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Regulatory Inspection Programme for Nuclear Fuel Cycle Facilities

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REGULATORY INSPECTION PROGRAMME FOR NUCLEAR FUEL CYCLE FACILITIES

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REGULATORY INSPECTION PROGRAMME FOR NUCLEAR FUEL CYCLE FACILITIES

INTERNATIONAL ATOMIC ENERGY AGENCY
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FOREWORD

Regulatory inspection is one of the core functions of the regulatory body for oversight of facilities and activities that give rise to radiation risks. As established in the IAEA safety standards, the regulatory body is responsible for developing and implementing a programme for the regulatory inspection of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and conditions of the authorization.

The IAEA has issued publications providing general recommendations for performing regulatory inspections of facilities and activities. In recent years the IAEA has also issued publications addressing the practical aspects of establishing and implementing regulatory inspection programmes for nuclear power plants and research reactors. However, similar information for nuclear fuel cycle facilities has not been available until now.

While some of the aspects covered in these publications are also applicable to nuclear fuel cycle facilities, there are specific aspects that need to be considered by the regulatory body to perform effective and efficient regulatory inspections of nuclear fuel cycle facilities. These specific aspects arise from the variety of such facilities and different types and degrees of hazards associated with their operation.

This publication aims to assist Member States in developing and implementing systematic regulatory inspection programmes for nuclear fuel cycle facilities, considering the wide range and varied nature of hazards associated with such facilities.

The IAEA wishes to thank all those who contributed to the development of this publication. The IAEA officers responsible for this publication were L. Valiveti and A. Shokr of the Division of Nuclear Installation Safety.

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1. INTRODUCTION

1.1. BACKGROUND

Requirement 27 of IAEA Safety Standard Series No. GSR Part 1 (Rev. 1) Governmental, Legal, and Regulatory Framework for Safety [1] states that "**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.**"

Paragraph 4.50 of GSR Part 1 (Rev. 1) [1] states:

> "The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections) and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach."

Guidance on performing regulatory inspections of facilities and activities is provided in IAEA Safety Standards Series No. GSG-12, Organization, Management and Staffing of the Regulatory Body for Safety [2] and IAEA Safety Standards Series No. GSG-13, Functions and Processes of the Regulatory Body for Safety [3].

Practical information related to the regulatory inspections of nuclear power plants is provided in Refs [4, 5]. Reference [6] supports regulatory bodies to develop their inspection programme for research reactors and to conduct their own training on research reactor inspection. No similar publication for nuclear fuel cycle facilities (NFCFs) is yet available.

Nuclear fuel cycle facilities include a wide range of facilities that employ diverse technologies and processes. These facilities typically process and handle radioactive and other hazardous material in various physical and chemical forms. The nature and diversity of the processes associated with nuclear fuel cycle facilities and associated activities include a broad range of hazardous conditions. Hence, the planning and conduct of regulatory inspections of these type of facilities needs additional considerations, including the development of a regulatory inspection programme. This publication provides practical information and specific considerations for the development of a regulatory inspection programme and the performance of regulatory inspections of NFCFs.

1.2. OBJECTIVE

The objective of the publication is to provide practical information based on the IAEA safety standards as well as Member States' practices on establishing and implementing regulatory inspection programmes for NFCFs.

The publication covers the elements of a systematic regulatory inspection programme, regulatory inspection process, and the interface of regulatory inspections with other functions and processes of the regulatory body during the operation stage of an NFCF.

The publication addresses the important areas of regulatory inspection in various types of NFCFs. It does not cover all inspection areas and is not intended to be used as a comprehensive reference by a regulatory body but could be used to supplement the regulatory body's overall inspection programme.

The target audience of the proposed publication are regulatory bodies and their technical support organizations dealing with regulatory inspection of NFCFs. The publication may also be useful for operating organizations in preparation for regulatory inspections, and for review of the safety of an NFCF by the senior management of the operating organization.

The information provided here describes good practices and represents expert opinion but does not constitute recommendations made on the basis of consensus by Member States.

1.3. SCOPE

The NFCFs that are within the scope of this publication include facilities for: the conversion, enrichment, and fabrication of fuel; the storage of spent nuclear fuel and the reprocessing of spent nuclear fuel; and nuclear fuel cycle research and development facilities and supporting ancillary facilities in which radioactive material is handled. Nuclear power plants, research reactors, facilities for the mining and processing of natural ore, and waste disposal facilities are outside the scope of this publication. This publication does not address the nuclear security aspects of NFCFs.

1.4. STRUCTURE

This publication consists of four Sections and three annexes. Section 2 of this publication addresses the necessary framework for regulatory inspection and development of a regulatory inspection programme for NFCFs, and the regulatory inspection process. Section 3 provides details of the aspects to be covered in various inspection areas relevant to NFCFs. Section 4 addresses the interface of regulatory inspection with other regulatory functions. Annex I provides a sample regulatory inspection programme for NFCFs based on the Canadian practice. Annex II provides practical information for the development of checklists that may be used by inspectors for various areas of inspections in an NFCF. Annex III provides an example of regulatory inspection process based on the practice of the regulatory body in India.

2. REGULATORY INSPECTION OF NUCLEAR FUEL CYCLE FACILITIES

2.1. GENERAL

2.1.1. Purpose and objectives of a regulatory inspection

The main purpose of regulatory inspection is to verify that the facilities are operated in compliance with the safety requirements. However, para. 4.49 of GSR Part 1 (Rev. 1) [1] states that: "Regulatory inspection cannot diminish the prime responsibility for safety of the authorized party, and cannot substitute for the control, supervision and verification activities conducted under the responsibility of the authorized party."

Regarding the objectives of regulatory inspection, para. 3.220 of GSG-13 [3] states:

> "Regulatory inspection is performed to make an independent check on the authorized party and the state of the facility or activity, and to provide confidence that the authorized party is in compliance with the safety objectives prescribed or approved by the regulatory body. This should be achieved by confirming that:
>
> (a) The authorized party is in compliance with applicable laws, regulations and authorization conditions and all relevant codes, guides, specifications and practices;
> (b) The authorized party has in place an effective management system, a strong safety culture, and self-assessment systems for ensuring the safety of the facility or activity and the protection of people and the environment;
> (c) The required quality and performance are achieved and maintained in the items and activities important to safety throughout the lifetime of the facility or activity;
> (d) Persons employed by the authorized party (including contractors) possess the necessary competence for the effective performance of their functions throughout the whole lifetime of the facility or activity;
> (e) Deficiencies and abnormal conditions are identified and promptly evaluated and remedied by the authorized party 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 regulations is identified and appropriately considered;
> (g) Any safety lessons learned are identified and disseminated to other authorized parties and suppliers and to the regulatory body as appropriate."

During the operation stage, the inspection of an NFCF is focused on verification that the facility is operated within the operational limits and conditions[1] specified in the safety assessment and established in the authorization, and to verify that the operations are carried out safely under a proper management system. During the regulatory inspection of an NFCF, the human, organizational and technical capabilities to operate facilities safely or to conduct activities safely, are also verified.

2.1.2. Framework for regulatory inspection

2.1.2.1. Role of the government

Principle 2 of the IAEA Safety Standards Series No. SF-1, Fundamental Safety Principles [7] states that "**An effective legal and governmental framework for safety, including an independent regulatory body, must be established and sustained.**"

Paragraphs 3.8–3.11 of SF-1 [7] and Section 2 of GSR Part 1 (Rev. 1) [1] give a detailed account of the responsibilities and functions of the government regarding the safety of facilities and activities.

The framework for safety based on the fundamental safety principles provides for the effective regulation of facilities and activities and for the clear assignment of responsibilities. Adequate legal authority, technical and managerial competence, and human and financial resources are necessary for the regulatory body to fulfil its responsibilities effectively. The role of the government with respect to regulatory inspection is to establish a legal and regulatory

[1] Also known as 'technical specification for operation' in some Member States.

framework for regulatory inspection and enforcement, and to establish an effectively independent regulatory body with sufficient authority (e.g., to access a facility, to collect evidence, to perform inspections, to seek necessary information), competent staff and financial resources for conducting regulatory inspections.

In some Member States multiple regulatory bodies (e.g., different regulatory bodies for operational safety and environmental safety) are involved in regulation of safety aspects related to NFCFs. In such cases, a robust legal framework for coordination between these regulatory bodies aids the effectiveness of regulatory inspections.

2.1.2.2. Role of the regulatory body

Paragraph 3.221 of GSG-13 [3] states:

> "Specific responsibilities of the regulatory body with respect to inspection should include the following:
>
> (a) Conducting planned inspections, at relevant steps of the authorization process;
> (b) Carrying out reactive inspections, as appropriate, in response to events;
> (c) Identifying and recommending necessary changes to the requirements approved by the regulatory body, as specified in the authorization or contained in the regulations;
> (d) Preparing reports to document inspection activities and their findings;
> (e) Ensuring that the authorized party has adequate, comprehensive and up to date information on the status of the facility or activity and information for demonstrating safety, and a procedure for keeping such information up to date;
> (f) Detecting degraded performance and potential non-compliances;
> (g) Tracking recurrent problems and non-compliances;
> (h) Verifying that corrective actions have been undertaken by the authorized party to resolve safety issues identified previously;
> (i) Developing procedures and directives as necessary for the effective conduct and administration of the inspection programme;
> (j) Determining and recommending suitable enforcement actions when non-compliance with regulatory requirements or a violation of the conditions of an authorization is encountered."

In the process of fulfilling these responsibilities, the regulatory body needs to structure its organization and manage its resources (including human and financial resources) effectively in conduct of regulatory inspections and other processes. Paragraphs 3.210–3.294 of GSG-13 [3] provide general guidance and recommendations on objectives, organization, types, planning, performance, records, and follow-up of regulatory inspection. The management system of the regulatory body needs to have provisions in place to prevent, identify and resolve the conflict of interest in the process of regulatory inspection, especially when engaging external experts. The aspects to be considered in deployment of external experts for various regulatory functions, including regulatory inspections, are addressed in Appendix I of GSG-12 [2].

Setting up formal and informal communication mechanisms between the inspecting staff and the operating organization enable fostering of mutual trust. The competence of the staff deployed for regulatory inspection and their conduct is the key factor to develop mutual respect between the regulatory body and the operating organization. The competence requirements for the staff of regulatory body involved in inspection are provided in paragraphs 6.42–6.45 of GSG-12 [2].

The results of regulatory inspections are sometimes used in regulatory decision making, such as the amendment, renewal, suspension or revocation of authorization or licence for operation of a facility. Senior inspectors with relevant facility and inspection area experience need to be deployed for such inspections. Other supporting inspectors may accompany such inspections for training and experience purposes.

The regulatory body needs to establish a mechanism for the resolution of issues or concerns identified during the inspections and to verify the corrective actions taken by the operating organization in subsequent inspections.

The regulatory body periodically reviews and updates the inspection programme and process for inspections based on its experience. The review can be based on the safety performance of the facility and also on relevant national and international operating and regulatory experiences. The IAEA/NEA Fuel Incident Notification and Analysis System (FINAS)[2] is one of the sources to obtain operating experience from the incidents that occurred worldwide in various NFCFs. The IAEA-TECDOC-1932, Operating Experience from Events Reported to the IAEA/NEA Fuel Incident Notification and Analysis System (FINAS) [8] summarizes the operating experience feedback from the events reported to FINAS, including root cause(s), lessons learned, and corrective actions taken to prevent the occurrence of similar events in other NFCFs.

2.2. REGULATORY INSPECTION PROGRAMME

A regulatory inspection programme provides a framework for planning and conducting inspections of NFCFs, and of the activities carried out in them. Physical on-site inspection is one of the common and effective form of regulatory inspection. However, extenuating circumstances may arise for which alternate approaches of inspection need to be implemented to provide reasonable regulatory oversight. Examples of alternate methods include remote or hybrid inspections. The adequacy and effectiveness of such types of inspections is evaluated by the regulatory body.

Paragraph 4.50 of GSR Part 1 (Rev. 1) [1] states:

> "The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections), and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach."

The inspection programme of a regulatory body for NFCFs needs to be developed based on a graded approach considering the factors like risk involved in operation of facility, maturity and complexity of the facility and safety performance of the facility. Section 2.3 gives further details on use of a graded approach in the development and implementation of a regulatory inspection programme for NFCFs. The extent and frequency of inspections may also be adapted in accordance with the trend of findings from previous inspections. The regulatory inspection programme may be included as a part of Level II documentation in the hierarchical structure of the integrated management system documentation given in Appendix IV of GSG-12 [2].

[2] https://www.iaea.org/resources/databases/irsni

Further information on the development of an inspection programme document for NFCFs, in line with the recommendations given in paragraphs 3.223–3.235 of GSG-13 [3] is given below:

The inspection programme document for NFCFs needs to cover all the areas of responsibility of regulatory body and needs to include the following sections:

– Introduction

This section includes a brief description of purpose and objectives of regulatory inspection and a statement highlighting that the regulatory inspection cannot diminish the prime responsibility for safety of the operating organization. See para. 4.49 of GSR Part 1 (Rev. 1) [1] for further information.

– Legal framework

This section includes the references to the laws and/or legal framework that empower the regulatory body to conduct regulatory inspection and enables the inspectors to have access to the facilities for the purposes related to regulatory inspection and verification of safety.

– Graded approach and categorization of facilities

This section includes the description of graded approach adopted in evolving the inspection programme. The description of graded approach needs to include the details of factors (e.g., hazard potential, complexity of the facility, maturity of the processes) considered in categorizing the facilities. The section also needs to include the categorization of various types of nuclear facilities for using a graded approach in development of the regulatory inspection programme.

– Types of inspection

This section describes the types of inspections planned to be conducted by the regulatory body. These include programmed inspections and reactive inspections, both announced and unannounced. Details on various types of regulatory inspection are provided in paras 3.236-3.251 of GSG-13 [3].

The section also includes description of provisions and procedures made for conducting:

- Additional inspections that may be based on operational performance, modifications in the facilities, licensing, and milestone activities;
- Reactive inspections that may be conducted in response to events, incidents, and accidents at the NFCFs, or in response to the operating experience feedback from similar facilities.

– Inspection areas and frequency of inspection

This section details the areas of inspection to be covered in the inspection programme, frequency of inspections and coverage of functional areas for specific categories of NFCFs. The important areas of inspection for an NFCF are detailed in Section 3 of this publication. The frequency of inspection of an NFCF may consider the safety performance of the facility in addition to the risk posed by operation of the facility.

– Conduct of inspections

This section describes the process of conduct of regulatory inspection including appropriate references to:

- The documents specifying the necessary qualifications, competences, roles and responsibilities of the inspectors;
- The procedures relating to planning, scheduling, and performance of regulatory inspections.

The section also presents a description of mechanisms and reference to the procedures for communication with the operating organization. The aspects of necessary submissions and arrangements to be made by the operating organization for smooth conduct of regulatory inspection may also be included in these procedures.

Further, this section includes the description of mechanisms and reference to the procedure for enforcement action by the inspectors. The section also includes references to procedures for preparation and dissemination of inspection reports and findings to the operating organization and other interested parties, as applicable.

– Process interface

This section includes the description of mechanisms and reference to the procedures for:

- The follow-up of the findings of regulatory inspection;
- The conduct of review and analysis of inspection findings and utilization of the feedback from the analysis;
- The interfacing of regulatory inspections with other core and support function of the regulatory body (e.g., safety review and assessment, development of regulations and guides).

The aspects of interface of regulatory inspection with other functions of the regulatory body are further addressed in Section 4.

– Continual improvement

This section includes the description of mechanisms and reference to the procedure for review and self-assessment of the regulatory inspection programme. Aspects such as review of inspector performance, and review of training, retraining and competence development programmes for the inspectors, may also be considered in the self-assessment. The section also provides a description of mechanisms and reference to procedures for obtaining feedback on the regulatory inspection process from the operating organization.

A sample regulatory inspection programme based on the Canadian practice is included in Annex I.

2.3. USE OF A GRADED APPROACH IN THE DEVELOPMENT AND IMPLEMENTATION OF A REGULATORY INSPECTION PROGRAMME

The IAEA safety standards require the use of a graded approach for inspections. Requirement 29 of GSR Part 1 (Rev. 1) [1] states that "Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach".

