and implications and the adequacy of corrective actions. A reactive inspection may be occasioned by an isolated incident or a series of lesser events occurring at the particular facility under consideration. Similarly, a reactive inspection may be made in response to a generic problem encountered at another plant or identified by the review and assessment staff of the regulatory body. Unlike planned inspections, which are scheduled, reactive inspections are only partly subject to planning by the regulatory body and may disrupt regulatory programmes and schedules. The regulatory body should assume that there will be a need for reactive inspections and should plan to meet its needs for staff and consultants accordingly. For example, in implementing the inspection programme, the regulatory body should establish a graded approach in responding to unforeseen circumstances. All available resources may be needed in responding to a serious event, whereas in the simplest of cases only one inspector may be needed. This pre-established graded approach in responding to special circumstances will assist in determining the appropriate level of resources for use in inspections.

3.11. The regulatory body should use the operator's reports of safety related activities or events for assistance in preparing for both planned and reactive inspections. Matters to be included in reports from the operator should be clearly defined so that difficulties in interpretation can be avoided. This information should include, for example, notification of:

- deficiencies in construction and non-compliances in design;
- abnormal test results;
- radioactive releases;

- any violation of operational limits and conditions;
- modifications and corrective actions;
- unexpected exposure of personnel;
- unavailability of safety related equipment;
- any other situation giving rise to potential hazards for workers, the public and the environment;
- events which may lead to misinterpretation by the public or matters which concern the public.

Announced and unannounced inspections

3.12. An announced inspection is an inspection of which the operator has been notified in advance by the regulatory body. The timing of the announcement may vary according to the circumstances of the inspection to be performed. Inspections may be announced, for example, when the regulatory body wishes to observe a specific test or activity, or to review a specific self-assessment by the operator while it is in progress.

3.13. The main advantage of announced inspections is that the regulatory inspector is able to discuss plans and needs with the operator's personnel in advance in order to secure assurances that documentation will be available for inspection, personnel will be available for interview and activities can be inspected as scheduled. Hence, the announcement of inspections may enhance their effectiveness. The advantage of unannounced inspections is that the actual state of the facility and the way in which it is being operated can be observed. Inspections may be carried out at any time of the day or night so as to provide a more complete picture of the situation at the facility.

SELECTION OF INSPECTION AREAS

3.14. Inspections by the regulatory body should be concentrated on areas of safety significance. These are those SSCs and activities affecting safety or processes important to safety which are identified as such in the safety documentation submitted by the operator or in the findings of the regulatory body's review and assessment, or which are stipulated in the conditions attached to the licence.

3.15. The regulatory body's attention to major inspection areas does not begin and end in a single stage but continues with varying degrees of emphasis throughout

the lifetime of the facility. This Safety Guide covers a wide range of types of facility, and it is not possible to provide for each type details of specific areas that would be subject to inspection at each stage of its lifetime. The degree to which the areas should be considered will depend on the nature of the facility and the risks associated with it. Major inspection areas for nuclear facilities are listed in the Appendix.

3.16. Whenever the operator makes use of the services or products of a contractor, the regulatory body should include the contractor's activities in its inspection programme in all stages of the authorization process. This may comprise inspection and surveillance of the design and manufacturing of components, including, where appropriate, activities performed in other States.

ORGANIZATION AND TECHNICAL RESOURCES FOR INSPECTIONS

3.17. The regulatory body, including a dedicated support organization if appropriate, should have staff capable of performing the activities needed for its inspection programme or, if outside consultants are used, staff capable of adequately supervising the consultants' work and independently evaluating its quality and the results.

3.18. It is neither necessary nor practicable for the regulatory body to be entirely self-sufficient in all technical areas relating to inspection. It may therefore be necessary for it to use consultants in specialized areas. It may occasionally be necessary owing to a heavy short term workload to augment the regulatory body's inspection staff with consultants having as much knowledge and experience as the regulatory body's inspection staff. Such consultants may be any of the following:

- Experts provided by other governmental bodies, technical societies or research institutes;
- Consultants or members of advisory committees with recognized skills and experience, provided that they are effectively independent of the operator and its contractors;
- Experts provided by or under the auspices of international organizations.

When consultants are engaged, arrangements should be made for them to have access to the facility and to any information necessary to perform their tasks. "The use of consultants shall not relieve the regulatory body of any of its responsibilities. In particular, the regulatory body's responsibility for making decisions and recommendations shall not be delegated." (Ref. [1], para. 4.4.)

EXTERNAL RELATIONSHIPS

Relationship with the operator

3.19. The regulatory body should establish requirements and guidelines for the operator that govern notification and reporting periods and the formats in which the notices and reports should be submitted.

3.20. The operator should, at all times, provide personnel conducting regulatory inspections with such equipment, assistance and support as may be necessary for discharging their responsibilities. This may include:

- on-site working facilities;
- transport at the site;
- access to means of communication;
- facilitation of access to all pertinent information;
- copies of relevant documents;
- meetings with appropriate staff;
- personal protection, including equipment for radiation protection.

Relationship with other governmental bodies

3.21. In addition to the regulatory body, other governmental bodies may participate in the regulatory process according to national practices. The regulatory body should establish and maintain liaison throughout the lifetime of the facility with other relevant governmental bodies, and should develop and, where practicable, formalize working procedures with such bodies, whether at the national, regional or local level. Such bodies may undertake their own inspections of the facility, and it may be appropriate for the regulatory body to conduct joint inspections with one or more of them. In planning an inspection programme and determining a specific inspection plan, the regulatory body should consider whether inspectors from these bodies should participate in the inspection.

3.22. It is particularly important that there should be liaison with other governmental bodies when enforcement action is contemplated. The regulatory body should keep the relevant governmental bodies informed since these bodies may be considering taking enforcement actions under different legal provisions and, if so, co-ordination of the enforcement actions should be considered. Similarly, the regulatory body should be advised of any enforcement actions under consideration by other bodies.

3.23. The areas which may be inspected by other governmental bodies should be identified. The latter could include but are not limited to:

- environmental protection authorities;
- authorities responsible for public liability issues;
- authorities for physical protection and/or safeguards;
- authorities for planning the use of water resources and land;
- authorities responsible for public and occupational health and safety;
- fire protection authorities;
- transport authorities;
- law enforcement bodies;
- bodies with responsibilities for civil engineering structures and buildings, and electrical and mechanical equipment;
- other bodies with responsibilities for emergency preparedness;
- other bodies with responsibilities for limits on releases of radioactive effluents.
- other regulatory authorities, particularly those performing similar functions.

3.24. The regulatory body should be aware of the relationships between the operator and other governmental bodies such as may be determined by national legislation, regulations and practices.

