

Regulatory Inspection and Enforcement

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Quality Assurance

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IAEA

International Atomic Energy Agency

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IAEA Safety Requirements

GSR Part 1

Requirement 27: Inspection of facilities and activities

The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization.

Requirement 28: Types of inspection of facilities and activities

Inspections of facilities and activities shall include programmed inspections and reactive inspections; both announced and unannounced.

Requirement 29: Graded approach to inspections of facilities and activities

Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.

IAEA Safety Requirements

Additional considerations from GSR Part 1

- The regulatory body shall develop and implement a programme of inspections to confirm compliance with regulatory requirements and any conditions specified in the authorisation
- The programme shall stipulate the frequency of inspections, the type of inspections and the areas and processes to be inspected according to a graded approach
- The regulatory body shall record the inspection findings and take appropriate actions
- Provision shall be made for free access by the regulatory inspectors at any time, including for unannounced inspections

IAEA Safety Requirements

Requirement 30: Establishment of an enforcement policy

The regulatory body shall establish and implement an enforcement policy within the legal framework for responding to non-compliance by authorized parties with regulatory requirements or with any conditions specified in the authorization.

Requirement 31: Requiring of corrective action by authorized parties

In the event that risks are identified, including risks unforeseen in the authorization process, the regulatory body shall require corrective actions to be taken by authorized parties.

IAEA Safety Requirements

Additional considerations from GSR Part 1

- The response of the regulatory body to non-compliances shall be commensurate with safety significance using a graded approach
- The regulatory body shall identify and record the nature of the non-compliances and the period of time for corrective action
- The authorised body shall be responsible for remedying non-compliances and shall perform a thorough investigation and take all measures to prevent a recurrence
- The regulatory body shall establish criteria for corrective actions, including facility shutdown if necessary
- On-site inspectors shall be authorised to require corrective action if there is imminent likelihood of significant safety events

IAEA Guidance on Regulatory Inspection

IAEA Safety Standards

for protecting people and the environment

Functions and Processes of the Regulatory Body for Safety

General Safety Guide

No. GSG-13



IAEA

International Atomic Energy Agency

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Objectives

The principal objectives of regulatory inspection and enforcement

- to provide a high level of assurance that all activities performed by the operator have been executed safely and
- to meet the safety objectives and licence conditions.

Regulatory inspection is performed to make an independent check on the operator and the state of the facility,

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 necessary to ensure safety.

Legal Authority

The regulatory body shall be granted sufficient legal authority for effectively conducting and co-ordinating inspection and enforcement actions

The regulatory body shall have **authority to:**

- establish regulations and issue guidance to serve as the inspection basis;
- enter the premises of any facility or any related establishment at any time for the purposes of inspection during the regulatory process;
- require the preparation of, access to and submission of reports and documents from operators and their contractors when necessary;

Legal Authority

- 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
- 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



Legal Authority

The regulatory body should have available several methods of enforcement to provide 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 implemented.

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Management Arrangements

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 organisational unit.

Types of Inspection

The regulatory body should conduct two general types of inspection:

- 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.

Types of Inspection

Planned inspections

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 and are scheduled in advance. 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.

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.

Team inspections may be multidisciplinary, provide an in-depth, independent and balanced assessment of the operator's performance. Team inspections are of particular value once safety problems have been identified, since normal inspections cover only small samples of the operator's activities.

Types of Inspection

Reactive inspections

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.

Reactive inspections are only partly subject to planning by the regulatory body and may disrupt regulatory programmes and schedules.

Types of Inspection

Announced and unannounced inspections

An **announced inspection** is an inspection of which the operator has been notified in advance by the regulatory body, for example, when it wishes to observe a specific test or activity, or to review a specific self-assessment by the operator while it is in progress. The main advantage of announced inspections is that the regulatory inspector is able to discuss plans 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

Inspections by the regulatory body should be concentrated on areas of safety significance, such as those SSCs and activities affecting safety or processes important to safety.

These should be identified 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.

Organization and Technical Resources

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.

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.

Advice on using external expert support is given in:

GSG-4 Use of External Experts by the Regulatory Body (2013)



External Relationships

Relationship with the operator

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.

Relationship with other governmental bodies

If other governmental bodies participate in the regulatory process liaison should be established and maintained by the regulatory body

Relationship with regulatory bodies of other States and international bodies

Information from regulatory bodies in other States with experience in inspecting similar facilities should be sought and it should be considered whether to set up an international grouping. The IAEA and other international bodies are also sources of information and expertise.

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Internal Guidance

- The regulatory body should issue internal guidance for its inspectors containing sufficient detail to ensure systematic and consistent inspection and the level of safety required.
- The guidelines should allow sufficient flexibility for inspectors to take the initiative in dealing with new concerns that arise.
- Inspectors should be given adequate training in following this guidance.