Other factors that can be considered in evolving graded approach to the regulatory inspection of NFCFs are the maturity and complexity of the type of the facility and specific safety performance of the facility. Paragraphs 2.8–2.10 of GSG-13 [3] and para. 3.4 of IAEA Safety Standards Series No. GSR Part 4 (Rev. 1), Safety Assessment for Facilities and Activities [9] give further information on consideration of maturity and complexity of the facility in application of graded approach. IAEA Safety Standards Series No. SSR-4, Safety of Nuclear Fuel Cycle Facilities [10] establishes requirements related to use of a graded approach related to application of certain safety requirements.

For the purpose of the use of a graded approach in the regulatory inspections, the facilities are first categorized based on the risk level associated with the facility and the activities. The non-radiological risks also need to be considered in categorization of the facilities. For example:

- The facilities which could have significant off-site impact (radiological or chemical) in accident conditions, and facilities where criticality accident cannot be ruled out by design, may be categorized as high hazard category facilities (e.g., reprocessing facilities, mixed oxide (MOX) fuel fabrication facilities).
- The facilities which could have insignificant or minor off-site impact in accident conditions but could have significant on-site impact (e.g., large scale contamination or radiation doses or chemical exposures above authorized limits) may be categorized as medium hazard category facilities (e.g., conversion and enrichment facilities).
- Other low hazard, and small-scale facilities may be categorized as low hazard category facilities.

The graded approach in frequency of inspections, coverage of inspection areas and conduct of inspections are generally based on the categorization of the facilities. Other factors that may be considered for use of a graded approach in development of an inspection programme for the NFCFs include:

(a) Maturity of facility and the operating organization:

  (i) Use of proven design and proven operating procedures and practices at the NFCF.
  (ii) Experience of the operating organization and the operating personnel in operating similar facilities.

(b) Complexity of the NFCF:

  (i) The extent of difficulty and complexity of the efforts needed for the processes and activities in the NFCF. Complex operations or intricate procedures necessitate the use of more stringent inspections as compared to simple operations and straightforward procedures.
  (ii) Reliability and complexity of the structures, systems, and components (SSCs) used in the facilities, including the use of unknown or new technologies in the SSCs.
  (iii) The accessibility of SSCs for maintenance, inspection, testing and repair.

(c) Operating experience:

(i) Operating experience feedback of the facility based on the periodic safety reviews, review and assessment by the regulatory body and the observations made in previous regulatory inspections. For this purpose, the operating experience of the facility during the past 5–10 years may be considered as a suitable reference period.
(ii) Operating experience of other similar facilities or activities.

(d) The legitimate concerns of interested parties regarding nuclear and radiation safety matters related to the NFCF.

(e) Experience of the regulatory body in regulation of similar facilities.

Ref. [11] proposes a generic methodology and documents Member States' practices on the application of a graded approach for regulatory inspection and other regulatory functions, for regulation of nuclear installations (including NFCFs).

2.4. REGULATORY INSPECTION PROCESS

2.4.1. Resource planning

A comprehensive inspection programme for all types of NFCFs can be developed based on the elements as described in Section 2.2. The programme is generally a planned inspection programme with two types of inspections:

- Baseline inspections focused on compliance verification (e.g., operational radiation protection, operational limits, and conditions);
- Special inspection focused on the licensee's activities or regulatory milestones (e.g., major modifications or licence renewal).

An annual inspection calendar is prepared taking account of the baseline inspection requirements at different NFCFs. This will help in identifying and allocating adequate resources for the inspection programme. Reactive inspection requirements (e.g., in case of significant events) may be unforeseen and need to be appropriately considered for resource planning.

2.4.1.1. Human resources

Selection of inspection team members needs to be completed sufficiently in advance to ensure the availability of competent inspectors. Section 2.4.2 provides information on the competency of the inspectors. The choice of inspection team may consider the type and scope of inspection, inspection objectives, and complexity of the process and technologies used in the NFCF. In general, one inspector is assigned one inspection area. Depending on the size, nature and type of facility, and the duration of the inspection, an inspector may be assigned more inspection areas. For large NFCFs with multiple installations, or complex technologies, additional inspectors may be assigned for assisting the responsible inspector in the inspection area.

Depending on the national practices and regulatory infrastructure, the regulatory body may also involve inspectors from its regional offices (or resident inspectors) or external experts in the regulatory inspection.

2.4.1.2. Duration

Planning of the inspection schedule, including the duration of inspection is necessary to ensure that the regulatory inspections are effective and efficient. The inspection schedule is prepared considering the objectives and scope of inspection and availability of inspectors for the relevant area of inspection. The duration of the inspection at the facility may also depend on the current safety issue(s), the inspection team, and the complexity of the facility. The duration of inspection is generally planned based on the regulatory experience, current practice of regulatory supervision, and the resources available with the regulatory body. The following aspects need to be considered for planning the duration of inspection of an NFCF:

- Type of inspection: A baseline inspection where all the inspection areas of the NFCF are covered, may take more time than a special inspection focused on specific safety issues.
- Facility status: Longer duration of inspection may be needed for an ageing facility, a facility that has experienced significant events, or a facility that includes multiple installations.
- Experience of inspectors: An inspector who is familiar with the facility may be able to complete the inspection in a shorter time than an inspector who is not familiar with the facility.
- Extent of documentation that needs to be reviewed: Although the review of documentation is done by the inspectors on a sample basis, significant effort would be necessary for inspection of NFCFs with a large number of SSCs.

2.4.2. Competencies and responsibilities of inspectors

Regulatory inspection takes place at the authorized facility where the authorized activity occurs. Hence, the inspectors need to be knowledgeable and competent to inspect the facility independently, applying various inspection methods, and making appropriate regulatory decisions on the site, without being drawn into the operating organization's decision-making process related to the operation of the facility.

2.4.2.1. Competency of inspectors

Inspectors need to have thorough knowledge and a clear understanding of the safety requirements that are relevant to the NFCF and have experience in their application. Additionally, they also need to have necessary qualification and experience related to the inspection area and/or the facility.

The inspector needs to be able to effectively:

- Observe and evaluate the activities at the NFCF to identify non-compliances;
- Review facility records and documentation to identify safety issues;
- Conduct independent tests and measurements for verification of safety;
- Interview staff of the operating organization to obtain relevant information.

2.4.2.2. Roles and responsibilities of inspectors

The authority vested in inspectors obliges them to conduct themselves professionally at all times in a manner that inspires confidence in, and respect for, their competence and integrity. In addition, inspectors are to be aware that inappropriate behaviour, both during and outside of

working hours, may discredit both the individual and the regulatory body. Inspectors need to demonstrate impartiality and independence in their decision making.

The inspector needs to:

- Independently verify information provided by the operating organization when appropriate;
- Adhere to regulatory positions and policies and avoid personal interpretations and opinions, when discussing issues with the licensee;
- Maintain a professional relationship with the licensee using good interpersonal relationship skills;
- Provide an accurate, unbiased and balanced account of an operating organization's performance and facility conditions in all communications, including the inspection reports;
- Focus on safety significant concerns, applying significance determination and enforcement guidance appropriately;
- Judiciously use the position and authority given to inspectors;
- Control off hours activities so that their ability to perform assigned duties is not impaired during duty hours.

A systematic programme for training and authorization of inspectors needs to be established by the regulatory body to impart the necessary knowledge and develop the necessary competencies. The regulatory body needs to clearly communicate the performance expectations to the inspectors and evaluate feedback from the operating organization regarding inspection activities.

2.4.3. Internal guidance

Paragraph 3.262 of GSG-13 states [3]:

> "The regulatory body should issue internal guidance for its inspectors on performing regulatory inspections in order to ensure a consistent approach to inspection while allowing sufficient flexibility for inspectors to take the initiative in dealing with new concerns that arise."

Paragraphs 3.263 and 3.264 of GSG-13 [3] provide further recommendations on the aspects that need to be covered in the internal guidance for the inspectors.

2.4.4. Preparation for inspection

In general, preparation for inspection includes development of a plan or methodology to conduct the specific inspection, selection of inspectors for the inspection team, development of necessary administrative documentation, official notification to the facility operator, and implementation of other legislative formalities.

The composition of the inspection team can be specified in the inspection plan, or in a separate administrative document. Usually, the inspection team includes an appointed team leader with a deputy (or deputies), and team members assigned to particular inspection areas.

The team leader is appointed from the senior staff, who have adequate knowledge and understanding of the regulatory basis, the facility, and sufficient level of management experience. The team leader is responsible for further execution of preparatory and inspection activities of the team. The team leader is expected to provide guidance and advise, as needed, to the inspectors to confirm their findings.

The inspection plan may specify the inspection timeframes, the list of areas and issues to be reviewed, the list of the facility buildings, structures, and components to be inspected and the list of facility documentation that needs to be made available for the inspection team at the facility.

While developing an inspection plan, in general, the following aspects are considered:

- Type of inspection;
- Duration of inspection;
- Inspection areas to be covered;
- Inspection methods to be used;
- Inspector competencies and number of inspectors;
- Inspection procedures;
- Inspection findings, violations and enforcement actions from previous inspections;
- Applicable inspection findings from similar facilities, if any;
- Regulatory experience feedback and inputs for other functions (e.g., notification and authorization, review and assessment, enforcement) of the regulatory body.

To achieve the objectives of an inspection, the inspector needs to plan and prepare for the inspection. The level of preparation needed depends on the type of inspection. For baseline inspections, inspection area specific checklists along with inspection procedures are necessary. In case of special or reactive inspections, the inspector may have to develop a specific strategy for performing the inspection.

The inspectors may need to develop specific checklists for the areas of inspection of the facility. These checklists need to be developed considering, inter alia, the safety requirements applicable to the facility being inspected, conditions of authorization of the facility, findings of the previous inspections, findings of periodic safety reviews and the corresponding implementation plan, and other safety and licensing documentation. Annex II provides examples of aspects that might be included in the inspection checklists for some of the areas of inspection for NFCFs.

The licensing and other safety documentation of the facility that needs to be considered in development of specific checklists may amongst others include the following:

- Safety analysis report;
- Operational limits and conditions;
- Design basis reports of safety related SSCs;
- Operating procedures including emergency procedures;
- Maintenance and surveillance procedures and associated records;
- Event reports and corrective action reports;
- Emergency preparedness and response plan.
- Previous inspection reports and action taken reports.

The operating organization needs to be appropriately notified of the purpose and scope of inspection including the schedule of inspection, the size of the inspection team, and the regulatory basis for inspection. The inspection plan may be communicated to the operating organization to facilitate their preparation for the regulatory inspection.

2.4.5. Performing regulatory inspection

2.4.5.1. Opening meeting

In the case of both announced as well as unannounced inspections, an opening meeting with the operating organization may be conducted to ensure that the inspection team and the operating organization have a common understanding of the purpose and scope of the inspection. The following aspects may be addressed in the opening meeting:

- Purpose, scope and areas of the inspection;
- Duration of the inspection and schedule of inspectors' visits;
- Inspection methods and procedures that will be used during the inspection;
- Details of important activities that may be observed, records and documents that may be reviewed, and personnel who may be interviewed during the inspection;
- Licensee inputs, if any, related to the inspection areas; and designation of counterparts, if any, for the inspection areas;
- Facility activities that may impact the scope or areas of the inspection;
- Any other logistical information for the inspection;
- Counterparts of the inspectors for the inspection areas;
- Address any questions from the licensee regarding the inspection.

2.4.5.2. Conduct of inspection

Conduct of regulatory inspection generally involves sample checks of the conditions of SSCs, compliance with procedures, and review of records maintained by the operating organization. Sample selection for the regulatory inspection sets the stage for a focused and productive inspection. Considerations related to selecting an appropriate sample and sample size include:

- The majority of a team's sample need to be chosen of the basis of risk. Samples need to include the most risk significant areas and operations of the facility.
- Periodically, the samples may also include some lower risk operations and areas of the facility as those areas may point to precursors or latent issues that are harder to detect given risk level.
- Samples need to also include items that need some physical observation so that the inspection encompasses performance-based activities and documentation review (e.g., pick samples where the operations or ongoing work can be observed, and review associated documentation).

The inspection plan needs to be followed to the extent possible, to ensure effective utilization of the inspection resources while meeting the inspection objectives. However, the inspector may deviate from the inspection plan depending on the safety significance of the observations at site. Such deviations need to be discussed within the inspection team and any change in plan notified to the licensee. During the inspection, the inspectors may refer the inspection checklists to ensure that the inspection is in line with the plan and important aspects are not being missed out.

During the course of inspection, if the inspector finds a situation in which continued operation of the facility or equipment can immediately affect the health and safety of the occupational workers, the public, or the environment, then it might be necessary for the inspector to ask the operating organization to take immediate and appropriate corrective actions. On-site enforcement action by the inspectors is generally limited to verbal or written notifications. The level of authority of an inspector to take an enforcement action on-site is documented in the regulatory policies of the regulatory body.

2.4.5.3. Inspection methods

Four basic methods for obtaining information during an inspection are in the following (see also GSG-13 [3]):

- Monitoring and direct observation;
- Discussions and interviews;
- Document evaluation;
- Independent tests and measurements.

Depending on the type of inspection being performed, the inspector needs to determine the method(s), which would be best to gather and evaluate the necessary information for the inspection. One way of initiating the inspection is to start with review of documents and records, followed by discussions with the licensee on the identified safety issues, facility walk-down for a physical verification of the equipment conditions or observe activities and discussions with the concerned staff of the facility.

Monitoring and direct observation

This inspection method involves the direct observation of activities in the NFCF. Monitoring and direct observation method is performance-based, that allow the inspector to determine whether the licensee is following procedures and meeting the regulatory requirements while performing their activities. The observations may be general in nature or may be focused on specific activities in order to gain an overall impression of the licensee's capabilities and performance.

Discussion and interviews

Formal and informal communication with the operating organization's personnel may be used to learn about, and understand, potential safety issues that may not be revealed during the inspector's observation of activities. Discussions with personnel are especially important in follow-up investigations to reconstruct events and assess the operating organization's response.

Insights on how the leadership and management of the NFCF promotes and fosters a strong safety culture can also be obtained during discussions with operating personnel. For example, the answers to the question of whether safety is promoted at all organizational levels over the outage schedule, during facility outages and non-routine operations may provide some insight to the safety culture of the licensee.

The inspectors may request interviews on a specific topic or with a specific individual. However, the inspector needs to consider the possible impact on the ongoing activities at the NFCF. Additionally, interviews and discussions always need to be conducted in a respectful manner.

Examination of documentation

Documents may be examined as part of the preparation for an inspection, as well as during the inspection. This method is used to reinforce direct observations by assessing the past performances. It also helps in gathering information during reactive inspections.

Examples of documents that may be examined include, but are not limited to:

- Control room logs;
- Maintenance and surveillance records;
- Post maintenance performance test records;
- Records of periodic testing and inspection;
- Facility modification reports;
- Training records (e.g., in operations, radiation protection, and emergency response);
- System descriptions, drawings, and operating procedures;
- Previous inspection reports;
- Work permits;
- Records of safety and operational performance;
- Operating experience feedback reports including event investigation reports.

Independent tests and measurements

An on-site confirmatory measurement can provide confidence to the inspector with respect to the operation of the facilities and activities within the operational limits and conditions or the conditions specified in the authorization. However, under no circumstances may an inspector operate facility equipment alone or affect facility operations or safety in any manner, when conducting tests and or taking measurements. A typical example of a measurement taken by an inspector would be the independent verification of radiation and contamination levels in specific areas of the facility against the measurements taken by the operating organization.

2.4.5.4. Evaluating inspection observations

For each observation, the inspector needs to evaluate its significance by using a graded approach. As an example, answers to a few questions (as listed below) about the observation will guide the inspector in evaluating its significance.

- Can it immediately affect the health and safety of the public or the environment?
- Can it immediately affect the health and safety of the workers of the facility?
- Can it immediately affect the safety of the facility?
- Has the concern been identified by the facility's corrective action programme, and have actions been initiated?
- If corrective actions have been initiated, when will they be completed?
- Is the facility being operated within the regulations and licence conditions while this condition still exists?
- How is the safety of the facility and the public being maintained?
- Are there violations of laws, requirements, regulations, standards, or procedures?
- Is there a need for immediate regulatory action, including enforcement?

During the initial evaluation of the observations, the inspector also needs to consider the following aspects which may affect possible regulatory action(s), including enforcement. The types of information may include, but are not limited to:

- How was the issue identified (e.g., by the operating organization or by the inspector)?
- Is there evidence of wilful non-compliance?
- Is this a repeated issue?