Relationship with regulatory bodies of other States and international bodies

3.25. “The safety of facilities and activities is of international concern. Several international conventions relating to various aspects of safety are in force. National authorities, with the assistance of the regulatory body, as appropriate, shall establish arrangements for the exchange of safety related information, bilaterally or regionally, with neighbouring States and other interested States, and with relevant intergovernmental organizations, both to fulfil safety obligations and to promote co-operation.” (Ref. [1], para. 4.11.)

3.26. There may be specific technical areas in which a regulatory body can obtain useful information for the inspection activities. It would be particularly useful to obtain information from regulatory bodies in other States with experience in inspecting similar facilities and it should be considered whether to set up an international grouping of such regulatory bodies. The IAEA and other international bodies are also sources of information and expertise.

3.27. A regulatory body may seek information internationally for such reasons as:

- the introduction of a type of facility of which experience has been gained in another State or other States;
- to add to the database of operating experience with specific facilities;
- to gain knowledge of different approaches to inspection;
- to gain knowledge of the management of the inspection activities;
- to gain knowledge of any of the operator's contractors in another State.

3.28. Information may be exchanged by means of meetings, submissions of documents, visits by experts and participation in inspections, but none of these means should in any way relieve the national regulatory body of its responsibilities for making decisions or recommendations.

4. PERFORMANCE OF REGULATORY INSPECTIONS

INTERNAL GUIDANCE

4.1. To ensure that all nuclear facilities in a State are inspected to a common standard and that their level of safety is consistent, the regulatory body should provide its inspectors with written guidelines in sufficient detail. The guidelines should be followed to ensure a systematic and consistent approach to inspection while allowing sufficient flexibility for inspectors to take the initiative in dealing with new concerns that arise. Appropriate information and guidance should be provided to the inspectors and each inspector should be given adequate training in following this guidance. Consideration should be given to the extent to which this guidance should be made available to the operator or to the public. Appropriate subjects for guidance and instructions for inspectors could include:

- (a) how to develop an inspection programme;
- (b) the legal basis for regulatory inspection and the scope of the inspector's authority;
- (c) the use of regulatory requirements, regulations and guides and industrial standards;
- (d) implementation of the inspection programme, including:
 - areas to be subject to inspection,
 - method of inspection to be used,
 - methods for selection of inspection samples,
 - relevant technical information and questionnaires;
- (e) reporting requirements and practices for inspectors;
- (f) policies of the regulatory body as they may affect inspection;

- (g) standards of conduct of inspectors;
- (h) enforcement policy, procedures and practices.

4.2. The authority vested in inspectors should oblige them to conduct themselves on the site in a manner that inspires confidence in and respect for their competence and integrity. They should, for example, make adequate preparation by gathering and reviewing all relevant information and data before proceeding on assignment and should be knowledgeable about the area which they are required to inspect. The importance of objectivity and fairness on the part of inspectors should also be stressed by the regulatory body in its guidance, together with the need to respect the rules for the facility as established by the operator.

INSPECTION PROGRAMME

4.3. “The regulatory body shall establish a planned and systematic inspection programme. The extent to which inspection is performed in the regulatory process will depend on the potential magnitude and nature of the hazard associated with the facility or activity.” (Ref. [1], para. 5.14.)

4.4. Regulatory inspection programmes should be comprehensive and should be developed within the overall regulatory strategy. These programmes should be thorough enough to provide a high level of confidence that operators are in compliance with the regulatory requirements and are identifying and solving all actual and potential problems in ensuring safety. The inspection programme should be developed so that the regulatory body can determine whether the operator has a functional self-assessment system of high quality and is conducting its activities in accordance with its own established procedures for ensuring that regulatory objectives and requirements are met.

4.5. Different methods may be used in establishing or modifying an inspection programme, with associated priorities, to achieve the objectives of regulatory inspections. The regulatory body should consider the following:

- the results of previous inspections;
- the safety analysis performed by the operator and the results of regulatory review and assessment;
- performance indicator programmes or any other systematic method for the assessment of the operator’s performance;
- operational experience and lessons learned from operating the facility and other similar facilities as well as results of research and development;

— inspection programmes of the regulatory bodies in other States.

4.6. The regulatory body should have the capability to undertake inspection activities at any time as necessitated by the normal operation of a facility or by any fault conditions or operator activities at a facility. For verification of the overall performance of the operator, inspections of adequate depth should be conducted in a wide range of subject areas and at appropriate intervals. Each planned inspection should have objectives which have previously been specified by the regulatory body to serve to the extent practicable as guidance for inspection personnel.

4.7. The planning of the programme of inspections will also be influenced by the locations of the regulatory body's offices and of the facility to be inspected. In particular, it will depend on whether inspectors are permanently at the facility site (resident inspectors) during one or more stages of the facility's lifetime. The general advantages and disadvantages of relying on resident inspectors, as opposed to non-resident inspectors, are considered in paras 3.20–3.22 of Ref. [2]. The use of resident inspectors may be more beneficial at certain stages than at others: for example, the use of resident inspectors may be particularly beneficial during commissioning to permit direct observation of commissioning tests.

4.8. Arrangements should be made to ensure that all relevant staff of the regulatory body can fully contribute to the planning of inspections and in particular, if the offices of the regulatory body are distributed over a wide area, that resident inspectors are involved in the planning process. This will ensure the best use of the skills and knowledge of its staff.

4.9. The regulatory body should have an overall plan for the programme of inspections that it is to undertake at a facility. In determining the intervals between inspections and the level of effort to be applied, the regulatory body should take into account the relative significance for the safety of the facility of each authorization stage and each inspection area.

4.10. The particular aspects that should be considered in determining the intervals between inspections in the various areas and the level of effort to be applied in the inspection include:

- the safety significance of the issues;
- the inspection methods and approaches used (for example, the use of resident inspectors may influence the intervals and the intensity of inspections);
- the qualified personnel and other resources available to the operator;

- the performance record of the operator and the facility, for example, the number of violations, deficiencies, incidents and problems and the number of reactive inspections;
- the results of the regulatory review and assessment;
- the type of facility;
- the personnel and other resources available to the regulatory body;
- the results of previous inspections.

4.11. To facilitate management of the allocation of resources for inspections, the regulatory body should develop site specific inspection plans in which the aforementioned factors are taken into account. The inspection plans should be recorded in such a way that they can easily be modified to take into account continuing activities, and they should be reviewed periodically and modified as necessary.

4.12. The inspection plan should be flexible enough to permit inspectors to respond to particular needs and situations. In a number of States it is the practice to allocate about three quarters of the resources of the overall inspection programme for planned inspections and to keep the remaining quarter available for reactive inspections. The regulatory body should establish a process of periodically evaluating the findings of inspections, identifying generic issues and making arrangements to enable inspectors from various plants, locations or projects to meet to exchange views and discuss the findings and issues.