Internal Guidance

The guidance for inspectors should include the following:

- Policies of the regulatory body regarding inspections.
- The legal basis for regulatory inspection and the scope of the inspector's authority.
- The use of regulatory requirements, regulations, guides and standards.
- The development of an inspection programme.
- The implementation of the inspection programme, including:
 - (i) Facilities (or areas of the facility) or activities to be subject to inspection;
 - (ii) Method of inspection to be used;
 - (iii) Methods for selection of inspection samples;
 - (iv) Use of relevant technical information;
 - (v) Use of inspection questionnaires;
 - (vi) Follow-up on inspection findings.
- Reporting requirements and practices for inspectors.
- Standards of conduct of inspectors.
- The enforcement policy, procedures and practices.

Inspection Programme

- Regulatory inspection programmes should be comprehensive and should be developed within the overall regulatory strategy.
- The 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.
- Each planned inspection should have objectives which have been specified by the regulatory body as guidance for inspectors.
- The inspection plan should be flexible enough to permit inspectors to respond to particular needs and situations.



Inspection Programme

It will also depend on whether inspectors are permanently at the facility site (resident inspectors).

In determining the intervals between inspections and the level of effort to be applied, the regulatory body should take into account the degree of hazard, the operations undertaken and the safety significance of each inspection area.



Methods of Inspection

The inspection programme 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 its contractors (the latter should be through the operator);
- 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.



Behaviour during Inspections

Inspectors should conduct themselves on the site in a manner that inspires confidence in and respect for their competence and integrity and should be knowledgeable about the area which they will inspect.

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**The importance of respecting the rules for the facility,
as established by the operator,
should be stressed during training**

Inspection Reports and Findings

- 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 in accordance with established internal procedures of the regulatory body.
- 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. The procedure may also provide for external distribution to appropriate bodies.



Inspection Reports and Findings

- Inspection findings should be sent to the operator for necessary corrective actions.
- Whenever enforcement 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 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 (except the confidential information)

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Management of Enforcement Actions

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 that corrective actions are performed.

The regulatory body shall have statutory powers to enforce compliance with its requirements, including the authority to require an operator to modify, correct or curtail any aspect of a facility's operation, procedures, practices or SSCs to ensure that the required level of safety is achieved.



Management of Enforcement Actions

Inspector's authority in relation to enforcement

- 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.
- If on the spot enforcement authority is not granted to inspectors, information should be sent to the regulatory body such that necessary actions are taken in a timely manner; information shall be transmitted immediately if it is judged that the health and safety of workers or the public are at risk, or the environment is endangered
- 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.



Management of Enforcement Actions

Factors in determining enforcement actions

A range of enforcement actions should be available such as issuing written requirements, warnings or directives or authorizations and the imposition of penalties. The enforcement should depend on consideration of the factors listed below :

- the safety significance of the deficiency and the complexity of the correction that is needed;
- whether a violation of a less serious nature has been repeated;
- the seriousness of the violation;
- whether there has been a deliberate or wilful violation of the limits and
- whether or not the authorized party identified and/or reported the non-compliance or the violation;
- whether the non-compliance or violation impacted the ability of the regulatory body to perform its regulatory oversight function;
- the past safety performance of the authorized party and the performance trend;
- the need for consistency and openness in the treatment of authorized parties.



Methods of Enforcement

Verbal or Written notification of non-compliance

In many cases it may be possible to resolve unsatisfactory situations with minor safety significance by means of discussion with the authorized party. If necessary, such a verbal notification should be formalized in a written notification, in accordance with the legal system of the State.

Written warnings or directives

Deviations from, or non-compliance with, the regulatory requirements as set out in regulations, or unsatisfactory situations that have more than minor safety significance, may be identified at facilities or in the conduct of activities. In such circumstances, the regulatory body should issue a **written warning or directive** to the authorized party, which should specify the nature and regulatory basis for each case and the period of time permitted for taking remedial action, and may provide guidance on the required corrective action(s). This is the most common form of enforcement action and will, in most cases, be sufficient to remedy the safety issue.

Methods of Enforcement

Penalties

The regulatory body should have the authority to impose or to recommend penalties; for example,

- fines on the authorized party, whether a corporate body or an individual;
- or to institute prosecution through the legal process, depending on the legal system and the authorization practices of the State.

The use of penalties is usually reserved for serious non-compliances with regulatory requirements and for repeated violations of the authorization conditions of a less serious nature.

Experience in some States suggests that imposing penalties on the authorized party rather than on individual workers is preferable as it is more likely to lead to improved safety performance.



Methods of Enforcement

Restriction or suspension of activities

If there is evidence of a deterioration in the level of safety, or in the event of a serious violation of the authorization conditions that, in the judgement of the regulatory body, poses an imminent radiological hazard to people or the environment, the regulatory body should require the authorized party to restrict or suspend the operation of specified facilities or activities and to take any further action necessary to restore an adequate level of safety.



Methods of Enforcement

Modification, suspension or revocation of the authorization

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.



Records of Enforcement

All enforcement decisions shall be confirmed to the operator in writing

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

Thank you for your
kind attention!

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