Based on the evaluation, the safety significance of the inspection observation is determined. This helps the regulatory body to formulate appropriate enforcement or follow-up actions.

2.4.5.5. Exit meeting

After completion of the inspection, the inspection findings are communicated to the operating organization in an exit meeting. The main objective of the exit meeting is to inform the operating organization on the inspection findings. The meeting is also an opportunity to brief the management about the strengths and weaknesses noticed during the inspection and also to get additional information, if any from the management regarding the findings.

During the exit meeting, the inspectors are expected to:

- Briefly restate the scope of inspection and overall conclusions, discuss any potential violations including a description of the finding and the requirement or licence condition that was not met;
- Provide the licensee the opportunity to respond;
- Cite facts, observations and examples during discussions;
- Keep the meeting short and to the point.

2.4.6. Inspection report

The findings of the regulatory inspection need to be formally recorded by the regulatory body and the same needs to be communicated to the operating organization in form of an inspection report.

Paragraph 3.285 of GSG-13 states:

> "The purposes of inspection reports are:
>
> (a) To record the results of all inspection activities relating to safety or of regulatory significance;
> (b) To document and record an assessment of the authorized party's activities in relation to safety;
> (c) To record discussions held with authorized party's staff, management and other concerned persons;
> (d) To provide a basis for informing the authorized party of the findings of the inspection and of any non-compliance with regulatory requirements, and to provide a record of any enforcement actions taken;
> (e) To record any findings or conclusions reached by inspectors;

(f) To record any recommendations by inspectors for future actions by the authorized party or the regulatory body and to record progress on recommendations from previous inspections;
(g) To inform other staff of the regulatory body of inspection results;
(h) To contribute to maintaining an organizational memory."

Depending on the regulatory body practices, a draft inspection report containing the observations made by the inspectors may be provided to the operating organization. The final inspection report may subsequently be formally issued by the regulatory body.

Inspectors need to use a standard report format developed by the regulatory body for documenting the inspection. GSG-13 [3] provides detailed information on the content of the inspection report. The information generally includes, but is not limited to:

- Identification of the facility inspected and dates of the inspection;
- Purpose and scope of the inspection;
- Names of the inspectors;
- Findings identified during the inspection;
- Regulatory assessment of the findings;
- Enforcement actions taken, if any;
- Corrective actions taken by the operating organization.

It is also desirable to categorize the deviations based on their safety significance in order to reflect the safety status of the facility in an objective manner.

2.4.7. Post inspection activities

Paragraph 3.294 of GSG-13 states:

> "A programme to systematically analyse and follow-up on inspection findings should also be established. The programme should include provisions for periodic review and surveillance of the follow-up actions to verify that the authorized party is taking the necessary actions in response to inspection findings. Upon satisfactory completion of the actions, the inspection findings should be formally closed and necessary documents and records should be maintained."

2.4.7.1. Follow-up and compliance review

The operating organization needs to submit a formal response to the regulatory inspection report in a time-bound manner, indicating the actions it has taken or proposed to take to correct the deficiencies and achieve compliance with the safety requirements. The response also needs to indicate any changes in the management systems to prevent such occurrences in the future.

The response has to be reviewed by the regulatory body and the following decisions may be taken based on the review:

- Formally close the deviation if the actions taken by the operating organization are satisfactory;
- Mark the deviation for verification in a future inspection;
- Keep the deviation pending and follow up if the actions taken are not adequate.

A centralized database for the inspection results (findings, corrective actions, status) will help the regulatory body keep track of the safety issues raised during regulatory inspections. This information may be used to identify potential areas for improvement in the safety performance of operating organization and also the regulatory processes.

2.4.7.2. Self-assessment of inspection process

The optimization and improvement of regulatory inspection process needs to be carried out on a continuous basis through a periodic self-assessment programme. Inputs from various interested parties (e.g., operating organization, inspection staff, safety review and assessment staff, licensing staff) may be obtained in the self-assessment process. The self-assessment of the inspection process is part of the management system requirements for the regulatory body.

Annex III gives an example of the regulatory inspection process based on the practice in India.

3. AREAS OF INSPECTION IN NUCLEAR FUEL CYCLE FACILITIES

3.1. OPERATING ORGANIZATION AND FACILITY MANAGEMENT

Paragraph 9.1 of SSR-4 [10] states:

> "The prime responsibility for safety rests with the operating organization of the nuclear fuel cycle facility. This prime responsibility includes the responsibility for supervising the activities of all other related groups, such as designers, suppliers, manufacturers and constructors, employers and contractors, as well as the responsibility for operation of the facility by the operating organization itself. The operating organization shall discharge this responsibility in accordance with its management system."

Requirement 55 of SSR-4 [10] states:

> "**The structure of the operating organization and the functions, roles and responsibilities of its personnel shall be established and documented, in accordance with a graded approach.**"

Paragraph IV.22 of GSG-13 [3] states

> "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 a strong safety culture."

The objective of the inspection is to determine if the operating organization recognizes and effectively fulfils its prime responsibility of ensuring the safety of the NFCF over its lifetime.

Section II-1 of Annex II provides additional information for preparation of specific checklists for this area of inspection.

3.2. MANAGEMENT SYSTEM

Paragraph IV.39 of GSG-13 [3] states:

> "Inspection of the effectiveness of the management system should include inspection of those indicators that 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 listen to 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 a strong safety culture."

Paragraph IV.40 of GSG-13 [3] states:

> "The authorized party'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 described earlier, activities such as: procurement, receipt, storage and handling of equipment; document control; and operating experience. In particular, the adequacy and effectiveness of the authorized party's performance of corrective actions should be assessed."

The objective of the inspection is to evaluate the management's involvement in the facility and its effectiveness in paying appropriate attention to operational issues. The aspects considered in the regulatory inspection of this area include the review of organization structure, identification and remediation of problems, demonstration of management's focus on safety, configuration management, self-assessment, and the quality assurance (QA) programme.

Section II-2 of Annex II provides additional information for preparation of specific checklists for this area of inspection.

3.3. TRAINING AND QUALIFICATION

Requirement 58 of SSR-4 [10] states that "**The operating organization shall ensure that all activities that may affect safety are performed by suitably qualified and competent persons.**"

Paragraph IV.20 of GSG-13 [3] states that "The adequacy of the authorized party's training programme for staff should be assessed routinely to ensure that the training reflects actual conditions in the facility."

The regulatory inspection of this area covers the aspects related to qualification and competence of operating personnel to ensure safety in all the activities. In some Member States, regulatory requirements may prescribe a formal authorization for certain administrative or operating positions for some of the NFCFs. In other cases, selection criteria for personnel are established in facility's management system in accordance with national requirements.

The assessment of the effectiveness of the qualification, training and retraining programme of the facility is done in this inspection. The qualification and competence of the operating personnel responsible for safety related activities is also verified in this inspection. In addition to the operating personnel, the scope of this inspection also needs to include the training

requirements for vendors, contractors, and suppliers, as applicable. If the assessment of specific training requirements is effectively covered in other areas of inspection (e.g., operational radiation protection, nuclear criticality safety, emergency preparedness), the inspection may be limited to the review of programmatic aspects and the areas that have not been covered in other regulatory inspections.

Section II-3 of Annex II provides additional information for preparation of specific checklists for this area of inspection.

3.4. CONDUCT OF OPERATIONS

Paragraph IV.18 of GSG-13 [3] states:

> "Inspections in the area of operations should focus on the control and execution of activities directly relating to operating a facility to the operational limits and conditions established by regulatory requirements and authorizations or by procedures or specifications. Inspectors should perform safety verification of: operating procedures; the operating configuration of systems important to safety; 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."

Paragraph IV.19 of GSG-13 [3] states:

> "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. The inspection programme in this area may necessitate sustained observations (e.g., in the control room) to cover 24 hour operation as necessary, and 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."

Paragraph IV.21 of GSG-13 [3] states:

> "A sampling review of safety systems should be performed to evaluate the following:
>
> (a) Any identified degraded equipment;
> (b) Discrepancies between installed components and/or system hardware and the facility drawings;
> (c) Controls for performing maintenance on equipment;
> (d) 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 degraded equipment repaired by 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."

The important aspects covered in this area of inspection include the verifications related to the following:

- Development and comprehensive application of operating procedures;
- Feedback of operating experience;
- Development and implementation of programmes for maintaining material conditions, housekeeping and cleanliness;
- Establishment and maintenance of systems for the control of records and reports;
- Conduct of safety related activities;
- Operational accident management programme.

In this publication, the regulatory inspection of the operational limits and conditions is covered as a separate area in Section 3.6.

Section II-4 of Annex II provides additional information for preparation of specific checklists for this area of inspection.

3.5. NUCLEAR CRITICALITY SAFETY

Requirement 66 of SSR-4 [10] states that "**All operations with fissile material shall be carried out to maintain an adequate margin of subcriticality, under operational states and conditions that are referred to as credible abnormal conditions or conditions included in the design basis.**"

Paragraphs 9.23–9.24 of SSR-4 [10] establish requirements on nuclear criticality safety staff in an NFCF. Paragraphs 9.83–9.85 of SSR-4 [10] establish requirements on criticality control in operation of NFCFs. Paragraphs 9.86–9.89 of SSR-4 [10] respectively establish additional requirements on criticality control in operation for enriched uranium fuel fabrication facilities MOX fuel fabrication facilities, uranium enrichment and conversion facilities, and fuel reprocessing facilities.

The purpose of the regulatory inspection in this area is to evaluate the performance of the nuclear criticality safety programme of the operating organization. The aspects covered in the regulatory inspection typically include the review of organizational aspects, procedures, training, operational control, alarms systems and emergency preparedness aspects related to nuclear criticality safety.

The regulatory inspection needs to confirm whether all operations with fissile material are being carried out ensuring an adequate margin of subcriticality considering normal operation and anticipated operational occurrences. The judgement on adequacy of margins needs to be based on the operational limits and conditions and the design basis of the facility. Aspects related to possible deviations in operating conditions like changes in equipment configuration and layout, changes in storage conditions, presence of transient neutron reflectors, accumulation of fissile material, and status of criticality alarm system need to be looked into during the area visits. During the inspection, aspects related to operator awareness and training need to be assessed by means of interaction with facility personnel.

Section II-5 of Annex II provides additional information for preparation of specific checklists for this area of inspection.

3.6. OPERATIONAL LIMITS AND CONDITIONS

Paragraph 6.58 of SSR-4 [10] states that "Operational limits and conditions are a set of rules setting forth parameter limits, the functional capability and the performance levels of equipment and personnel for the safe operation of a facility."

Requirement 57 of SSR-4 [10] states that "**The operating organization shall ensure that the nuclear fuel cycle facility is operated in accordance with the set of operational limits and conditions.**"

Paragraph 9.38 of SSR-4 [10] states that "The operating organization shall maintain sufficient records to demonstrate compliance with operational limits and conditions."

The operational limits and conditions of a nuclear fuel cycle facility may include safety limits, safety system settings, limiting conditions for safe operation, periodic testing and surveillance, actions to be taken in case of operation outside operational limits or conditions, and administrative controls. The purpose of inspection in this area is to obtain confirmation that the facility is being operated in accordance with the operational limits and conditions required for safety.

Section II-6 of Annex II provides additional information for preparation of specific checklists for this area of inspection.

3.7. MAINTENANCE, PERIODIC TESTING AND INSPECTION

Paragraph IV.32 of GSG-13 [3] states:

> "Inspection in the area of maintenance and testing should comprise assessments of the implementation of the maintenance and testing programme. These should cover:
>
> (a) All types of maintenance performed on structures, systems and components and maintenance of the physical condition of the facility;
> (b) 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."

The regulatory inspection in this area also needs to consider sample review or observation of some of the activities. The following aspects may be looked into during the regulatory inspection:

- Capability of the individuals performing the maintenance, periodic testing and inspections;
- Interface between the maintenance staff and the operations staff;
- The adequacy and usability of the procedures;
- The control and calibration of the test equipment;
- Involvement of management to ensure that the programme for maintenance, periodic testing and inspection is effective;
- Maintenance backlogs, if any;
- Repetitive equipment repairs;
- Condition assessment reports;
- Management of spare parts and obsolescence management;
- Self-assessment of the maintenance, periodic testing and inspection programme.

Section II-7 of Annex II provides additional information for preparation of specific checklists for this area of inspection.

3.8. MODIFICATIONS

Requirement 61 and paras 9.56–9.61 of SSR-4 [10] establish requirements related to operational control of modifications in an NFCF.

Paragraph 3.133 of GSG-13 [3] states:

> "Throughout the lifetime of the facility or activity, modifications may be made to equipment, to management arrangements and to operational procedures. Where these modifications potentially affect safety, they should be subjected to proper consideration by the authorized party. The regulatory body should ensure that proposed modifications are categorized by the authorized party in accordance with their safety significance. This categorization should follow an established procedure, which may be subject to agreement or approval by the regulatory body. Modifications that are categorized as significant to safety should be submitted to the regulatory body for review and approval or agreement. The regulatory body should inspect the modifications for compliance with the established categorization procedure on a regular basis."

Paragraph IV.37 of GSG-13 [3] states:

> "Modifications may be simple or complex and may involve changes to engineering, operating procedures and/or the organizational structure. For major modifications to the structures, systems, and components of a facility, most of the planning, design and manufacture will be performed prior to outages. The regulatory body should inspect the authorized party's record to determine whether its modification process has been effective in controlling modifications in a manner that is appropriate for their safety significance. Where required, the regulatory body should also inspect submissions by the authorized party 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 authorized party's staff who perform the modifications are suitable for the function they are performing."

Modifications could be done in NFCFs for various reasons including safety improvements, process developments (e.g., increased efficiency, increased capacity, enhanced recovery, and reduced cycle time), operating experience, and addressing technological developments, ageing and obsolescence. Modifications may also be needed in NFCFs due to possible changes in characteristics of raw materials and change in product specifications. Modifications might also have an impact on maintenance activities or ageing of SSCs.

Generally, the modifications that are categorized to be of higher safety significance are submitted to the regulatory body for review and assessment. Other modifications are implemented based on the internal reviews by the operating organization. The key aspect that needs to be looked into during a regulatory inspection is the implementation and effectiveness of the programme for control of modifications. The inspection needs to focus on the internal

process of the operating organization in classification of modifications, the implementation and updating of operating and safety documents as the result of the modification.

Section II-8 of Annex II provides additional information for preparation of specific checklists for this area of inspection.

3.9. OPERATIONAL RADIATION PROTECTION

IAEA Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [12] establishes requirements for the protection of people and the environment from harmful effects of ionizing radiation in planned exposure situations and emergency exposure situations that are applicable for all nuclear installations including NFCFs. Requirement 67 and paras 9.90–9.101 of SSR-4 [10] establish requirements related to operational radiation protection in an NFCF.

IAEA Safety Standards Series No. GSG-7, Occupational Radiation Protection [13] provides recommendations on the control of occupational exposure, including the technical and organizational aspects.

Paragraph IV.24 of GSG-13 [3] states that: “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”. This includes the review of the aspects related to organizational structure for radiation protection, control of occupational exposure, control of contamination, records of occupational radiation doses, and transport arrangements for radioactive material on the site.

Section II-9 of Annex II provides additional information for preparation of specific checklists for this area of inspection.

3.10. OPERATIONAL RADIOACTIVE WASTE MANAGEMENT AND ENVIRONMENTAL PROTECTION

IAEA Safety Standards Series No. GSR Part 5, Predisposal Management of Radioactive Waste [14] establishes the requirements for the predisposal management of radioactive waste of all types, covering all the steps in its management from its generation up to its disposal, including its processing, storage, and transport. These requirements are applicable to all facilities and activities. Requirement 68 and paras 9.102–9.108 of SSR-4 [10] establish requirements on establishing and implementing a programme for management of radioactive waste and effluents in an operating NFCF.

IAEA Safety Standards Series No. SSG-41, Predisposal Management of Radioactive Waste from Nuclear Fuel Cycle Facilities [15] provides recommendations on the predisposal management of radioactive waste generated at NFCFs. IAEA Safety Standards Series No. GSG-16, Leadership, Management and Culture for Safety in Radioactive Waste Management [16] provides recommendations on developing and implementing management systems for safety during radioactive waste management at NFCFs.

The regulatory inspection in this area needs to cover the aspects related to generation, processing (including pre-treatment, treatment, and conditioning), storage and on-site transport of radioactive waste, the release of radioactive effluents and the environmental monitoring programme. The management systems for ensuring safety in radioactive waste management also need to be covered in this inspection area.