4.13. The operator should notify the regulatory body of its schedules for carrying out activities and tests of regulatory interest and should submit or make available to the regulatory body in a timely manner the procedures for these activities. To facilitate this process, the regulatory body should specify well in advance to the operator the activities and tests of which it wishes to be informed. Notification to the regulatory body by the operator should be as prompt as is warranted by the situation according to established procedures.

PREPARATION FOR AN INSPECTION

4.14. Before an inspection is carried out, the inspection personnel should be thoroughly prepared for the task. The type of preparation will depend on the type and method of inspection. Preparation may include a review of the following:

- regulatory requirements relating to the inspection area;
- past operating experience relating to the inspection area;

- findings of previous inspections and enforcement actions relating to the inspection area;
- past correspondence between the regulator and the operator relating to the inspection area;
- the safety documentation and operational limits and conditions;
- documentation on operation and design for the facility;
- the operator's management procedures and quality assurance programme.

4.15. Preparations should be made by the individual or team (including any consultants) who will be conducting the inspection. Furthermore, it may be useful to establish a special plan for the inspection and to compile a questionnaire and a list of the documents to be reviewed with the operator.

METHODS OF INSPECTION

4.16. The inspection programme of the regulatory body should incorporate and use a variety of methods:

- monitoring and direct observation (such as of working practices and equipment);
- discussions and interviews with personnel of the operator and the contractor;
- examinations of procedures, records and documentation; or
- tests and measurements.

In individual inspections, one or more of these methods should be employed in a balanced way, depending on the specific issues being considered.

Monitoring and direct observation

4.17. The inspection programme of the regulatory body should include provision for direct monitoring of SSCs, human factors significant to safety (performance of operating personnel, managerial attitudes), tests and other safety related activities carried out by the operator.

4.18. The regulatory body may prescribe certain categories of SSCs, tests and activities which should be directly observed by its inspectors in whole or in part. In some cases, the regulatory body may require regulatory monitoring of a specific structure, system, component, test or activity as a condition for the operator to be permitted to proceed to subsequent stages of work or operation. Monitoring is most likely to be of benefit during the commissioning stage, or as a means of verifying

corrective action at any stage over the lifetime of the facility as required by the regulatory body after an abnormal occurrence or a finding of serious non-compliance.

4.19. The regulatory inspection programme should provide time for general surveillance of the facility site by regulatory inspectors. Such surveillance is aimed at gaining an overall impression of the operator's capabilities and performance and is not restricted to specifically designated components and systems or designated scheduled activities and tests. Examples of areas for observation include:

- the control room and shift handovers;
- radiation protection practices including boundaries of controlled areas;
- safety systems;
- fire barriers;
- housekeeping;
- the presence of management;
- internal and external interfaces and communications;
- arrangements for emergency preparedness.

Discussion and interviews with operator personnel

4.20. Regulatory inspectors should, as appropriate, communicate directly with the operator's personnel responsible for supervising and performing the activities and tests being inspected. This is especially important in follow-up investigations in which the inspector is engaged in reconstructing events and assessing the operator's response.

4.21. The operator's personnel should be kept appropriately informed of inspection activities and it should be ensured that the operator responds to inspection findings. These considerations can be partly satisfied by means of discussions and interviews. Interviews with the facility manager and, as appropriate, with other senior managers should be standard features of most inspection visits. In interacting with the operator's personnel, the inspector should exercise mature judgement concerning the prerogatives and responsibilities of the facility's management.

Examination of procedures, records and documentation

4.22. The operator should be required to record all activities, results and considerations important to safety in the siting, design, construction, commissioning, operation and decommissioning or closure of the facility.

4.23. Examination of the operator's documentation contributes to the regulatory body's verification of the operator's compliance without unduly disrupting work

schedules or interfering with the operator's primary responsibility for the safe siting, design, construction, commissioning, operation and decommissioning of the facility. Documentation examined by regulatory inspectors may include:

- procedures and schedules for maintenance and testing;
- quality assurance records;
- test results and data;
- operational and maintenance records;
- records of deficiencies and incidents;
- modification records including modifications to management and operating procedures;
- training records;
- radiological safety records.

4.24. The regulatory body should examine samples of the operator's documentation sufficient to satisfy itself that the operator is fulfilling the requirements for authorization and is operating in accordance with the practices proposed by the operator and approved by the regulatory body.

4.25. The examination of documentation by regulatory inspectors may in some cases take place in part off the site, for example at headquarters, and can contribute towards their preparation for inspection of the facility.

Tests and measurements

4.26. The extent to which the regulatory body does its own testing and measurement work independently of the operator varies greatly between States, depending upon such factors as the qualifications of personnel available to the regulatory body, its regulatory philosophy, and the experience and demonstrated performance of operators. However, the regulatory body should not engage in the conduct of tests or measurements which would necessitate its assuming direct operational control of the facility or any of its systems. In some States, the inspection staff of the regulatory body conduct physical tests and measurements as part of the inspection programme. Tests of components and systems of the facility should only be undertaken after consultation with the facility's management. In most instances, these tests and measurements replicate and serve as an independent verification of tests and measurements performed by the operator. The conduct of these tests and measurements by the regulatory body shall not relieve the operator of its prime responsibility for safety.

4.27. Since the regulatory body itself conducts only limited testing, a detailed review should be carried out of a sample of the operator's procedures for tests and its

interpretation of their results. If external experts are used to monitor the tests and measurements, their reports also should be reviewed.

4.28. Whatever its inspection programme may be, the regulatory body should be able to carry out tests and measurements as necessary or should obtain the capability by using consultants.

INSPECTION REPORTS AND FINDINGS

4.29. A report of each regulatory inspection should be prepared by the inspector (or inspectors) who performed the inspection. The report should be reviewed and approved according to established internal procedures. The scope, layout, content, timing and distribution of inspection reports may vary according to the:

- general administrative and legal structure in the State and the requirements established by the regulatory body;
- type of facility and its stage of authorization;
- location of the inspection, whether on or off the site;
- type of the inspection, whether planned or reactive.

4.30. Depending on practices in the States concerned, inspection reports should be written for each team inspection, each special inspection and each site visit by non-resident site inspectors or, for example, for weekly inspection activities carried out by resident inspectors.

Purposes of inspection reports

4.31. The purposes of inspection reports are to:

- record the results of all inspection activities relating to safety or of regulatory significance;
- document and record an assessment of the operator's activities in relation to safety;
- record discussions held with facility staff, plant management and other concerned persons;
- provide a basis for notifying the operator of the findings of the inspection and of any non-compliance with regulatory requirements, and to provide a record of any enforcement actions taken;
- record any findings or conclusions reached by inspectors;

- record any recommendations by inspectors for future actions by the operator or the regulatory body and to record progress on recommendations from previous inspections;
- inform other members of the regulatory body;
- contribute to maintaining an institutional memory.