Section II-10 provides additional information for preparation of specific checklists for this area of inspection.

3.11. FIRE AND CHEMICAL SAFETY

3.11.1. Fire safety

Requirement 69 of SSR-4 [10] states that "**The operating organization shall make arrangements for ensuring protection against fire and explosion.**"

The adequacy of the fire protection and prevention programme, including the management's attention to this area, needs to be covered in the inspection of fire safety. This includes review of arrangements for preventing, detecting, and extinguishing fires, controlling the spread of fires, and providing sufficient protection from fire to permit the facility to be brought to a safe and stable state.

The inspection includes the verification of aspects related to the management system for fire protection, fire protection procedures, human performance management of fire protection personnel, operating performance of fire protection systems, review of fitness for service of the fire protection SSCs, and emergency management. Additionally, based on the national regulatory framework, the inspection may also cover aspects related to determination of compliance with the national standards related to conventional fire safety aspects. The inspection may look for evidence that fire prevention procedures have been followed and protection system have been maintained, verification of fire separation features, minimization of combustible materials, condition of the firefighting equipment and its and accessibility and availability.

Section II-11.1 of Annex II provides additional information for preparation of specific checklists for this area of inspection.

3.11.2. Chemical safety

Requirement 42 of SSR-4 [10] states that "**The design shall ensure that personnel, the public and the environment are protected against toxic chemical exposures associated with radioactive material.**"

Requirement 70 of SSR-4 [10] states that "**The operating organization shall establish and implement a programme for controlling the risks associated with industrial and chemical hazards to workers and the public and shall keep the risks as low as reasonably achievable.**"

Paragraph 9.2 of SSR-4 [10] states:

> "The operating organization shall establish an appropriate management structure for the nuclear fuel cycle facility and shall provide the necessary infrastructure for operations to be conducted safely. The operating organization shall ensure that adequate resources are available for all functions relating to the safe operation and utilization of the nuclear fuel cycle facility, such as criticality safety, maintenance, periodic testing and inspection, radiation protection, application of the management system, emergency preparedness and response and other relevant supporting activities, and shall take into account industrial safety and chemical safety."

In the context of this publication ‘chemical safety’ refers to aspects related to protection from exposure to toxic chemicals. Aspects related to process chemistry need to be addressed as part of other inspection areas like operational limits and conditions, conduct of operations and nuclear criticality safety, as applicable. Aspects related to toxic chemical exposures associated with radioactive material are addressed in this publication. Information on safety requirements and guidance related to conventional chemical safety aspects may be found in relevant national regulations and standards, or international codes of practice, such as Ref. [17].

The regulatory inspection in this area needs to cover the verification of the effectiveness of the facility programme for controlling the risk of toxic chemical exposure to personnel, public and the environment. This may be done by verification of the arrangements for the planning, implementation, monitoring and review of the relevant preventive and protective measures, including aspects related to procedures for ensuring confinement and control of toxic chemical exposures associated with radioactive material, detection systems, training, accident management and emergency preparedness.

Section II-11.2 of Annex II provides additional information for preparation of specific checklists for this area of inspection.

3.12. EMERGENCY PREPAREDNESS

IAEA Safety Standards Series No. GSR Part 7, Preparedness and Response for a Nuclear or Radiological Emergency [18] establishes requirements for preparedness and response for a nuclear or radiological emergency.

Paragraph 3.1 of GSR Part 7 [18] states:

> “The goal of emergency preparedness is to ensure that an adequate capability is in place within the operating organization and at local, regional and national levels and, where appropriate, at the international level, for an effective response in a nuclear or radiological emergency. This capability relates to an integrated set of infrastructural elements that include, but are not limited to: authority and responsibilities; organization and staffing; coordination; plans and procedures; tools, equipment and facilities; training, drills and exercises; and a management system.”

Paragraph IV.38 of GSG-13 [4] states:

> “Inspection in the area of emergency preparedness and response should include a review of emergency response plans and procedures in order to verify that the arrangements for dealing 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 of a nuclear or radiological emergency, 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.”

The response to a nuclear or radiological emergency may involve many national organizations including the operating organization and other response organizations at various levels (local, regional, national or, at times, international). In the context of this publication, the regulatory inspection of this area is limited to the verification of the capabilities and fulfilment of the responsibilities of the operating organization regarding emergency preparedness and response

measures in the facility. Emergency exercises may also be witnessed by the inspectors not only to confirm that the emergency planning is adequate and that its implementation is effective, but also to confirm that the deficiencies and corrective actions noted during the emergency exercise are captured and corrected by the facility.

Section II-12 of Annex II provides additional information for preparation of specific checklists for this area of inspection.

4. INTERFACE OF REGULATORY INSPECTION WITH OTHER REGULATORY FUNCTIONS

The details of interface of regulatory inspection with specific core functions and support functions of the regulatory body are given in the following sections.

4.1. REGULATIONS AND GUIDES

Compliance with the safety requirements established in the relevant regulations are verified during a regulatory inspection. The legal and governmental framework gives the regulatory body the authority to conduct regulatory inspections and to take enforcement actions with respect to the facilities and activities under its purview. The regulations and guides developed by the regulatory body with respect to regulatory inspection ensure stability and consistency in all regulatory processes including the regulatory inspection.

The regulations and guides need to provide information to the operating organization regarding the authority and responsibilities of the regulatory body relevant to the regulatory inspection process. This information includes the objectives, principles, criteria, and decision-making process used as a basis for conducting regulatory inspections, making observations, and taking enforcement actions during the regulatory inspections. The information also needs to include the methods for appeal or remedy against the decisions made during the regulatory inspection.

The regulatory body needs to implement a mechanism and develop procedures for the inspectors to provide feedback regarding identified areas where the regulations or guidance is inadequate or needs further clarification or improvements. The regulatory body also needs to develop internal guidance for the regulatory inspectors in sufficient detail to ensure that:

- The inspectors clearly understand their authorities and responsibilities regarding inspection and enforcement during the inspection;
- The facilities and activities are inspected to a common standard, and there is consistency in the expected level of safety and decision making;
- The inspection programme and its implementation are based on a graded approach;
- The administrative procedures and guidelines for enforcement actions are clear.

4.2. AUTHORIZATION

The fulfilment of the conditions of the authorization for the facility is addressed in the regulatory inspection. Inputs from other regulatory processes like review and assessment, and regulatory inspection are considered when making decisions regarding the issue, renewal, amendment, suspension, or revocation of the authorization of an NFCF. Baseline or additional

special inspections may be conducted by the regulatory body for the purpose of obtaining information necessary in decision making related to authorization.

Decision making related to enforcement actions like suspension or revocation of the authorization needs to be supported based on the inputs obtained from the regulatory inspection of the facility prior to the enforcement action.

Depending on the national regulatory framework, the conditions for the authorization may also include the responsibility of the operating organization to provide necessary access for designated staff of the regulatory body to the premises of an NFCF, and documents relating to safety.

4.3. REVIEW AND ASSESSMENT

The review and assessment process needs to interface with the regulatory inspection process to get inputs on the actual status of the facility. The inputs from regulatory inspection will help to determine whether the facility is operating within the specified operational limits and conditions, and as per the commitments made by the operating organization in the safety assessment, periodic safety review or the licensing documentation, as applicable. The safety significant observations of regulatory inspection and the actions taken by the facility to address these aspects are part of review and assessment process of the NFCF.

In the review and assessment process, a detailed review of the information submitted by the operating organization is made for the purpose of arriving at a regulatory decision. The decision may relate to the authorization of a facility or permission to conduct certain activities by the operating organization. During the review and assessment process, verification of the claims made by the operating organization in the licensing documentation or other submissions, could be obtained through regulatory inspections. The regulatory inspections provide information regarding the actual conditions of the facility and provide expedient information especially during the review of events and accidents.

The review and assessment process also includes the review of operational and safety status of the facility, which is submitted to the regulatory body in the form of periodic reports related to status of the facility, occupational radiation doses, radioactive waste, events, and other aspects. These reviews provide inputs to the areas to be covered during regulatory inspections. These inputs include the following:

(a) Specific areas to be visited during the inspection for obtaining information or confirmation of status regarding operation, maintenance or availability, or for verification of:

    (i) Status of specific safety systems or items important to safety;
    (ii) Modifications, if any;
    (iii) Radiation levels in specific areas;
    (iv) Availability of specific monitoring, control or alarm systems.

(b) Specific aspects of management systems and interfaces, especially with contractors (e.g., qualification of contractors).

(c) Observation of specific activities during the regulatory inspection, including:

    (i) Specific operation or maintenance activities, to check whether they are being carried out as per the procedures;

(ii) Specific tests (e.g., logic tests, availability tests or response time tests) or operations to be conducted based on request from the regulatory body or the inspector, taking into account the impact of the test on the operability and safety of the plant, and ensuring that the operating organization is informed sufficiently in advance of any tests that need preparation time;
(iii) Deployment of competent and qualified staff for specific activities carried out in the NFCF.

(d) Specific documents or records to be verified on the site, including:

(i) Maintenance and calibration reports of specific SSCs;
(ii) Area access records for specific controlled areas.

(e) Interaction with site personnel:

(i) Checking of operator awareness;
(ii) Checking of management involvement in fostering safety culture;
(iii) Communication and cooperation at all levels.

The regulatory inspection can also be used to obtain supplementary information and data necessary for review and assessment process based on the actual conditions at the facility or the internal documentation of the operating organization.

The regulatory body may also decide to conduct special inspections or unannounced inspections based on the observations from review and assessment. The findings of the review and assessment may be utilized in the development or update of checklists, as necessary, for the regulatory inspections.

Based on the review and assessment of incident reports submitted by the operating organization, the regulatory body may conduct or arrange for an independent investigation through a regulatory inspection. The purpose of these inspections is to check if the incidents have been properly investigated to arrive at the root cause, and necessary remedial actions have been taken. The findings of the review and assessment, supplemented by the inputs from the regulatory inspections, form the basis for enforcement actions.

4.4. ENFORCEMENT

Enforcement actions are taken by the regulatory body to address non-compliances of the operating organization with specified conditions and requirements. Such actions are sensitive as they could involve imposing restrictions on the operation of a facility, or the activities conducted therein and could provoke legal challenges from the operating organization. Hence, any enforcement action taken by the regulatory body needs to be based on legal statutes, regulations, scientific principles, and clear evidence. The regulatory inspection process could provide evidence necessary to support the enforcement action based on actual observations at site regarding to the human, technological and organization factors that form the basis for decision making.

The enforcement actions taken by the regulatory body are based on safety significance and are generally in the form of verbal or written notification of non-compliance, written warnings or directives, penalties, restriction or suspension of activities, or modification, suspension, or revocation of the authorization. In certain situations, where there is an imminent danger to the life or health of people, or to the environment, it could be necessary for the inspector to take an

enforcement action on-site during the regulatory inspection. The authority for an inspector to take an enforcement action on-site is determined by the legal and regulatory framework. On-site enforcement actions by inspectors are generally limited to verbal or written notifications or written warnings and directives. Decisions related to higher levels of enforcement need to be taken by wider consultation within the regulatory body, involving senior management and subject matter experts.

The regulatory body needs to develop and implement clear administrative procedures regarding enforcement actions. These procedures include the need for informing or involvement of other regulatory or governmental authorities. All regulatory inspectors and other staff of the regulatory body need to be trained in and knowledgeable about these procedures.

Regulatory inspections are also conducted to verify the operating organization's response to regulatory enforcement actions. Such inspections are necessary to confirm that the operating organization has taken satisfactory measures to address the deficiencies and there is a reasonable assurance that the required level of safety is achieved or could be achieved.

The inspection reports relating to enforcement actions (e.g., taking an enforcement action or permitting the activities or operation of the facility) need to clearly document and provide or refer to necessary evidence as the basis for enforcement action or subsequent permissions.

4.5. EMERGENCY PREPAREDNESS

The role of the regulatory body in emergency preparedness is to verify that adequate on-site arrangements are in place for handling postulated emergencies, and necessary provisions are available for coordination with responsible organizations for dealing with an off-site emergency.

In addition to the periodic regulatory inspections in the area of emergency preparedness and response, the regulatory body may need to observe and evaluate the emergency preparedness exercises carried out by the operating organization, especially for the high hazard NFCFs that might have off-site impact. In some Member States, the regulatory body periodically conducts inspections or posts observers for the emergency preparedness and response exercises.

The regulatory body may deploy its observers or inspectors during the actual emergency response for the purpose of observing the actions taken by the operating organization. However, it needs to be ensured that the actions of the regulatory body do not impede the timely response to the emergency.

Further details on the role of regulatory body in emergency preparedness and response for a nuclear or radiological emergency are given in GSR Part 7 [18].

4.6. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

Communication and consultation with interested parties regarding the safety of NFCF may be necessary for gaining public trust and protecting the regulatory body's credibility.

The regulatory body needs to inform and may consult the interested parties about the regulatory processes including the regulatory inspection, safety status of the NFCF and the decisions of the regulatory body regarding safety of the facility. Sharing of appropriate information regarding the findings of the regulatory inspection helps in development of open and inclusive process of communication with interested parties. While sharing the information regarding the

findings of regulatory inspection and actions taken by the facility for addressing the findings, the regulatory body needs to:

(a) Ensure an adequate level of protection for sensitive information related to the NFCF;
(b) Address the legitimate concerns of interested parties in nuclear and radiation safety related matters;
(c) Ensure that sharing of information does not result in undue influences that might adversely affect the safety or operability of the facility.

The regulatory body needs to develop and implement a policy regarding communication and consultation with interested parties. The policy needs to be based on the legal and regulatory framework in the country. For sharing appropriate information with the interested parties, the regulatory body needs to develop an information and knowledge management system that include the findings of the inspection, actions taken by the operating organization in response to the inspection findings and the decisions of regulatory body based on the findings. Such a system will help to provide interested parties with requested information in a timely manner.

IAEA Safety Standards Series No. GSG-6, Communication and Consultation with Interested Parties by the Regulatory Body [19] provides recommendations on meeting the safety requirements concerning communication and consultation with the public and other interested parties by the regulatory body.

4.7. OTHER SUPPORT FUNCTIONS

The process of regulatory inspection of NFCFs needs administrative support within the regulatory body, in the form of the provision of necessary financial and human resources. The provision of equipment (e.g., personal protective equipment, radiation monitors) for regulatory inspection and provisions for dose management of inspectors is also necessary. The management of documents and records relevant to the regulatory inspection is also an important support function necessary for efficient conduct of inspections.

The regulatory inspection process needs to be provided with necessary legal support, for example to ensure the legal protection of inspectors in discharging their responsibilities during the regulatory inspection of NFCFs.

The regulatory inspection process may be useful in identifying the areas of research and development necessary to demonstrate safety. The regulatory body may conduct the research and development activities itself, identify suitable external support organizations to conduct the activities, or ask the operating organization to conduct activities.

The regulatory inspection process can be further improved by establishing cooperation with international agencies experienced in safety and operation of NFCFs. Such cooperation will enable the sharing of relevant regulatory experiences and help develop the competence of regulatory inspectors.

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ANNEX I.

SAMPLE REGULATORY INSPECTION PROGRAMME FOR NUCLEAR FUEL CYCLE FACILITIES

A sample regulatory inspection programme document based on the Canadian practice is given below:

I-1. INTRODUCTION

The Canadian Nuclear Safety Commission (CNSC) regulates the use of nuclear energy and materials to protect health, safety, security and the environment; to implement Canada's international commitments on the peaceful use of nuclear energy; and to disseminate objective scientific, technical and regulatory information to the public.

CNSC defines an inspection as the process by which CNSC staff gather data directly at the site of a licensed activity and analyse that data, for the purpose of evaluating whether a licensee is in compliance with the requirements of the regulatory framework. The main purposes of inspection and enforcement activities are to ensure that:

- The licensee's activities, facilities, equipment and work performance meet regulatory requirements;
- The licensing basis documents are adhered to;
- The workers possess the necessary competence for the effective performance of their functions;
- Deficiencies and deviations are identified by the licensee and are corrected or justified without undue delay;
- Any lessons learned are identified by the licensee and communicated to interested parties;
- The licensee is managing safety in a proper manner.

CNSC inspections do not diminish the licensee's prime responsibility for safety or substitute for the control, supervision, and verification activities that the licensee has to carry out.

The CNSC's conduct of inspection process is built on the following principles:

1) Inspections are consistent and transparent;
2) Inspection activities are open to formal scrutiny;
3) Inspections are planned, coordinated and controlled activities;
4) Inspection standards of performance and methodology are defined;
5) Inspections are conducted following approved inspection procedures;
6) Inspection objectives and criteria are defined and communicated to the licensee;
7) Inspections are conducted within the safety and control area framework;
8) Roles and responsibilities for conducting inspections are defined;
9) Inspections are documented in official and timely reports;
10) Inspection processes and procedures are subject to continuous improvement.

I-2. LEGAL FRAMEWORK

Inspections are led by an inspector designated by the CNSC as stated under Section 29 of the Nuclear Safety and Control Act (NSCA). Section 30 of the NSCA authorizes an inspector to inspect a nuclear facility in order to verify compliance with the NSCA, the regulations, an order or decision made under the NSCA or a condition of a licence.

Under its internal management system, the CNSC has developed various process documents to establish a common understanding of inspection activities and to describe the consistent, systematic approach to conducting inspections according to its legal framework. In the case of nuclear fuel cycle facilities (NFCFs), key documents include but are not limited to the following:

- CNSC's Overview of Conducting an Inspection (Ref. [I–1]);
- CNSC's Overview of Conducting Inspections at Directorate of Nuclear Cycle and Facilities Regulation (DNCFR) Facilities (Ref. [I–2]);
- CNSC's Overview of Assure Compliance for Nuclear Fuel Cycle and Research Reactor Facilities (Ref. [I–3]);
- Risk-Informed Baseline Compliance Process for Nuclear Cycle and Facilities Regulation (DNCFR) Licensed Facilities and Activities (Ref. [I–4]).

I-3. GRADED APPROACH AND CATEGORIZATION OF FACILITIES

The regulatory inspection programme for the NFCFs is based in accordance with a graded approach considering the risk associated with operation of the facility and activities carried out in the facility. Based on this approach, Canadian NFCFs are characterized as provided in Table I-1.

TABLE I-1. GRADED APPROACH AND CATEGORIZATION OF FACILITIES

Category	**Context**	**Examples of types of facilities**
High	The nature of the hazard associated with the licensed activity is high. The consequence of an accidental release of nuclear or hazardous substances at the facility would pose a high risk to human health and/or the environment.	Uranium processing facilities, mines, and mills.
Medium	The nature of the hazard associated with the licensed activity is moderate. The consequence of an accidental release of nuclear or hazardous substances at the facility would pose a risk to human health or the environment. Evaluated in consideration of the amounts and types of nuclear and hazardous substances, level of handling or physical activity needed, complexity of operations, number of staff and contractors, level and quality of containment, potential for loss of control.	Fuel fabrication facilities, nuclear substance processing facilities.

TABLE I-1. GRADED APPROACH AND CATEGORIZATION OF FACILITIES (cont.)

Low	The nature of the hazard associated with the licensed activity is low. The consequence of an accidental release of nuclear or hazardous substances at the facility would pose little risk to human health or the environment. Evaluated in consideration of the amounts and types of nuclear substances, short half-lives, minimal handling, low complexity, fail-safe nature of reactor design, complexity of operations, potential for loss of control, level and quality of containment, organizational robustness, consequence of loss of control and quality of programmes.	Small-scale waste processing facilities.

I-4. TYPES OF INSPECTION

The purpose, scope, objectives, and approach for each inspection needs to be clearly established and documented, for the sake of transparency and clarity. The purpose of the inspection can be as simple as being part of the compliance plan, or in response to a trigger that causes the inspection to be conducted. The scope sets boundaries for the inspection such as what locations, systems or activities are to be inspected. Establishing the scope identifies how much work is needed. Objectives are what the inspection team sets out to achieve by conducting a particular inspection. Objectives can be broad (to verify licensee compliance with NSCA requirements) or specific (to verify licensee compliance with CNSC security requirements).

In most cases, inspections are either planned or reactive inspections. For the planned inspections, the trigger will have been predetermined by the compliance plan for a given licensed nuclear facility. Reactive inspections can be triggered from the findings and observations during desktop reviews, technical assessments, events, or the occurrence of rare or unplanned regulated activities. Inspections may also be announced or unannounced. All inspections have an element of planning, even unannounced inspections. If inspectors are given the authority to conduct unannounced inspections, these are carried out following a set of pre-determined criteria using a pre-determined checklist developed as part of the planning for unannounced inspections.

'Type I' inspections which include in-depth examination of licensee's processes and operations are conducted by CNSC for the purpose of verification of licensee's programmes, processes or practices. When the verification of the results of licensee's processes (not the processes themselves) is sufficient, CNSC conducts 'Type II' inspections. Unannounced inspections are conducted by CNSC, if the likelihood that the inspection outcome will be affected by advance notification is high.

I-5. INSPECTION AREAS

Safety and control areas are a collection of 14 technical topics used by the CNSC to assess, review, verify and report on regulatory requirements and performance across all regulated facilities and activities. The documents in this category provide requirements and guidance. Table I-2 provides the details of the safety and control areas covered as applicable, in the regulatory inspection programme of Canadian NFCFs (Refs. [I–5, I–6]).

TABLE I-2. SAFETY AND CONTROL AREAS USED BY THE CNSC

Safety and control area	Definition	Specific areas
Management system	Covers the framework that establishes the processes and programmes needed to ensure an organization achieves its safety objectives, continuously monitors its performance against these objectives, and fosters a healthy safety culture.	• Management system; • Organization; • Performance assessment, improvement and management review; • Operating experience, problem identification and resolution; • Change management; • Safety culture; • Configuration management; • Records management; • Supply and contractor management; • Business continuity.
Human performance management	Covers activities that enable effective human performance through the development and implementation of processes that ensure a sufficient number of licensee personnel are in all relevant job areas and have the necessary knowledge, skills, procedures and tools in place to safely carry out their duties.	• Human performance programme; • Personnel training; • Personnel certification; • Work organization and job design; • Fitness for duty.
Operating performance	Includes an overall review of the conduct of the licensed activities and the activities that enable effective performance.	• Conduct of licensed activity; • Procedures; • Reporting and trending; • Outage management performance; • Safe operating envelope; • Severe accident management and recovery; • Accident management and recovery.
Safety analysis	Covers maintenance of the safety analysis that supports the overall safety case for the facility. Safety analysis is a systematic evaluation of the potential hazards associated with the conduct of a proposed activity or facility and considers the effectiveness of preventative measures and strategies in reducing the effects of such hazards.	• Deterministic safety analysis; • Hazard analysis; • Probabilistic safety analysis; • Criticality safety; • Severe accident analysis; • Management of safety issues (including research and development programmes).

TABLE I-2. SAFETY AND CONTROL AREAS USED BY THE CNSC (cont.)

Safety and control area	Definition	Specific areas
Physical design	Relates to activities that impact the ability of SSCs to meet and maintain their design basis given new information arising over time and taking changes in the external environment into account.	• Design governance; • Site characterization; • Facility design; • Structure design; • System design; • Component design.
Fitness for service	Covers activities that impact the physical condition of structures, systems and components to ensure that they remain effective over time. This area includes programmes that ensure all equipment is available to perform its intended design function when called upon to do so.	• Equipment fitness for service / equipment performance; • Maintenance; • Structural integrity; • Ageing management; • Chemistry control; • Periodic inspection and testing.
Radiation protection	Covers the implementation of a radiation protection programme in accordance with the radiation protection regulations. The programme must ensure that contamination levels and radiation doses received by individuals are monitored, controlled and maintained as low as reasonably achievable (ALARA).	• Application of ALARA; • Worker dose control; • Radiation protection programme performance; • Radiological hazard control.
Conventional health and safety	The implementation of a programme to manage workplace safety hazards and to protect workers.	• Performance; • Practices; • Awareness.
Environmental protection	Covers programmes that identify, control and monitor all releases of radioactive and hazardous substances and effects on the environment from facilities or as the result of licensed activities.	• Effluent and emissions control (releases); • Environmental management system; • Protection of people; • Assessment and monitoring; • Environmental risk assessment.
Emergency management and fire protection	Covers emergency plans and emergency preparedness programmes that exist for emergencies and for non-routine conditions. This area also includes any results of participation in exercises.	• Conventional emergency preparedness and response; • Nuclear emergency preparedness and response; • Fire emergency preparedness and response.

TABLE I-2. SAFETY AND CONTROL AREAS USED BY THE CNSC (cont.)

Safety and control area	Definition	Specific areas
Waste management	Covers internal waste-related programmes that form part of the facility's operations up to the point where the waste is removed from the facility to a separate waste management facility. This area also covers the planning for decommissioning.	• Waste characterization; • Waste minimization; • Waste management practices; • Decommissioning plans.
Security	Covers the programmes needed to implement and support the security requirements stipulated in the regulations, the licence, orders, or expectations for the facility or activity.	• Facilities and equipment; • Response arrangements; • Security practices; • Drills and exercises; • Cyber Security.
Safeguards and non-proliferation	Covers the programmes and activities needed for the successful implementation of the obligations arising from the Canada/International Atomic Energy Agency (IAEA) safeguards agreements, as well as all other measures arising from the Treaty on the Non-Proliferation of Nuclear Weapons.	• Nuclear material accountancy and control; • Access and assistance to the IAEA; • Operational and design information; • Safeguards equipment, containment and surveillance; • Import and export.
Packaging and transport	Programmes that cover the safe packaging and transport of nuclear substances to and from the licensed facility.	• Package design and maintenance; • Packaging and transport; • Registration for use.

I-6. FREQUENCY OF INSPECTIONS

The frequency of regulatory inspection of various categories of NFCFs and the functional areas to be covered are based on a graded approach. This process begins with a risk ranking exercise, based on a set of criteria aimed at identifying the risk profile of licensed facilities. Once the facilities and activities are ranked in terms of the risks they pose, this information is used to develop recommendations for the type and frequency of compliance activities that need to be conducted for each facility. The 10-year risk-informed baseline compliance strategy is reviewed every year and revalidated every 5 years.

The baseline frequency of regulatory inspection of NFCFs to be covered over a 10-year period are given in Table I-3. They are listed by safety and control area and based on a graded approach.

TABLE I-3. BASELINE FREQUENCY OF REGULATORY INSPECTION OF NFCFs OVER A 10-YEARS PERIOD

Inspection topics (listed by safety and control area)	**High risk facilities**	**Medium risk facilities**	**Low risk facilities**
General inspection*	10	5	3
Management system	3	2	
Human performance management	2	1	
Operating performance	1		
Safety analysis	2	1	
Physical design and fitness for service	2	1	
Radiation protection	2	1	
Conventional health and safety**			
Environmental protection	2	1	
Emergency management and fire protection	2	1	
Waste management	2		
Security	2	1	
Safeguards and non-proliferation***			
Packaging and transport	2	1	

Note: * Includes compliance verification against several safety and control areas in one inspection.
** Compliance verification included as part of all general inspections.
*** Compliance verification frequency is facility-specific.

In addition, facility-specific inspections are added to the above noted 10-year baseline based on several factors including, but not limited to, licensed activities that need additional inspections that are not part of the baseline plan. Facility specific and performance informed (reactive) compliance activities can augment baseline activities but cannot reduce them without justification.

I-7. CONDUCT OF INSPECTIONS

Inspection planning is performed to ensure a planned, coordinated, and management controlled approach to inspection activities. Planning the inspection and identifying its purpose, scope and objectives help determine what resources are needed, as well as to set the inspection boundaries, clarify roles and responsibilities, and keep the inspection team focused.

Inspections also typically involve a preliminary exchange between licensee representatives and the inspection team. This will include such things as introductions, logistics, and health and safety discussions. The field inspection begins upon the arrival of the inspection team at the location to be inspected and ends once the team delivers the preliminary summary of findings to the licensee's representative. The entire inspection team is responsible for accessing the inspection site safely and in accordance with all safety and security requirements. CNSC staff health, safety and security are paramount. CNSC staff are not to engage in any activity that would endanger their health and safety, or those of others. All CNSC-issued personal protective equipment needs to be worn appropriately and in good working condition, according to manufacturer specifications. This includes calibrated survey meters, appropriate safety footwear, safety glasses, and hard hats as necessary.

All information gathered during the inspection are recorded as facts; however, only facts that are verifiable will be used to support inspection findings. These facts and findings may, in turn, be analysed to identify non-compliances, develop inspection conclusions and, potentially, provide the basis for enforcement actions. Inspection facts are collected using the following inspection methods: monitor and observe; review procedures, records, and other documents; conduct interviews or discussions with personnel; and conduct sampling, testing and measurements.

The inspection team also conducts interviews and discussions, to gather facts pertinent to the scope and criteria of the inspection, and to support observed facts. Such discussions are typically less formal and less structured than interviews but can also reveal important information. With the help of the team members, the lead inspector prepares the preliminary summary of findings. This summary includes any findings and items of non-compliance identified by the inspection team during the inspection. It is also good practice to include any positive findings or programme strengths. The intent of the preliminary summary is to allow the licensee to begin corrective action on important issues as soon as possible.

All gathered inspection data is analysed against established criteria and regulatory requirements, to develop inspection findings. The analysis of inspection facts may also lead to enforcement actions. The final analysis, which supports the findings, conclusions, and enforcement actions, will be documented in a final report submitted to the licensee. Whenever non-compliances are identified, the lead inspector acts as the official channel for communication with the licensee, so that appropriate actions may be taken.

The lead inspector is responsible for the preparation and issuing of the final inspection report. The scope, layout, content, timing, and distribution of inspection reports may vary, according to the type of facility or licensed activity, location of the inspection, or type of inspection.

All steps and pertinent information are captured in a tool called ‘Case Management’, which is a central electronic repository for licensing, certification and compliance workflows, information and functionality and provided inspectors easy access to information and tracking of CNSC’s core licensing and compliance activities.

Once the inspection report has been issued, all enforcement actions are recorded in the CNSC’s Regulatory Information Bank and tracked until closure. The Regulatory Information Bank is a comprehensive and powerful internal online tool that provides staff across all regulatory service lines with the ability to monitor and report on licensee commitments. Lead inspectors ensure all pertinent inspection records kept on file electronically are complete, accurate, and correct. Finally, any lessons learned as well as any improvement recommendations are shared with team members and other inspectors.

I-8. CONTINUAL IMPROVEMENT

The inspection programme for Canadian NFCFs and its implementation are subject to self-assessment by the CNSC. However, the inspection programme may be reviewed and revised as and when necessary.

REFERENCES TO ANNEX I

[I–1] CANADIAN NUCLEAR SAFETY COMMISSION, Internal Management System Document: Overview of Conducting an Inspection, CNSC Electronic Document Number: 3817913. Revision Number: 27, CNSC, Ottawa (2019).

[I–2] CANADIAN NUCLEAR SAFETY COMMISSION. Internal Management System Document: Overview of Conducting DNCFR Inspections, CNSC Electronic Document Number: 3871053. Revision Number: 5, CNSC, Ottawa (2020).

[I–3] CANADIAN NUCLEAR SAFETY COMMISSION, Internal Management System Document: Overview of Nuclear Fuel Cycle and Research Reactors Program-Assure Compliance, CNSC Electronic Document Number: 5512059, Revision Number: 1. CNSC, Ottawa (2020).

[I–4] CANADIAN NUCLEAR SAFETY COMMISSION, Internal Management System Document: Risk-Informed Baseline Compliance Process for Nuclear Cycle and Facilities Regulation (DNCFR) Licensed Facilities and Activities, CNSC Electronic Document Number: 5158156, Revision Number: 2, CNSC, Ottawa (2018).

[I–5] CANADIAN NUCLEAR SAFETY COMMISSION. Internal Management System Document e-Doc# 3410839 version 19, CNSC, Ottawa (2023).

[I–6] CANADIAN NUCLEAR SAFETY COMMISSION, Safety and control areas, https://nuclearsafety.gc.ca/eng/resources/publications/reports/powerindustry/safety-and-control-areas.cfm

ANNEX II.

PRACTICAL INFORMATION FOR PREPARATION OF SPECIFIC CHECKLISTS FOR VARIOUS AREAS OF INSPECTION OF A NUCLEAR FUEL CYCLE FACILITY

This Annex provides information on the aspects that might be included in the inspection checklists for regulatory inspection of a nuclear fuel cycle facility (NFCF). The Annex covers some of the important aspects in the inspection areas and is not to be considered as a comprehensive checklist for conducting regulatory inspection of an NFCF.