Content of inspection reports

4.32. Inspection reports should typically contain:

- identification of the facility inspected, the purpose and date of the inspection and the inspectors' names;
- the methods used in the inspection (interviews, observations, review of documents);
- reference to applicable requirements;
- criteria used in the assessment;
- details of facility areas, activities, documents, processes, systems or components which have been inspected, assessed or reviewed;
- a record of actual or potential problems relating to safety;
- a record of the results of any checks for compliance with the terms and conditions of the authorization for the facility and applicable national regulations;
- a record of any deficiency or violation found in regulatory inspections, including a record of which requirements or regulations have been contravened;
- a record of any regulatory action taken by inspectors and any consequent action taken by the operator in the period covered by the report;
- a record of discussions held with the facility's staff, the operator's managers and other persons, including a record of discussions with facility managers about points of concern;
- a record of the inspectors' opinion about the operator's or relevant facility manager's response to any matter of concern to which their attention was drawn after a regulatory inspection;
- a record of the findings or conclusions of the inspectors, including corrective or enforcement actions that should be taken;
- a record of recommendations made by inspectors for future action, such as a need to advise other inspectors or operators about particular problems, proposals for further inspections or proposals for enforcement actions.

Distribution and use of inspection reports

4.33. Inspection reports should be distributed according to established procedures in order to provide for the following:

- a basis for future regulatory action;
- a contribution to maintenance of the regulatory history of the facility by providing a record of inspections, discussions and associated findings and conclusions;
- a basis for identifying major or generic issues which necessitate special inspections, changes to inspection plans or generic regulatory action;
- information to regulatory staff responsible for review and assessment;
- information to regulatory staff responsible for reporting incidents;
- information to regulatory staff responsible for regulations and guides;
- a basis for periodic reviews of inspection findings, including trends and root causes;
- information to regulatory staff responsible for the development of requirements for authorization or new regulations;
- a means of sharing information with other site inspectors working at different locations;
- a means of passing information to interested parties or governmental bodies;
- self-assessment activities.

4.34. Inspection findings should typically be discussed at regular meetings attended by groups of site inspectors. The inspection reports should be distributed according to an established procedure. This should include internal distribution of the reports within the regulatory body, including distribution to personnel performing regulatory review and assessment if they are in different organizational units. The procedure may also provide for external distribution to bodies supervising the regulatory body or to organizations with jurisdiction over the facility.

4.35. Inspection findings should be forwarded to the operator for necessary corrective action. Whenever corrective action is needed, a formal communication including findings detailed in inspection reports should be sent to the operator as part of the enforcement procedures. In some States the full inspection report is forwarded to the operator. In communications with the operator, caution should be exercised in identifying individuals by their name or their post because of the possible implications (including those of a legal nature) for the individuals concerned.

4.36. Documents that are made available to the inspector by the operator during an inspection should be referenced in the inspector's report of the inspection. Inspection reports and copies of documents received should be stored in a manner that permits ready retrieval.

Publication of inspection findings

4.37. In order to inform the public of the safety of nuclear installations and of the effectiveness of the regulatory body, findings of inspections and regulatory decisions may be made publicly available. The extent to which such information is made publicly available will depend on the legal provisions in the State concerned.

4.38. Although it may be the practice in some States to publish individual inspection reports, some inspection reports may contain confidential information, such as security information, information which the regulatory body may wish to use in connection with future regulatory actions, personal or medical information relating to individuals and proprietary information. Such information should be withheld. However, in the interests of confidentiality it may be undesirable to show which information has been withheld. In such cases, therefore, only the general findings of the inspection and regulatory decisions should be made available to the general public.

4.39. All information exchanged between the regulatory body, other governmental bodies, the operator, its contractors, advisory committees and the regulatory body's consultants and, as appropriate, members of the public should be formally recorded upon receipt and stored in a manner that permits ready retrieval.

5. REGULATORY ENFORCEMENT

MANAGEMENT OF ENFORCEMENT ACTIONS

5.1. The organizational structure of the regulatory body should enable enforcement actions to be taken at an appropriate level. The managerial responsibilities for enforcement actions include:

- applying the policy of the regulatory body with regard to enforcement actions;
- determining the level of an inspector's authority to carry out enforcement actions;
- ensuring that enforcement actions are carried out properly and in accordance with due legal process in the State concerned and that corrective actions are performed.

5.2. The regulatory body shall have statutory powers to enforce compliance with its requirements as specified in the applicable regulations and in licence conditions, including the authority to require an operator to modify, correct or curtail any aspect of a facility's operation, procedures, practices or SSCs, as necessary, to ensure that the required level of safety is achieved. Within the legal framework in which it is established, the regulatory body may develop and issue enabling regulations detailing procedures for determining and exercising enforcement actions as well as the rights and obligations of the operator.

5.3. "Enforcement actions are designed to respond to non-compliance with specified conditions and requirements. The action shall be commensurate with the seriousness of the non-compliance. Thus there are different enforcement actions, from written warnings to penalties and, ultimately, withdrawal of an authorization. In all cases the operator shall be required to remedy the non-compliance, to perform a thorough investigation in accordance with an agreed time-scale, and to take all necessary measures to prevent recurrence. The regulatory body shall ensure that the operator has effectively implemented any remedial actions." (Ref. [1], para. 5.18.)

Inspector's authority in relation to enforcement

5.4. "The extent of the authority of the regulatory inspectors to take on the spot enforcement actions shall be determined by the regulatory body." (Ref. [1], para. 5.23.) The degree of authority given to an inspector may depend on the structure of the regulatory body and on the inspector's role and experience.

5.5. "Where on the spot enforcement authority is not granted to individual inspectors, the transmission of information to the regulatory body shall be suited to the urgency of the situation so that necessary actions are taken in a timely manner; information shall be transmitted immediately if the inspectors judge that the health and safety of workers or the public are at risk, or the environment is endangered." (Ref. [1], para. 5.24.)

5.6. Enforcement actions taken on the spot by regulatory inspectors are appropriate only in abnormal situations. In normal situations, decisions concerning enforcement actions, particularly those involving fines, curtailment of activity or suspension of authorization, should be approved by the regulatory body in accordance with the procedures established in the State concerned.