II-1. OPERATING ORGANIZATION AND FACILITY MANAGEMENT

The objective of the inspection is to determine if the operating organization recognizes and effectively fulfils its prime responsibility of ensuring the safety of a nuclear fuel cycle facility over its lifetime. For this purpose, the following verifications may be done during the regulatory inspection:

(1) The inspector may examine the organizational chart, management section of the safety analysis report, quality assurance (QA) programme, policy documents, job descriptions for safety related posts, and discuss with relevant personnel to verify whether:

   (a) A clearly defined operational structure is available to and understood by relevant personnel;
   (b) Functions and responsibilities are clearly defined and understood by relevant personnel;
   (c) Necessary infrastructure is provided for conduct of safe operations;
   (d) Adequate resources are provided for safe operation of the nuclear fuel cycle facility (NFCF) (see para. 9.2 of IAEA Safety Standards Series No. SSR-4, Safety of Nuclear Fuel Cycle Facilities [II–1]);
   (e) Clearly defined and effective communication routes are established, when different organizations share the safety related structures or systems, and resources;
   (f) A dedicated organization and specific rules for on-site transport is established in accordance with national regulations, if any;
   (g) A procedure ensuring that all activities involving radiation exposure or potentially involving exposure are planned, supervised and carried out such that exposure is minimized;
   (h) Hazards arising due to modification of the facility are addressed;
   (i) A system to ensure that periodic summary reports are prepared on safety related issues which are reviewed by the safety committee and submitted to the regulatory body if so required;
   (j) Availability of adequate facilities and services in all facility states is ensured;
   (k) Sufficient authority and resources are provided to facility management to enable them to fulfil their duties effectively.

(2) The inspector may assess the structure of the operating organization and the functions, roles and responsibilities of its personnel, and verify whether:

(a) The responsibility for the safe operation of the facility has been clearly defined in a written delegation of responsibility by the operating organization to the authorized personnel.
(b) The lines of authority and arrangements for communications between the following as specified in para. 9.9 of SSR-4 [II–1] are established:

(i) Senior management of the facility;
(ii) Safety committee(s);
(iii) Nuclear criticality safety staff;
(iv) Radiation protection personnel;
(v) Groups responsible for maintenance, modification, and engineering;
(vi) Personnel responsible for establishing and applying the management system.

(c) Proposed organizational changes to the structure and associated arrangements, which might be of importance to safety, are evaluated in advance.

(d) The operating organization has identified a responsible person who is suitably qualified and experienced for directly supervising of the operation of the NFCF.

(e) The knowledge management (including knowledge and skills) and human resource policies are developed considering the long-term objectives to ensure that behaviours and attitudes supporting a strong safety culture are ensured.

(f) All certified or authorized operating personnel have necessary authority to fulfil the responsibilities of the post.

(3) For undertaking a deeper review of the organization, the inspector may examine the structure and responsibilities of all the support functions as well as those directly involved in the operation of the NFCF. This may include maintenance, training, nuclear criticality safety, operational radiation protection and waste management.

(4) The degree of independence of the radiation protection personnel, nuclear criticality safety staff, and industrial safety staff from operations management may be reviewed.

(5) The inspector may verify whether all the posts that can affect safety have been identified and appropriate written description of responsibility and associated authority provided to the individuals holding the posts.

(6) Interviews may be conducted with a selection of the staff including the senior management and operating personnel to assess the degree to which the responsibilities of their posts are defined and understood, and that they are suitably qualified and experienced for their positions. The interviews may be utilized to verify whether the operating personnel have adequate standard of understanding and a proper attitude toward safety.

II-2. MANAGEMENT SYSTEM

The objective of the inspection is to evaluate the management's involvement in the facility and its effectiveness in paying appropriate attention to operational issues. For this purpose, the following verifications may be done during the regulatory inspection.

(1) The inspector may examine the documentation and records related to management systems, and discuss with relevant personnel to ascertain whether:

(a) The management system is established and being effectively implemented;
(b) The management system has been considered by the safety committee and, where required, by the regulatory body;
(c) There is evidence that audits and reviews are conducted to verify the application of QA to items important to safety;
(d) An individual has been identified who is responsible for the implementation of the programme;
(e) An organization chart indicating important positions and lines of command and communication within and outside the organization is available and whether the necessary human resources are available as indicated in the organization chart;
(f) An established interface or liaison with external agencies exists;
(g) Mechanism is in place to assess and evaluate changes in the management organization before the changes are made.

(2) The inspector may review records related to training to confirm the fulfilment of training and qualification requirements of senior management as per the management system requirements.

(3) For the purpose of corroborating the demonstration that management is focused on safety, the inspector may review the following:

(a) Operating experience feedback programme;
(b) Event reports and corrective action reports, procedures or other documents which detail on the mechanism for identification and remediation of safety related deficiencies or problems;
(c) Other relevant programmes of the facility;

and discuss with relevant operating personnel to ascertain:

(a) The extent of involvement of the management in the process of identifying, assessing and reviewing safety related deficiencies;
(b) The adequacy and effectiveness of the channels of communication or communication methods available for reporting issues related to safety, to the management;
(c) The knowledge of key senior officials on the recent safety deficiencies identified in the facility.

(4) The inspector may review the configuration management programme and modification programme of the facility, discuss with relevant operating personnel, monitor and directly observe to verify whether:

(a) The facility has established and implemented a configuration management system to evaluate, implement, and track changes to the facility in accordance with the requirements and the licensing basis of the facility.
(b) The modifications involving new processes at existing facilities meet the requirements.
(c) As applicable, the procedures and the modifications address the following aspects:

(i) Justification for the modification;
(ii) Impact of the modification on safety;
(iii) Review and revision of operating procedures, and other facility documentation, including licensing documentation;

(iv) Training of operating personnel regarding the modifications (including in the use of revised procedures as applicable) prior to the operationalization of the modifications;
(v) Authorization of the modification (e.g., facility level, regulatory body);
(vi) Control on temporary modifications (including permissible duration and information to relevant personnel).

The aspects related to configuration management and modifications may be covered in detail in the inspection area related to modifications. As part of the regulatory inspection on management systems, a programmatic review would be suitable.

(5) The inspector may ascertain the management's willingness to listen by:

(a) Checking and understanding the various mechanisms available to report (directly or indirectly) safety issues to the management;
(b) Checking the records for the same to understand the periodicity of such reporting and the disposition of the concerns reported;
(c) Verifying (through means of interaction) with facility staff if they know the existence of such methods or mechanisms, and if they know, how effective do they consider they are?

(6) The inspector may review the documents and records related to self-assessment programme, and interact with relevant personnel to ascertain:

(a) The availability of procedures to conduct self-assessment;
(b) Whether various functions of the facility are identified for carrying out self-assessment;
(c) The findings and status of compliance with the observations of the self-assessment;
(d) Types of assessment tools available to verify the management's functions (e.g., self-assessment or 360º assessment).

(7) The inspector may review the documents and records related to the QA programme, discuss with relevant operating personnel, perform direct observations, and independent tests and measurements to ascertain the following:

(a) Whether the QA programme has included the organizational structure, functional responsibilities, levels of authority and interfaces for those managing, performing, assessing and improving the adequacy of processes;
(b) The availability of trained, qualified or certified personal for operation as necessary and their records of training, qualification or certification as applicable;
(c) The availability of approved facility 'Operation QA manual' and its review periodicity;
(d) Whether organization chart indicating important positions and lines of command and communication within and outside the organization is available;
(e) Whether the QA group is sufficiently independent and reports to top management;
(f) Availability of QA staff as per the planned organization chart;
(g) Where required by codes, standards, specifications or other special requirements, whether personnel performing activities affecting quality (e.g., personnel responsible for non-destructive examinations, welders and key operating personnel) have been certified;
(h) Whether testing and measuring devices have been controlled, calibrated and adjusted at specified intervals or before use, to maintain accuracy within prescribed limits;

(i) Whether record of calibration of equipment or instruments have been maintained and these records are traceable to the equipment (e.g., use of adhesive stickers, marking on the equipment) prior to their use;
(j) The types of QA audit identified, availability of procedure for conduct of audits, conduct of audits as per the audit requirements and resolutions of the audit findings.

The regulatory body may also cover the aspects related to QA in detail as a separate inspection area, if necessary.

II-3. TRAINING AND QUALIFICATION

The objective of the inspection in this area is to verify that all activities that may affect safety are performed by suitably qualified and competent persons, and to assess the adequacy of the operating organization's programme for training and qualification. For this purpose, the following verifications may be done during the regulatory inspection:

(1) The inspector may, by examination of procedures, records and documentation related to training and qualification programme, and by discussions and interviews with operating personnel, verify whether the training reflects the actual conditions in the facility.

(2) The inspector may, by examination of procedures, records and documentation related to training and qualification programme and by discussions and interviews with operating personnel, verify the effectiveness of training, drills and exercises for emergency preparedness and response, including those for fire, nuclear criticality, and other events as applicable.

(3) The inspector may, by examination of procedures, records and documentation related to training and qualification programme, and by discussions and interviews with operating personnel, verify whether the training of operating personnel reinforces the behaviours and attitudes supporting a strong safety culture.

(4) The inspector may, by review of the programme and documentation related to the training and qualification programme, and by discussions and interviews with operating personnel, assess whether the senior management has overall responsibility for implementation, evaluation and ensuring effectiveness of the programme. This needs to include the responsibilities for ensuring that all individuals selected for duties that impact safety are given the training and retraining necessary for the safe operation of the facility, and that this training and retraining is appropriately evaluated.

(5) The inspector may, by review of documents and procedures related to the training programme, assess whether the necessary qualification, experience and training requirements of operating personnel are clearly documented. This includes the requirements for formal authorization of operating personnel, if applicable. The inspector may additionally, by discussions and interviews with operating personnel, verify whether necessary training and instruction to enable them to perform their duties correctly for all facility states is being given.

(6) The inspector may, by examination of procedures, records and documentation related to operational limits and conditions, and to the training and qualification programme, verify the implementation and assess the effectiveness of administrative controls related to training and retraining of personnel.

(7) The inspector may, by examination of procedures, records and documentation related to the training and qualification programme, and by discussions and interviews with operating personnel, verify whether:

(a) Periodic confirmation of competence of the operating personnel is being done;
(b) Refresher training is being done as per the programme;
(c) Retraining or requalification of personnel who have had extended absence from the authorized duties is being done as necessary.

(8) The inspector may, by examination of procedures, records and documentation related to the training and qualification programme, verify whether the training programme covers all aspects of the facility, in all operating states and accident conditions, and is commensurate with the hazards. The inspector may confirm if the training includes the following areas:

(a) Design features;
(b) Safety analysis;
(c) Human and organizational factors;
(d) Operational limits and conditions;
(e) Operating procedures;
(f) Radiation protection;
(g) Criticality safety;
(h) Arrangements for accident management;
(i) Emergency preparedness and response;
(j) Waste management;
(k) Industrial safety (including fire safety and chemical safety);
(l) Relevant information of operating experience including any precursors to, or trends in, adverse conditions for safety, and corrective actions;
(m) Interfaces between safety and security.

(9) The inspector may, by monitoring and direct observation, and by discussions and interviews with operating personnel, verify whether the operating personnel are given suitable training before the start of their duties.

(10) The inspector may verify whether the training programme is reviewed and audited in line with the management system requirements (see para. 9.46 of SSR-4 [II–1]).

(11) The inspector may, by examination of procedures, records and documentation related to the training and qualification programme, verify whether specific training and drills are conducted for relevant external personnel involved in emergency response (e.g., firefighters, rescue services).

(12) The inspector may, by examination of procedures, records and documentation related to the training and qualification programme, and by discussions and interviews with operating personnel, verify whether specific training including appropriate practical training is given in the following areas, as applicable to the facility:

(a) Glovebox operations, including actions to be taken if contamination occurs.
(b) Safe handling and processing of large quantities hazardous chemicals (e.g., UF_6) and appropriate action in the event of a chemical release.
(c) Detection of overexposure for facilities where chemical hazards, radiological hazards and criticality hazards are present.

(13) The inspector may, by examination of procedures, records and documentation related to the training and qualification programme, and by discussions and interviews with operating personnel, verify whether additional training of relevant staff in the newly developed procedures is provided, as necessary, when the activities that are not covered by existing procedures are conducted.

II-4. CONDUCT OF OPERATIONS

The objective of regulatory inspection of this area is the verification of activities directly relating to operating the NFCF. This inspection includes the review of operating procedures, operating experience feedback programme, operational housekeeping and material conditions, records, and reports, conduct of safety related activities and operational accident management programme. The review of compliance with operational limits and conditions is covered in a separate inspection area (see Sections 3.6 and Annex II-6) in this publication.

II-4.1. Operating procedures

The purpose of the inspection is to evaluate and conduct a sampling review of operating procedures, including new and revised procedures, to verify that approved procedures governing facility operations exist and cover normal operations, anticipated operational occurrences, unplanned or infrequent operations and accident conditions. For this purpose, the following verifications may be done during the regulatory inspection.

(1) The inspector may conduct a sample review of operating procedures, in order to verify whether:

   (a) The operating procedures include direct and clear description of operational sequence, limits, and conditions for normal operation mode.
   (b) The instructions for anticipated operational occurrences include instructions on safe return to normal mode, safe termination of operations, or shutdown of facility.
   (c) The operational limits and conditions, as well as the safety limits and conditions established in operating procedures, are consistent with those declared in safety analysis documentation presented to the regulatory body as part of the licensing procedure.
   (d) The operating procedures clearly communicate what should be observed by personnel performing the operation.
   (e) The operating procedures are adequate for the facility design and take into account all facility modifications implemented.

(2) The inspector may verify compliance with the operating procedures on a sample basis by monitoring and direct observation.

(3) The inspector may review the documents and records related to the management of procedures, and discuss with operating personnel, to verify whether:

   (a) The operating procedures are developed for all safety related operations that may be conducted over the lifetime of the facility.
   (b) The operating procedures are developed by operating personnel in cooperation with facility staff who interface (internally and externally) with the operations organization whenever possible. Interface examples can include, but are not limited to the following:

(i) Designer and manufacturer;
(ii) Radiation protection;
(iii) Maintenance;
(iv) Staff internal to the operating organization.

(c) The operating procedures are prepared in accordance with management system procedures that govern the format, development, review and control of such procedures as necessary.
(d) The operating procedures at the NFCF are reviewed and updated on regular basis based on experience in using the procedures and in compliance with the use of management system.
(e) The operating procedures are readily available for use by operators as necessary.
(f) The personnel are trained to use the operating procedures necessary to perform their duties.
(g) The activities not covered by existing procedures, including infrequent, non-routine or new operations, are governed by a procedure which covers:

(i) A process for planning the activity;
(ii) The preparation, review, and approval of a procedure(s) that addresses conducting the activity;
(iii) The prior approval of the activity before the activity is started;
(iv) The additional training of relevant staff on the relevant procedure(s) and approved activity.

II-4.2. Operating experience feedback

The purpose of the inspection is to confirm whether the operating experience feedback programme supports the safety of the facility. For this purpose, the following verifications may be done during the regulatory inspection:

The inspector may review the documents and records related to the operating experience feedback programme of the facility, events and corrective actions and discuss with operating personnel to verify that:

(a) The operating experience feedback system is documented and consistent with relevant regulatory requirements, including timeframes and scope of investigation in case of significant occurrences;
(b) The operational occurrences or events are categorized based on their causes and consequences;
(c) The investigation of events aims to find the root causes;
(d) The operating experience feedback is available for personnel involved in operation and maintenance activities, as well management of facility;
(e) The operating experience feedback system is effective and ensures prevention of reoccurrences or similar occurrences.

II-4.3. Operational housekeeping and material conditions

The purpose of the inspection is to verify whether the organization has developed and implemented programmes to maintain a high standard of material conditions, housekeeping and cleanliness in all working areas. For this purpose, the following verifications may be done during the regulatory inspection.

(1) The inspector may assess the condition of structures, systems and components (SSCs) important to safety and other SSCs by monitoring and direct observation, or by performing independent tests and measurements on a sample basis to ascertain:

(a) The degradation of SSCs;
(b) Whether there are discrepancies between installed SSCs and the facility drawings;
(c) Whether there are adequate controls for performing maintenance of SSCs;
(d) The quality of the log keeping, record keeping and routine monitoring of equipment by the operating personnel;
(e) The effectiveness of the operating personnel in getting degraded equipment repaired by maintenance staff or its prompt evaluation to ensure operability.

(2) The inspector may review the documents and records related to the maintenance of the facility and visit the various areas of the facility, on sample basis to verify whether:

(a) The administrative controls are established to ensure the following as required by para 9.71 of SSR-4 [II-1]:

(i) The operational premises and SSCs are well maintained;
(ii) Adequate illumination as necessary is provided for the work, in all working areas and premises;
(iii) Temporary storage is controlled and limited.

(b) The degraded SSCs are identified, reported, and corrected in a timely manner. Examples of degradation may include, but are not limited to the following: leaking, corrosion spots, loose parts, damaged parts, inadequate thermal insulation.
(c) A programme for monitoring material degradation of vessels and containers holding mixtures of corrosive chemicals with fissile or highly radioactive materials is established and in effect.
(d) The necessary identification and labelling of SSCs has been done, including the equipment, rooms, piping, and instrumentation.

II-4.4. Records and reports

The purpose of the inspection is to verify whether the operating organization has established and is maintaining a system for the control of records and reports in the facility. For this purpose, the following verifications may be done during the regulatory inspection.

(1) The inspector may review the records and reports of the facility on a sample basis and discuss with relevant operating personnel to verify whether:

(a) The operating organization retains and maintains up to date, all essential information concerning the design, construction, commissioning, current configuration and operation of the facility;
(b) The operating organization has established and implemented a process for generating and controlling records and reports that have safety significance for both operation and decommissioning. Applicable records and reports include the following:

(i) Licensing documentation revisions;
(ii) Periodic safety review results;
(iii) Commissioning documentation including commissioning procedures, commissioning test reports and results;

(iv) Operating procedures;
(v) Modification history and relevant data;
(vi) Operational records of the NFCF;
(vii) Maintenance, testing, surveillance, and inspection data;
(viii) Reports related to events and incidents;
(ix) Radiation protection data and personnel monitoring data;
(x) Data associated with the quantity, location, and movement of nuclear and other radioactive material;
(xi) Effluent discharge records;
(xii) Records of the storage of radioactive waste;
(xiii) Records of the radioactive waste transport;
(xiv) Records of environmental monitoring;
(xv) Records of the main work activities that were performed in different areas within the NFCF.

(c) The procedures that govern management and management systems used for the generation, collection, retention and archiving of records and reports are established and being implemented.
(d) The data repositories including logbooks, checklists and other appropriate records are filled, dated and signed correctly.
(e) The records of non-compliance and the measures taken to return the facility to compliance are documented and retained.
(f) The retention periods are established for records and that the operating organization retains records for the specified retention periods.
(g) The established records management system includes provisions for storing and maintaining records and reports, including the need of offsite storage of documents for access in an emergency is considered.
(h) The records management system involves the archiving of obsolete documents and that personnel only use the current effective version (i.e. latest version) of each document.

II-4.5. Conduct of safety related activities

The purpose of the inspection is to verify whether safety related activities are being analysed and controlled adequately to ensure safety of the NFCF. For this purpose, the following verifications may be done during the regulatory inspection.

(1) The inspector may on sample basis, review the relevant documentation, procedures and reports related to safety related activities, discuss with operating personnel, and by monitoring and direct observation verify whether:

(a) The operational activities are assessed and controlled in accordance with the potential risks associated with ionizing radiation and related toxic chemicals.
(b) The level of assessment and control for ionizing radiation and related toxic chemicals is commensurate with the associated activity's safety significance.

(2) For non-routine activities that are not covered by the existing operating procedure, the inspector may verify that:

(a) A specific safety review is conducted for the operation or test and that a special procedure is developed for the activity.
(b) When special procedures are developed, they need approval, and they are developed in accordance with the management system requirements.

(3) The inspector may verify that the operations department has a process for, and formally communicates and interfaces with other non-production departments as it relates to changes in operations and matters that could impact safety. Examples of such departments include maintenance, criticality safety, radiation protection, environmental, security, material control and accounting.

II-4.6. Operational accident management programme

The purpose of inspection is to confirm whether an accident management programme based on the results of the safety analysis is established by the operating organization. For this purpose, the following verifications may be done during the regulatory inspection.

(1) The inspector may review the documents and records related to the accident management programme, including the accident management guidelines on a sample basis, and discuss with operating personnel to verify that:

   (a) An accident management programme is established and implemented. The programme needs to cover the requirements, steps, and guidelines for both reducing the risk of accidents and returning the facility to a controlled, safe state condition that can be maintained, if an accident occurs;
   (b) The accident management programme is inclusive of chemical hazards associated with nuclear activities;
   (c) The accident management programme establishes organizational arrangements for accident management, including requirements and provisions for communication and training in relation to programme implementation;
   (d) The accident management programme includes identification of instrumentation for monitoring facility state, severity level of an accident, and equipment used for control and mitigation of an accident.

(2) The inspector may by monitoring and direct observation or by tests and measurements on a sample basis, ascertain the condition of SSCs necessary for accident management.

II-5. NUCLEAR CRITICALITY SAFETY

The objective of the inspection is to determine whether the facility's nuclear criticality safety programme is effective in ensuring that established subcritical margins are not exceeded under both normal and credible abnormal conditions. For this purpose, the following verifications may be done during the regulatory inspection.

(1) The inspector may by examination of procedures, records and documentation related to the organizational aspects of the nuclear criticality safety programme and by discussions and interviews with management and operating personnel verify whether:

   (a) The operating organization has appointed qualified nuclear criticality safety staff, who are knowledgeable about the physics of nuclear criticality and the associated safety standards, codes and best practices;
   (b) The operating organization has clearly established responsibilities for nuclear criticality safety;
   (c) The nuclear criticality safety staff are familiar with the facility design and operations;
   (d) The nuclear criticality safety functioning is to the extent necessary, independent of the operations management;

(e) Suitably qualified and experienced personnel have been deployed for operations that may impact nuclear criticality safety;
(f) The operations involving nuclear criticality safety are governed by written procedures;
(g) The deviations from procedures and unexpected modifications in process conditions that affect nuclear criticality safety have been reported to management and were investigated promptly;
(h) The information about incidents and events in other facilities of the same type have been studied and lessons learnt have been considered as part of the operating experience feedback;
(i) The safety of operations with fissionable materials is reviewed periodically as per the frequency specified in the management system, and whether the following aspects have been addressed in the reviews:

(i) Whether the procedures are being followed by all personnel;
(ii) Whether process conditions have been altered in any way that would affect nuclear criticality safety.

(2) The inspector may, by examination of procedures, records and documentation related to the nuclear criticality safety programme and the programme of training, retraining and qualification of the operating personnel, and by discussions and interviews with the operating personnel, verify whether:

(a) The nuclear criticality safety staff are involved in the training of personnel, and in development of operating procedures that may need nuclear criticality control.
(b) The relevant operators and other staff are aware of nuclear criticality hazard and nuclear criticality safety requirements in their work area.
(c) The persons participating in operations with fissionable materials are familiar with, and understand the procedures.
(d) The operating organization has established a nuclear criticality safety training programme and verify the following aspects related to the training programme:

(i) Whether training requirements are determined for all levels of staff and clearly documented;
(ii) The technical adequacy of the contents of nuclear criticality safety training programme for performing the jobs;
(iii) Whether all the relevant facility staff have participated in the training programme;
(iv) Whether the evaluation of the effectiveness of training programme is being done;
(v) Whether refresher training is being conducted.

(3) The inspector may, by examination of procedures, records and documentation related to the nuclear criticality safety programme and by discussions and interviews with the operating personnel, verify whether:

(a) The procedures specify all parameters that are intended to ensure nuclear criticality safety.
(b) The procedures are available and are effective to manage the operations, so as to exclude inadvertent mixing of powders, pellets and rods of different fissile materials and enrichments (if applicable).
(c) The necessary procedures and processes in place so that, prior to starting new or modified operations, the facility personnel responsible for nuclear criticality safety can ensure that all equipment is consistent in dimension and material with that described in nuclear criticality safety documents.

(d) The procedures for the transfer or temporary movement of fissile material are available for all operational states.
(e) The procedures are available to ensure nuclear criticality safety during dismantling of equipment whose safety is controlled by geometry.

(4) The inspector may, by examination of procedures, records and documentation related to the nuclear criticality safety programme, by monitoring and direct observation, and by discussions and interviews with the operating personnel, verify whether:

(a) The movement of fissionable material both within a specific area of the facility or within the whole facility site is controlled (by procedures, processes or where applicable, by design).
(b) The observed nuclear criticality safety controls in the facility are consistent with those described in nuclear criticality safety documents.
(c) As required by para. 9.83 of SSR-4 [II–1], the criticality safety assessment is reviewed in accordance with the established procedures before changing:

(i) The location of process equipment;
(ii) The connections of the process equipment;
(iii) The location of neutron reflectors.

(d) The following confirmations are being done prior to the beginning of operations and are being controlled as necessary during the operation:

(i) Dimensions of vessels;
(ii) Physical properties (e.g., mass, density), chemical properties (e.g. concentration) and nuclear properties (e.g. absorber or reflector contents) of the materials being transferred and handled;
(iii) Distances between the equipment;
(iv) Adequacy of neutron absorbers and control of reflectors between process and storage equipment as necessary.

(e) The prescribed minimum distance is being maintained between the process units and storage units handling fissile material.
(f) A surveillance programme is developed and implemented for detection and prevention of uncontrolled accumulation of fissile material.
(g) The provisions for prevention of double batching are in place and effective.
(h) Appropriate labels, signs, and area posting are kept in all areas where operations with fissionable materials are performed.
(i) The labels contain complete information that provides material identification and limits on parameters which are subject to procedural control.
(j) The content of fissile material is being monitored during transfer or transport of radioactive waste, and is in accordance with the approved or accepted criticality safety requirements for such wastes.
(k) The observed methods of storage of fissile material and related operational practices are as per the approved procedures.
(l) An access control system is in place for storage areas.
(m) There is a presence of significant quantities of combustible materials in the storage areas and, if so, a suitable fire protection system is available.
(n) The on-site transfer or transport of fissile material is being done as per the approved procedures.
(o) The off-site transport of fissile material is being done as per the approved procedures.

(5) The inspector may verify the process and material balances of the facility to confirm that there is no unaccounted accumulation of fissile material.

(6) The inspector may, by examination of procedures, records and documentation related to the nuclear criticality detection and alarm system, by monitoring and direct observation, and by discussions and interviews with the operating personnel, verify whether:

(a) The nuclear criticality detection and alarm system is operational in all the necessary areas (as identified in the safety analysis report or design basis documents).
(b) The nuclear criticality detection and alarm system's alarms are functional and distinct from other alarms and audible at all necessary places.
(c) The maintenance, periodic testing and inspection of nuclear criticality detection and alarm system is done as per the requirements, and necessary records are maintained.
(d) Instructions regarding response to nuclear criticality detection and alarm system signals are posted at strategic locations within areas of alarm coverage.

(7) The inspector may, by examination of procedures, records and documentation related to the emergency preparedness and response to a nuclear criticality event, by monitoring and direct observation, and by discussions and interviews with the operating personnel, verify whether:

(a) The emergency response procedures related to nuclear criticality safety are prepared and approved as necessary.
(b) The conditions that might be encountered at the facility due to nuclear criticality safety accident have been effectively communicated to the on-site and off-site emergency response organizations (e.g., fire protection, medical).
(c) The emergency response measures that are to be avoided due to nuclear criticality safety concerns (e.g., use of water during the fire where enriched material is present) are explicitly specified in the emergency response plans.
(d) Immediate evacuation zones and evacuation routes are established based on nuclear criticality safety assessments or simulations of postulated accidents.
(e) The instrumentation and equipment needed to respond to a nuclear criticality accident is provided (e.g., sufficient amount of neutron absorbers) in accordance with the documented emergency response procedures.
(f) Exercises and drills related to nuclear criticality safety are being planned, conducted and evaluated, with the involvement of nuclear criticality safety staff.
(g) The documentation of emergency response centre includes the contact details of necessary nuclear criticality safety staff who would be available to perform their functions during a nuclear criticality safety emergency.

II-6. OPERATIONAL LIMITS AND CONDITIONS

The objective of the regulatory inspection of this area is to confirm whether the NFCF is being operated in accordance with the operational limits and conditions that provide a basis for safety of the facility, and whether sufficient records are being maintained to demonstrate compliance with operational limits and conditions. For this purpose, the following verifications may be done during the regulatory inspection.

(1) The inspector may use the following methods:

(i) Review of records maintained by the operating organization, including operating logbooks, stored historical data of parameters in the instrumentation and control systems, field checklists, surveillance reports, test reports, training records and duty rosters.
(ii) Verification of the instrumentation settings (this may be done by means of physical verification when settings are visible or relevant plant records when settings cannot be visually ascertained (e.g., setting on a relief valve of a pressure vessel)).
(iii) Monitoring of process parameters from control room, instrument panels or from on field instrumentation where possible.
(iv) Discussions and interviews with operating personnel.

to verify that:

(a) The management system of the operating organization addresses the requirement of operation of the facility within the operational limits and conditions for safety.
(b) The proposed changes or the violations in any operational limits and conditions for the facility are reviewed by the safety committee.
(c) Appropriate controls are provided to maintain operating parameters within the operational limits and conditions (checked on a sample basis).
(d) Necessary indications (e.g., alarms) are available for the parameters specified in operational limits and conditions (checked on a sample basis).
(e) The facility is being operated with the operating personnel specified in the operational limits and conditions (in terms of e.g., number, qualification, duties).
(f) The facility has been operated within the safety limits specified in the operational limits and conditions (detailed check).
(g) The operating organization is maintaining sufficient records to demonstrate compliance with operational limits and conditions.
(h) The safety system settings are as specified in the operational limits and conditions (checked on a sample basis).
(i) The facility is being operated within the limiting conditions for safe operation related to operating parameters and minimum operable equipment (checked on a sample basis).
(j) If the facility has operated outside the operational limits and conditions, whether:

(i) The necessary corrective actions have been taken within the specified time;
(ii) An investigation of the cause and the consequences has been conducted by facility management;
(iii) Appropriate actions to prevent a recurrence have been taken;
(iv) The regulatory body has been notified accordingly in a timely manner as necessary.

(k) The operating procedures referred in the operational limits and conditions have been followed, when applicable (checked on a sample basis).
(l) The transfer of hazardous materials has been done as specified in the operational limits and conditions, when applicable (checked on a sample basis).
(m) The periodic testing and surveillance of the applicable SSCs is being conducted as specified in the operational limits and conditions (checked on a sample basis).

(n) The administrative controls specified in the operational limits and conditions are being maintained and complied with (checked on a sample basis).
(o) The training programme includes the operational limits and conditions for all the relevant operating personnel.

(2) The inspector may on sample basis, review the testing and surveillance reports to check the adherence to procedures and acceptance limits in the operational limits and conditions, as applicable.

(3) The inspector may, by examination of procedures, records and documentation related to the modifications in the facility, verify whether the impact on applicable operational limits and conditions have been considered during planning and execution of modification of the facility.

II-7. MAINTENANCE, PERIODIC TESTING AND INSPECTION

The objective of the regulatory inspection of this area is to confirm whether effective programmes for maintenance, periodic testing and inspection are established and implemented at the facility for the items important to safety, and whether these programmes support the long-term safety of the facility. For this purpose, the following verifications may be done during the regulatory inspection.

(1) The inspector may review the programme for maintenance, periodic testing and inspection, to ascertain its adequacy and effectiveness. For this purpose, the inspector may examine procedures, records and documentation related to the programme including the master list of SSCs; preventive maintenance plans and schedules; procedures and records of maintenance, periodic testing, and inspection; records of corrective maintenance; and documents and reports related to self-assessment of the programme.

(2) The inspector may review the planning and scheduling of the maintenance, periodic testing and inspection activities and select some of the activities for monitoring and direct observation. In sample selection, consideration need to be given to all types of maintenance activities. For these activities, the inspector may review the relevant procedures, observe the activities, interview relevant personnel and assess whether the programme, procedures and the capability of the maintenance technicians to perform their assigned tasks, are adequate. During the observation the inspector needs to pay attention to observe the compliance with procedure, usage of proper tools, isolation and tagging controls, and coordination with other groups (e.g., operations, radiation protection), and systems being returned correctly to their operational states. These sample reviews may include:

(a) Calibration of safety related instrumentation (e.g., radiation monitors, criticality alarms);
(b) Periodic inspection and testing of pressure vessels;
(c) Verification of integrity and leak rates for the structures (e.g., glove boxes, hot cells, enclosures) containing the radioactive material;
(d) Maintenance of safety related pumps and valves;
(e) Surveillance of safety related electrical systems (e.g., circuit breakers, transformers).