FACTORS IN DETERMINING ENFORCEMENT ACTIONS

5.7. A range of enforcement actions should be available to the regulatory body, such as the issuing of written requirements, warnings or directives or orders to curtail activities, the modification or revocation of licences or authorizations and the imposition of penalties. The enforcement should depend on consideration of the factors listed in para. 5.8, but in many cases it may be possible to resolve the non-compliance by means of discussion with the operator. Whenever such a process is inappropriate or has been unsuccessful it may be necessary to invoke one of the formal measures; however, caution should be exercised in considering the imposition of penalties. In determining the enforcement measure to be applied, it should be noted that for some facilities or at some stages of a facility's lifetime the option to curtail activities may not be available.

5.8. The factors to be taken into account by the regulatory body in deciding which enforcement action is appropriate in each case should include:

- the safety significance of the deficiency and the complexity of the correction that is needed;
- the seriousness of the violation;
- whether a violation of a less serious nature has been repeated;
- whether there has been a deliberate or wilful violation of the limits and conditions specified in the authorization or in regulations;
- who identified and reported the non-conformance;
- the past performance of the operator and the trend in performance;
- the need for consistency and transparency in the treatment of operators.

METHODS OF ENFORCEMENT

Written warnings or directives

5.9. Deviations from or violations of authorization requirements or unsatisfactory conditions may occur at any stage of the facility's lifetime. Under such circumstances the regulatory body should consider issuing a written requirement, warning or directive to the operator.

5.10. Any written requirement, warning or directive should specify the nature of and the regulatory basis for each violation, deviation or unsatisfactory situation; it should also specify a period of time for taking corrective action and may provide guidance on the nature of the corrective action. This is the most common form of enforcement action and should, in most cases, suffice to remedy the safety issue.

Orders to curtail specific activities

5.11. The regulatory body should require the operator to curtail specific activities in the event of serious non-compliance in the construction stage, apparent deterioration of the facility's SSCs or serious violations which in the judgement of the regulatory body pose an imminent radiation hazard to workers, the public or the environment. In the operational stage, for example, this could mean requiring reductions in power, pressure, temperature or other parameters, including, if necessary, temporary shutdown of the facility.

Modification, suspension or revocation of the authorization

5.12. In the event of persistent or extremely serious non-compliance or significant contamination of the environment due to a serious malfunction or damage to the facility, the regulatory body should modify, suspend or revoke the authorization, depending on the nature and severity of the conditions at the facility. In considering the withdrawal of authorization, the regulatory body should give careful consideration to ensuring that activities vital to safety, even in a shutdown state, continue to be performed by a legally authorized operator.

Penalties

5.13. The regulatory body should have the authority to impose or recommend penalties, such as fines on the operator as a corporate body or on individuals, or to institute prosecution through the legal process, depending upon the legal system and authorization practices in the State concerned. The use of penalties is usually reserved for serious violations, for repeated violations of a less serious nature or for deliberate and wilful non-compliance. Experience in some States shows that imposing penalties on the organization rather than on individuals is preferable and is more likely to lead to improvements in safety performance.

PERFORMANCE OF THE ENFORCEMENT PROCESS

5.14. The regulatory body should adopt clear administrative procedures and guidelines governing the use and implementation of enforcement actions. All inspectors and other staff of the regulatory body should be trained in and should be knowledgeable about the procedures and guidelines. The procedures and guidelines should state the policy of the regulatory body for the use of regulatory and

enforcement measures and the associated authority delegated to inspectors and other regulatory body staff. Depending on national practices, the need to allow the operator to state a point of view on regulatory decisions, to respond to enforcement notifications and to appeal against enforcement decisions should be recognized and taken into account in the procedures and guidelines. The procedures and guidelines should cover in detail the decision making approach of the regulatory body in determining the level of actions to be taken and the way in which the actions should be taken, including dealing with failure of the operator to comply with requirements for regulatory enforcement.

5.15. Provided that there is no immediate threat to safety, the regulatory body should allow reasonable periods of time for the operator to complete corrective actions. These time periods should depend on the seriousness of the issues and the complexity of the corrective actions required. However, in an integrated approach to safety, the contribution of each deficiency for which corrective action is required to the total risk for the facility should be considered.

5.16. Procedures should stipulate which other governmental organizations, if any, should be informed in the event of enforcement notifications. In some States, public notification is required or is undertaken as a matter of common practice.

5.17. The circumstances under which it is appropriate to carry out further inspections to determine whether the operator has responded to regulatory and enforcement measures should be stated in the regulatory procedures. The purpose of these inspections should be:

- to confirm that the operator has complied with the enforcement measures within the period of time specified;
- to check that the enforcement measures intended to protect the workers, the public and the environment from potential radiological consequences have been taken by the operator even though the operator may intend to appeal against the notification of the regulatory body.

RECORDS OF ENFORCEMENT

5.18. “All enforcement decisions shall be confirmed to the operator in writing” (Ref. [1], para. 5.22.). Internal records of decisions concerning enforcement actions and any supporting documentation should be kept in such a way that they will be readily accessible and retrievable.

6. ASSESSMENT OF INSPECTION AND ENFORCEMENT ACTIVITIES

6.1. The regulatory body should have a system to audit, review and monitor all aspects of its inspection and enforcement activities to ensure that they are being carried out in a suitable and effective manner. It should be ensured by means of this system that any changes necessary in inspection and enforcement activities owing to improvements in methods are implemented. The following points should be considered in this system:

- internal guidance for inspections;
- inspection methods;
- allocation of resources for inspections;
- procedures in the regulatory body relating to inspection activities such as procedures for planning inspections and for dealing with outstanding issues;
- procedures for co-ordinating inspection activities with the regulatory review and assessment process;
- procedures for involving consultants in inspection activities;
- procedures relating to enforcement actions;
- the effectiveness of enforcement actions;
- record keeping and documentation.

Appendix

INSPECTION AREAS FOR NUCLEAR FACILITIES

A.1. This appendix sets out areas of nuclear facilities that may be of particular interest for inspection at different stages of the authorization process.

SITE EVALUATION STAGE

A.2. Before the construction of a nuclear facility is begun, the regulatory body should monitor as appropriate, by means of its inspection programme, site preparation activities undertaken by the operator, including verification of site characteristics and authorized excavation and earthwork.

A.3. The specific objectives of regulatory inspection in these areas include verification that the operator is undertaking siting activities in full conformity with existing regulatory requirements and assurance that the work on site preparation does not proceed beyond that permitted by any authorization in force. During site preparation, the regulatory body should also confirm that the site characteristics remain consistent with the description presented by the operator in its licence application and in the subsequent supporting documentation submitted to the regulatory body. This is vital for disposal sites, for which the action of a major barrier to the movement of radionuclides is dependent on the characteristics of the site. In addition, inspectors should be alert to any new conditions or information revealed as a result of activities for site preparation, which should then be considered by the regulatory body in making subsequent decisions on authorization.

DESIGN AND CONSTRUCTION STAGE

A.4. The chief objectives of the regulatory inspection programme in the design and construction of the facility are to verify that:

- Safety related materials and SSCs meet the requirements established by the regulatory body and conform to good practices;
- Construction activities associated with manufacturing and installing SSCs and items are conducted in accordance with regulatory requirements and in conformity with general safety objectives;

- The as-built configuration of SSCs is in conformity with the assumptions made in the regulatory review and assessment, any deviation is analysed and justified and the documentation is updated accordingly;
- The operator's system and procedures for quality assurance and inspection are adequate to ensure the conformance of equipment to the technical specifications.

A.5. The regulatory body should inspect design and construction activities in a number of areas in order to attain these objectives. In particular, the following areas should receive close attention in the construction stage, primarily because of the difficulty of detecting and correcting deficiencies in these areas once fissile and radioactive material has been brought to the site and the facility enters the active commissioning stage:

- (a) mixing and placement of concrete and its reinforcement, especially in:
 - foundations,
 - safety related structures, particularly containment structures;
- (b) construction of cooling intakes and discharge systems;
- (c) installation of safety related components, particularly:
 - containment and shielding boundaries,
 - internals of vessels which will contain fissile and radioactive material,
 - equipment to be used in radiation areas;
- (d) installation of safety related control, protection and power systems;
- (e) areas of the facility that are inaccessible after construction is completed, particularly systems and components embedded in the foundations or the building structure;
- (f) housekeeping in respect of safety related SSCs;
- (g) the quality assurance systems of the designer, manufacturer and constructor.

COMMISSIONING STAGE

A.6. Activities associated with commissioning will normally begin before construction is completed. Accordingly, the regulatory body should be prepared to inspect areas of commissioning activity in parallel with activities of the construction stage. In some States the regulatory body approves the commissioning programme and its agreement should be obtained before advancing beyond certain hold points.

A.7. Inspection by the regulatory body during the commissioning stage should focus on four broad areas of the operator's activity:

- (1) testing before the introduction of fissile and radioactive material;
- (2) initial introduction of fissile and radioactive material;
- (3) testing of operations involving fissile and radioactive material;
- (4) other commissioning activities.

Testing before the introduction of fissile and radioactive material

A.8. The inspection area of testing before the introduction of fissile and radioactive material encompasses those activities and tests performed before the introduction of such material by the operator in order to demonstrate that SSCs function properly and conform to design requirements. It also covers the inspection and acceptance criteria for the receipt at the facility of fissile and radioactive material. The regulatory inspection programme should include:

- examination of documented procedures to verify that they accord with the conclusions of the regulatory review and assessment;
- review of the implementation of these procedures;
- direct observation of the performance of certain key pre-operational tests;
- examination of the results of selected tests;
- confirmation of the integrity of any engineered barriers.

A.9. The number of tests and the key tests that are to be examined and directly witnessed by the regulatory body will vary depending on such factors as the importance of the test for safety and whether the facility to be commissioned is the first of its kind or one of several similar facilities. The regulatory body should, however, place particular emphasis on inspection by the examination of documentation and by the direct observation of some of the tests performed on:

- SSCs that prevent unsafe conditions or that mitigate the consequences of anticipated operational occurrences and accident conditions;
- SSCs whose failure to operate properly will require action from one or more safety related components or systems.

A.10. This may involve the regulatory body in inspecting tests of:

- safety systems (such as instrumentation and control systems, shutdown systems and standby systems);
- the integrity of the containment and shielding boundaries (such as hydraulic tests of pressurized structures) as appropriate;
- the susceptibility of SSCs to vibration or to other design loads;

- secondary containment integrity (such as overpressure and leak rate tests) as appropriate;
- emergency power systems as appropriate;
- communication capabilities;
- ventilation systems;
- integrated cold and hot functional tests.

Initial introduction of fissile and radioactive material

A.11. In the regulatory inspection programme, close attention should be paid to operator activities relating to the preparation for and actual introduction of fissile and radioactive material. Regulatory inspection personnel should be present at the facility site to observe some of these activities directly.

A.12. Although some of these tests may be performed at times other than the time when fissile and radioactive material is first introduced, the regulatory body should inspect the following:

- tests of the main control room;
- access control and implementation of the radiation protection programme;
- emergency preparedness and demonstration of the emergency plan;
- systems for monitoring radioactive releases and meteorological monitoring systems;
- the distribution of fissile and radioactive material (such as the fuel loading pattern in a reactor) and process calculations and/or criticality calculations, as appropriate;
- systems involved in the handling or movement of radioactive or fissile material.

Testing of operations involving fissile and radioactive material

A.13. The inspection area of testing of operations involving fissile and radioactive material encompasses activities of the operator performed in conditions up to nominal operating conditions. At this point, SSCs are tested in an operational environment to ensure that they have been constructed and installed properly and are capable of functioning in compliance with the design requirements. Consideration should be given to the performance of radiation surveys of facility shielding (such as concrete walls) during starting up of the facility. This will help to identify any voids or faulty joints in the shielding or any radiation penetrating through joints. In the event of such an occurrence, alterations should be made prior to further operation. During this period the operator carries out tests at increasing operational levels; this testing

includes the recording and analysis of data relating to temperatures, pressures, radiation levels, flows and variations in process parameters as well as other relevant parameters.

A.14. Regulatory inspection personnel shall examine and assess the safety aspects of a sample of the operator's procedures for conducting operational tests. In addition, as the tests are completed, a sample of the test documentation and the results of the inspection should be examined by regulatory personnel to verify that the tests have been completed in accordance with the test instructions and that the results are acceptable. Regulatory inspection should also include the monitoring and direct observation of several tests.

A.15. Tests during this stage, which should be subject to regulatory review and inspection, will depend on the type of facility being commissioned. They include tests to demonstrate as far as possible that:

- the facility is being operated in accordance with the descriptions given in the safety analysis report;
- systems respond to malfunctions in accordance with the claims made in the safety analysis report.

Other commissioning activities

A.16. In addition to the examination of documentation and the surveillance of tests, there are a number of other areas necessitating inspection by the regulatory body in the commissioning stage. The ability of the operator's management to progress from supervising construction to supervising operation and its arrangements for doing so should also be inspected. This inspection should cover the management's provisions for putting the emergency plan into effect and for the training and qualification of operating personnel. Hold points during the operational testing stage and into the full operational stage should be closely monitored. These areas largely overlap, necessitating continuing attention in inspections during the operation stage.

OPERATION STAGE

A.17. Once the facility has attained the authorized operation stage, the regulatory body shall implement an inspection programme to verify systematically the operator's compliance with regulatory requirements and achievement of general safety objectives, and to detect potential safety problems. This verification should consist of: a balanced approach to monitoring and direct observation of activities;

interviews with personnel, including managers; review of qualifications of the operator's personnel; and sampling of documentation. For waste management facilities and particularly for waste disposal facilities, the structure of the programme and the tests to be carried out will primarily relate to conformance to the relevant design criteria and waste acceptance criteria for the facility and will constitute an element in providing confidence for the long term safety case. For all facilities, these inspections should cover the aspects detailed in paras A.18–A.41.

Operations

A.18. The area of operations should include the control and execution of activities directly relating to operating a facility to the operational limits and conditions established by regulatory requirements or by procedures or specifications. Inspection personnel should perform safety verification of: operating procedures; the operating configuration of safety related systems; control room activities; and the abilities of the operations staff to perform their duties. Simulator training and the responses of operating staff to abnormal events and emergency conditions, as well as the adequacy of the management's actions, should also be assessed. In performing this safety verification, the reviews described in paras A.19–A.22 should be carried out.

A.19. *Operating procedures.* A sampling review of operating procedures should be performed, including all the procedures for normal operations, anticipated operational occurrences and accident conditions. Inspections should be focused on the operating personnel's adherence to procedures, including operational limits and conditions. The usability and adequacy of the procedures should also be evaluated. This may necessitate sustained observations in the control room. The inspection programme in this area may necessitate sustained observation to cover 24 hour operation as necessary, in particular shift turnovers. The inspectors should check the availability of safety systems and the presence of alarm systems, and the way in which they are handled by the operations staff.

A.20. *Operator's training programme.* The adequacy of the operator's staff training programme should be assessed routinely to ensure that the training reflects actual conditions in the facility.

A.21. *Safety systems.* A sampling review of safety systems should be performed to evaluate: any identified degraded equipment; discrepancies between installed components and/or system hardware and the facility drawings; controls for performing maintenance on equipment; and the quality of performance of the operations staff in log keeping and record keeping and in routine monitoring of equipment. Note should be taken of the effectiveness of the operations staff in getting

the degraded equipment repaired by the maintenance staff or its prompt evaluation to ensure operability. Inspection of the facility should also include observations of non-safety-related areas to ensure that they have no adverse effects on the safety related areas of the facility. The adequacy of the fire protection and prevention programme, including the management's attention to this area, should be noted in these inspections.

A.22. *Management.* The management's involvement in the facility and its effectiveness in paying appropriate attention to operational issues, including abnormal events, should be evaluated. In inspections it should be considered: whether the organizational structure is suitable; whether there are adequate numbers of staff; how well management and staff communicate; and how the management emphasizes the importance of safety and fosters safety culture.

Outages

A.23. Inspections should cover outage activities. In addition to providing opportunities to observe modifications being made to the facility, outages provide opportunities to observe activities in areas that are not always accessible during normal operation. Certain activities such as inspections in highly radioactive areas or the maintenance and repair of highly contaminated systems present a challenge to the operator's organization. Outages can provide valuable insights into the management's ability to perform tasks outside the normal operational mode. Furthermore, movements of fissile and radioactive material need to be well controlled and special checks may be necessary before returning the facility to normal operation to ensure that it is still within its safety justification. Before returning the facility to normal operation, it is usual for the regulatory body to perform a special inspection.

Radiation protection and radioactive waste management

A.24. The area of radiation protection should cover all related activities at the facility, including radiation protection of staff and contractor personnel and of the public [5–7]. The area of radioactive waste management should cover treatment, conditioning, storage and transport of waste, the release of effluents and the environmental monitoring programme [8].

A.25. *Organizational structure for radiation protection.* The structure of the organization responsible for the implementation of the radiation protection programme, the procedures necessary for implementation of the programme, the effectiveness of the management and its commitment with respect to radiation protection, including application of the optimization principle, should all be assessed

in the inspection. Indicators of the effectiveness of the management are the levels of exposure of personnel, levels of contamination in working areas, levels of releases of effluents, and the understanding on the part of management and workers of their responsibilities in the implementation of the radiation protection programme. Any self-assessments performed by the operator under this programme should be reviewed.

A.26. *Records of occupational radiation doses.* Inspection personnel should selectively review records of individual occupational doses, including internal and external doses. Activities should be observed to ensure that procedural and management controls are effective. This includes controls for radiation areas and contamination areas as well as inspection of activities for internal and external dosimetry. Exposures of personnel that result in the operator's reference levels for effective doses or intakes being exceeded should be noted. Records of radiation protection training and retraining should be assessed.

A.27. *Effluents.* The inspection programme should include verification that any releases of effluents are within the authorized discharge limits. This should include the review of systems for the treatment of radioactive waste and for the monitoring of effluents. Training and qualifications for technicians and workers employed in the areas concerned should also be reviewed.

A.28. *Environmental monitoring.* The environmental monitoring programme should be reviewed to ensure that all environmental monitoring is performed in accordance with established procedures. Independent measurements may be performed to verify the accuracy of the operator's monitoring equipment and the results of measurements.

A.29. *Waste management.* The implementation of arrangements for on-site waste treatment, conditioning and storage should be reviewed and records should be inspected. In particular, the waste characterization process, the compliance with any requirements for waste storage or disposal, and the records for these processes should be subject to inspection.

A.30. Whenever unpackaged waste is stored or waste packages are stored or have been placed in a waste repository pending a decision on closure of the facility, degradation of the waste with time may occur. The storage conditions for the waste and the waste packages should be inspected at appropriate intervals to provide confidence that the waste remains suitable for treatment or that the waste packages will be suitable for retrieval, transport and further steps in radioactive waste management, as necessary.

A.31. Transport arrangements for radioactive material on the site should be examined. Receipt and dispatch arrangements should be inspected and attention should be paid to the integrity of packages, residual levels of contamination and associated records.

Maintenance and testing

A.32. Inspection in the area of maintenance and testing should comprise assessments of the implementation of the maintenance and testing programme. These should cover:

- all types of maintenance performed on SSCs and maintenance of the physical condition of the facility;
- testing, including the conduct of all surveillance testing activities, all in-service inspection and testing, calibration of instruments, equipment operability tests and other special tests.

A.33. Direct observation by the regulatory body should include a sampling of the operator's inspection and testing activities, including such tests as: calibration of nuclear instrumentation systems; verification of containment integrity; testing of local leak rates for the containment; testing of piping support and restraint systems; tests for safety pumps, valve capacity and stroke timing; and surveillance tests for breakers and transformers. Inspectors should note the capability of the individuals performing the tests and, for complex surveillances, should assess the interface between the surveillance personnel and the operations staff involved in the performance of the test. The adequacy and usability of the procedures should be assessed and the control and calibration of the test equipment should be observed. The inspection personnel should observe the manager's involvement in these programmes to ensure that the programmes are effective and that safety equipment is properly maintained, with few recurring problems. Maintenance backlogs, the intervals at which repetitive equipment repairs are carried out and the amount of maintenance work actually being performed should be routinely noted, as these may be early indicators of declining performance in the maintenance programme. In this connection, a large backlog of repairs, a high number of equipment failures and a low level of maintenance activity may be indicative of a maintenance programme that is difficult to manage and requires a disproportionate amount of documentation. Self-assessment activities in these programmes should be observed and their findings should be routinely reviewed.

A.34. A sample of maintenance activities including inspection and testing should be routinely observed to assess the adequacy of programmes and procedures and the

capability of the maintenance technicians to perform their assigned tasks. The planning and scheduling of maintenance should be assessed to ensure that maintenance activities are performed by competent staff and are properly coordinated, and that repairs to equipment are handled in accordance with appropriate priorities. All types of maintenance activities should be observed. Before initiating maintenance work, special attention should be paid to the isolation and tagging of safety systems which are out of service. Inspectors should observe the compliance with procedures for these isolation and tagging controls in order to evaluate their adequacy and should evaluate the procedures for ensuring that systems are returned correctly to their operational state. The in-service inspection programme and the in-service testing programme should be reviewed to ensure that their purpose, which is to ensure the early detection of degradation of equipment and components, is being served. Programmes, procedures and data should be reviewed and evaluated, particularly for those maintenance tasks that can be performed only during outages. Data which may indicate that a high number of component systems need repair may necessitate an in-depth review of the programmes. Repairs to piping systems, pumps, valves, electrical systems and instrumentation and control systems should all be selectively sampled for review. Welding on systems of safety significance should be observed, including examination by non-destructive means.

Engineering

A.35. Engineering usually provides necessary support to the operations or maintenance staff anywhere in the facility at any time. Engineering usually assists operations staff with the evaluation of non-conforming or degraded conditions and assists maintenance staff in the performance of activities in the course of which problems may arise. Inspection personnel should review a sample of the evaluations for non-conforming or degraded conditions for both adequacy and quality, and should observe the interface between the maintenance and engineering support groups.

A.36. The inspector should walk down part of a system to assess how well systems are being maintained and should note any non-conformance. Any problems identified by the inspector but not known to the facility's management would call into question the adequacy of the support programme for system engineering.

Modifications

A.37. Modifications may be simple or complex and may involve changes to engineering, operating procedures and the organizational structure. For major modifications to the SSCs of a facility, most of the planning, design and manufacture will be performed prior to outages. The regulatory body should inspect the operator's

record to determine whether its modification process has been effective in controlling modifications in a manner which is appropriate for their safety significance. Where required, the regulatory body should also inspect submissions by the operator to the regulatory body concerning a modification. The details of the process should be checked in the inspections by sampling specific modifications and reviewing their execution and their implications for documentation, such as the need for changes to safety related documentation, for updating of maintenance schedules and engineering drawings and for changes to operational procedures and training modules. These checks may involve other parts of the regulatory body in addition to the inspection unit. The regulatory body should also determine whether the qualifications of the operator's staff who perform the modifications are suitable for the function they are performing.

Emergency preparedness

A.38. Inspection of the area of emergency preparedness and response should include a review of emergency response plans and procedures in order to verify that the means of coping with an emergency are adequate. Procedures for the detection and classification of an emergency and for decision making in an emergency should be assessed. Procedures for notification, communication, shift staffing, shift augmentation, dose calculation and dose assessment should also be evaluated. Emergency exercises should be witnessed to ensure that the emergency planning is adequate and that its implementation is effective.

Physical protection

A.39. Inspection of the area of security should include a review of all activities relating to access control, the physical protection of equipment in safety related areas and fitness for duty programmes, as applicable. Inspection personnel should routinely monitor the controls on access to the facility. The effects of the hardware for physical protection on accessibility and the ability of the operator to operate the facility safely should be routinely assessed. Inspection personnel should also review the fitness for duty programme and assess its effectiveness.

Quality assurance programme

A.40. The operator's quality assurance programme should be reviewed to ensure that it is comprehensive and adequately implemented. The review should cover, in addition to the activities discussed earlier, such activities as: procurement, receipt, storage and handling of equipment; document control; and operational experience. In particular, the adequacy and effectiveness of the operator's performance of a

programme of internal audit and self-assessment and implementation of the resulting corrective actions should be assessed.

Effectiveness of management systems

A.41. Inspection of the area of effectiveness of management systems should include inspection of those indicators which demonstrate that the management system is focused on safe operation and on the identification and remediation of problems and weaknesses within the programme. This includes the management's involvement in day to day operations and its routine presence in the facility. What is most important is whether the management demonstrates a willingness to hear of problems and then to ensure that problems are promptly evaluated and solved. The management's ability to create an environment in which problems are openly identified and discussed and self-assessment programmes are effectively supported helps to foster an appropriate safety culture for operation.

DECOMMISSIONING STAGE

A.42. During the decommissioning stage of a nuclear facility, inspection activities should be concentrated on:

- the adequacy of the operator's procedure for the control of each stage of decommissioning;
- the removal of radioactive material;
- the strategy for management of radioactive material;
- the drainage of any fluid;
- decontamination and dismantling activities;
- the waste management strategy for the treatment, conditioning, storage and disposal of all radioactive waste;
- the physical condition of the facility, especially surveillance of the integrity and/or the availability of relevant SSCs, including protective barriers, and the appropriateness of the procedures at each stage of decommissioning;
- characterization of the residual activity;
- physical protection, safeguards and access control;
environmental monitoring, radiological monitoring and surveillance, including plans for radiation protection for workers and the public;
- the adequacy and maintenance of instrumentation and control systems for long term safety;
- decommissioning records.

A.43. After a long period of safe enclosure, some of these regulatory inspection activities may be reduced in thoroughness and frequency.

Closure of waste disposal facilities

A.44. Before the regulatory body considers the release of any waste disposal facility from further regulatory control, inspection activities should be concentrated on:

- conformance with the overall waste inventory;
- sealing arrangements for the facility including any measures to prevent intrusion;
- arrangements for any environmental monitoring after closure.

Areas of interest relating to the release of a facility and/or site from regulatory control

A.45. Before releasing a site from any further control, the regulatory body should carry out an inspection to confirm that any residual activity has been reduced to acceptable levels. For waste disposal facilities, the release from control will be related to the long term safety of the facility as set out in the post-closure safety case.

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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, registration, etc.

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.

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.

regulatory 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.

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

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