(3) The inspector may, by direct observation on a sample basis, and review of programme and procedures, evaluate the adequacy and effectiveness of the procedures for isolation and tagging controls, post maintenance testing and ensuring that systems are returned correctly to their operational state.

(4) The inspector may review the programme and records of periodic testing and inspection to ascertain whether there is early detection of degradation of SSCs.

(5) The inspector may review the programme, procedures and data related to the maintenance tasks that can be performed only during shutdown state to ascertain whether these tasks are being planned and implemented effectively.

(6) The inspector may also review the records or data related to repair of SSCs, to ascertain the effectiveness of the preventive maintenance programme. The reviews for this purpose may include safety related vessels, piping systems, pumps, valves, electrical systems and instrumentation and control systems.

(7) For the purpose of verification that the maintenance, periodic testing, and inspection programme continually incorporates lessons learned from facility and operating experience, the inspector may review the records of root cause analysis of incidents (including minor incidents) at the facility, to check whether any improvements in the programmes have been identified.

(8) The inspector may, by examination of procedures, records, and documentation; and by discussions and interviews with personnel, assess the effectiveness of procedures for identifying and rectifying the deviations from the maintenance procedures.

(9) The inspector may, by review of the training records, and discussions with personnel, ascertain the effectiveness of the programme to ensure competence of the maintenance personnel.

(10) The inspector may by examination of relevant procedures and records, and by discussion with personnel, verify whether non-routine maintenance activities are conducted in accordance with prepared plan and procedures specific for that activity.

(11) The inspector may examine the documents and records related to standards and calibration of testing equipment to ascertain the accuracy and suitability of the testing equipment for the purpose.

(12) The inspector may review the programme and records related to spare part management to ascertain whether sufficient spares of necessary quality are available at the facility, and they are stored appropriately.

II-8. MODIFICATIONS

The objective of the regulatory inspection of this area is to confirm whether the modifications done in the facility are in accordance with safety requirements. For this purpose, the following verifications may be done during the regulatory inspection.

(1) The inspector may review the documents, procedures and reports related to the programme for the control of modifications to the facility, including the list of modifications made to the installation, procedures for modifications and the safety analysis relating to

modifications to verify whether the following requirements established by para. 9.57 of SSR-4 [II-1] are addressed:

"The operating organization shall be responsible for ensuring that:

(a) For multifacility sites, a modification in the nuclear fuel cycle facility will not adversely affect the operability or safety of associated or adjacent facilities.

(b) The management system is applied at all stages in the preparation and performance of the modification to ensure that all applicable safety requirements and criteria are satisfied.

(c) The relevant safety documentation (e.g., the safety assessment report and operational limits and conditions) of the facility is applied by all individuals involved in making a modification, and protection of the public and protection of the environment are optimized.

(d) The relevant licensing documentation for each modification is prepared and the associated requirements for review and approval are met. These may include the requirement to obtain the approval of the regulatory body for the modification.

(e) All personnel who will be involved in making a proposed modification are suitably trained, qualified, and experienced for the task and, if necessary, are trained in advance on the effect of the modification on facility operations and the safety characteristics of the facility.

(f) All documents affected by the modification that relate to the safety characteristics of the facility, such as the safety assessment report, the operational limits and conditions and the relevant procedures for operation, maintenance, and emergencies, are promptly updated as necessary."

(2) The inspector may verify whether the modifications consider the feedback of operating experience from the facility and other facilities, as applicable.

(3) The inspector may discuss with operating personnel and review the records related to modifications, associated radioactive waste generation and radiation exposure, and ascertain whether:

(a) In implementing modifications, the radiation exposure of the workers involved has been kept as low as reasonably achievable and the protection of the public and environment, if applicable, has been optimized;
(b) All personnel involved in making a proposed modification are suitably trained, qualified and experienced for the task and understand the effect of the modification on facility operations and the safety characteristics of the facility;
(c) Temporary modifications are clearly identified at their location and at any relevant control position;
(d) There is a system established for notifying timely the relevant facility personnel of temporary modifications and their consequences on operational safety.

II-9. OPERATIONAL RADIATION PROTECTION

The purpose of regulatory inspection of this area is to assess whether the radiation protection programme of the operating organization is in compliance with the regulatory requirements, being correctly implemented and that the objectives of the programme are being met. For this purpose, the following verifications may be done during the regulatory inspection.

(1) The inspector may review the structure of the organization and procedures for the implementation of the radiation protection programme, to assess the adequacy of the programme.

(2) The inspector may assess the effectiveness of the management and its commitment with respect to radiation protection by:

  (a) Examination of the documents and records related to the management system to assess whether:

    (i) An independent radiation protection group has been established within the operating organization;
    (ii) The necessary number of qualified, knowledgeable, and technically competent radiation protection officers have been appointed;
    (iii) Adequate resources are available for all functions relating to radiation protection;
    (iv) Clear lines of authority and arrangements for communication are established between senior management, radiation protection personnel and different groups of operating personnel (e.g., maintenance, engineering, operations).

  (b) Discussion and interviews with personnel (management, supervisors and workers) to assess the level of understanding of their responsibilities in the implementation of the radiation protection programme.
  (c) Monitoring or direct observation, examination of procedures and records, discussions with personnel, to assess the application of the optimization principle.
  (d) Examination of the records of the levels of occupational exposure of personnel.
  (e) Direct monitoring and examination of the records of the radiation levels and levels of contamination in working areas.
  (f) Examination of the records of levels of releases of effluents.
  (g) Review of the records and documentation related to the self-assessment of the programme.

(3) The inspector may, by examination of procedures, records and documentation related to the operational radiation protection programme, and by discussions and interviews with relevant personnel, ascertain whether the advice and concerns of the radiation protection personnel are being taken into consideration during development and implementation of operational procedures at the facility.

(4) The inspector may assess the effectiveness of the procedural and management controls related to operational radiation protection by:

  (a) Review of the records of occupational exposure, including internal and external doses, and comparison with dose constraints and dose limits.
  (b) Review of the identification, labelling and access control arrangements for the controlled areas.

(c) Review of the procedures, records and documentation relating to radiation work permit system, especially for maintenance activities.
(d) Monitoring and direct observation of the activities on a sample basis.
(e) Review of the activities related to dosimetry (both internal and external).
(f) Review the records related to non-compliances with the radiation protection programme and the corrective actions taken.
(g) Examination of training records related to radiation protection. This may include the records of training of operating personnel, emergency response personnel and trainees, as applicable (see item (5) below on training).

(5) The inspector may by discussions and interviews with operating personnel, and examination of procedures, records and documentation, assess the effectiveness of training programme. The reviews for this purpose include verification whether:

(a) The training promotes behaviour and attitudes supporting a strong safety culture in the aspects of radiation protection.
(b) The scope of training on radiological hazards is commensurate with the hazard posed.
(c) The operating personnel are trained appropriately on radiation protection.
(d) Retraining on operational radiation protection is conducted on regular basis.
(e) Internal and external firefighters and other personnel relevant for emergency response are provided training relevant to their response functions.

(6) The inspector may, by examination of procedures, records and documentation, and discussions and interviews with operating personnel, verify whether effective arrangements are in place for generating and controlling the data, records and reports related to radiation protection and personnel monitoring. The inspector may also verify whether all workers who may be occupationally exposed to radiation are having their doses measured, recorded, and assessed.

(7) The inspector may, by monitoring and direct observation, and by examination of procedures and records relating to sampling and analysis, assess whether these activities are being organized to minimize the doses to operating personnel. For this purpose, the inspector may review the arrangements related to sampling devices, sample storage and transfer methods, and sample analysis.

(8) The inspector may, by monitoring and direct observation, by discussions and interviews with operating personnel, and by examination of procedures and records, assess whether the time, distance and shielding requirements instituted for the personnel handling and inspecting radioactive material, are adequate.

(9) The inspector may, by direct observation verify whether adequate and appropriate radiation monitoring equipment (both stationary and portable) are provided at the facility. For this purpose, the inspector needs to give consideration for all operational states and accident conditions. The procedures and records relating to calibration and maintenance of radiation monitoring equipment may also be checked.

(10) The inspector may, by direct observation and monitoring and by examination of records, verify whether:

(a) The radiation levels in the controlled areas are appropriately displayed.
(b) The actual radiation levels in the areas during the visit are consistent with the radiation levels displayed.
(c) Temporary radiation shielding is provided where necessary during the maintenance activities.

(11) The inspector may by direct observation and monitoring, and examination of procedures and records, assess whether the spread of radioactive contamination is being controlled and minimized as far as reasonably achievable. The inspector may also verify whether:

(a) The access to the areas where contamination levels are high is being restricted commensurate with the hazard.
(b) The confinement of fine radioactive powders and aqueous radioactive solutions is being closely monitored.
(c) The maintenance operations are being controlled by physical and administrative measures.
(d) Adequate ventilation is being provided in the areas during regular operation (especially during the transfers of radioactive material) and maintenance.
(e) Respiratory protection is being provided for the workers where necessary.

(12) The inspector may, by direct observation and examination of relevant documentation, assess whether the arrangements for firefighting are adequate in the areas where there is a risk of release of radioactive material in a fire. The inspector may also assess the adequacy of measures for the radiation protection of firefighting personnel and the management of releases to the environment, in case of fire in such areas.

(13) The inspector may assess the effectiveness of special arrangements made for protection and safety for female workers, visitors, and trainees under 18 years of age.

(14) The inspector may, by examination of procedures, records and documentation, by monitoring and direct observation, and by discussions and interviews with operating personnel, assess the safety of transport arrangements for radioactive material on the site. The aspects that may be looked into for this purpose include the receipt and dispatch arrangements, integrity of packages and the residual levels of contamination on the package surfaces.

(15) The inspector may, by direct observation and monitoring, by discussions and interviews with operating personnel, and by examination of procedures and records, assess the effectiveness of the following:

(a) External dosimetry:

(i) Whether the external dosimetry is provided by a dosimetry service authorized by the regulatory authority;
(ii) Whether all operating personnel, as well as visitors and contractors, are assigned dosimeters and they are being used as necessary;
(iii) Whether the dosimeters are stored at appropriate and designated storage locations in the low background areas;

(iv) Whether control dosimeters are stored at the dosimetry storage location where the workers' dosimeters are kept when not in use;
(v) Whether electronic personal dosimeters (EPDs) are needed.

(b) Internal dosimetry:

(i) Whether the doses are assigned based on the appropriate dose estimation method (e.g., ambient dosimetry, lung counting, urine analysis or other bioassay measurements);
(ii) Whether the screening levels and investigation levels have been established and implemented for internal dosimetry.

(c) Personal protective equipment (PPE):

(i) Whether there is a sufficient quantity of PPE (including respiratory protective equipment), and it is made available when needed for use;
(ii) Whether PPE is stored and tested based on relevant standards;
(iii) Whether the workers (including contractors and trainees) are trained in the use of PPE.

(d) Contamination monitoring and control:

(i) Whether the air samplers are functioning appropriately;
(ii) Whether the area ventilation systems and containment systems are operating as per the operational limits and conditions;
(iii) Are facilities available for monitoring of contamination when exiting the controlled areas;
(iv) Are appropriate facilities for personal and equipment decontamination available.

II-10. OPERATIONAL RADIOACTIVE WASTE MANAGEMENT

The purpose of the inspection is to assess whether the facility's programme for safe management of radioactive waste is being effectively implemented considering the generation, processing and on-site transport of radioactive waste, release of effluents, and environmental monitoring. For this purpose, the following verifications may be done during the regulatory inspection.

(1) The inspector may examine the management system documents related to radioactive waste management to ascertain whether the following radioactive waste management activities are covered:

(a) Minimization of radioactive waste generation;
(b) Characterization of radioactive waste;
(c) Processing (including pre-treatment, treatment and conditioning) of radioactive waste within the facility;
(d) Storage of radioactive waste within the facility;
(e) On-site and off-site transport of radioactive waste.

(2) To assess the effectiveness of the management system, the inspector may by examination of the procedures, records and documentation, by discussions and interviews with operating personnel, or by monitoring and direct observation, review the following:

(a) The radioactive waste management strategy. This includes routes for the discharge of effluents and radioactive waste storage facilities;
(b) Provision of adequate human, financial and other resources for the safe management of radioactive waste;
(c) The clarity in allocation of accountabilities and responsibilities for management of radioactive waste, and communication of the expectations for safety to all personnel;
(d) The liaison arrangements with the regulatory body and other radioactive waste management facilities (including suitably qualified and experienced contractors, where relevant) with the aim of defining and optimizing arrangements for transfers of radioactive waste;
(e) Processes and procedures to take into account interdependencies between the steps in the minimization of radioactive waste generation and radioactive waste management;
(f) Processes and procedures that are incorporated in the management system to identify and manage human, technological and organizational factors affecting safety in management of radioactive waste;
(g) Periodic reviews and self-assessment of the systems relating to the management of radioactive waste;
(h) Provisions for effective knowledge transfer (e.g., recording and archiving of information), where radioactive waste management is likely to occur over long periods;
(i) The levels of release of effluents and findings of environmental monitoring.

(3) The inspector may by examination of procedures and by discussions and interviews with operating personnel, assess the level of understanding on the part of management and workers of their responsibilities related to radioactive waste management.

(4) The inspector may examine the procedures and records related to release of effluents to assess whether the releases are within the authorized discharge limits. The inspector may by examination of documentation, procedures and records review the effectiveness of systems for the treatment of radioactive waste and for the monitoring of effluents. The training and qualifications of the workers in this area may also be reviewed by the inspector.

(5) The inspector may review the documentation, procedures and records related to the environmental monitoring programme to verify whether the environmental monitoring is being performed in accordance with the programme. The inspector may by independent confirmatory tests or measurements verify the accuracy of the monitoring equipment or results of the measurements by the operating organization.

(6) The inspector may by monitoring or direct observation, by discussion and interviews with operating personnel, and by examination of procedures, assess the adequacy and effectiveness of arrangements for the characterization, on-site waste treatment, conditioning, and storage of radioactive waste.

(7) The inspector may by direct observation and monitoring assess the levels of radiation and contamination in the storage areas for unpackaged and packaged radioactive wastes. The inspector may review the storage conditions to ascertain that the waste remains suitable for further steps (e.g., retrieval, transport, or processing) in radioactive waste management, as necessary.

(8) The inspector may by examination of procedures, records, and documentation, by direct observation or by discussions and interviews with operating personnel, ascertain the effectiveness of the:

(a) Arrangements for minimization of the generation of radioactive waste at the facility. The inspector may verify whether the control measures are applied in the order specified in para. 4.6 of IAEA Safety Standards Series No. GSR Part 5, Predisposal Management of Radioactive Waste [II–2], namely: "reduce waste generation, reuse items as originally intended, recycle materials and, finally, consider disposal as waste";
(b) Management of radioactive waste generated during the maintenance, decontamination (of equipment and personnel) and periodic clean out of the facility;
(c) Transport arrangements for radioactive waste on the site (for this purpose, the inspector may look into the aspects relating to receipt and dispatch arrangements, integrity of packages, and residual levels of contamination on the radioactive waste packages).

(9) The inspector may, by examination of procedures, records, and documentation, and by discussions and interviews with operating personnel, assess the adequacy of arrangements for generating and controlling the records and reports related radioactive waste management, including:

(a) The data on quantity and activity content of radioactive waste generated;
(b) The records of classification and processing of radioactive waste;
(c) The records of the discharges of effluents;
(d) The records of unplanned releases and spills;
(e) The records of the storage and transport of radioactive waste;
(f) The results of environmental monitoring.

The inspector may also assess the arrangements for ensuring that the information for waste characterization is retrievable, especially for the radioactive waste that is stored, pending the provision for disposal.

(10) The inspector may, by examination of procedures and records related to sampling and monitoring of waste and effluents, ascertain whether the frequency of the sampling and sample analysis is established and implemented in accordance with the potential environmental impact, and with a graded approach.

(11) The inspector may examine the procedures, records and documentation related to the environmental monitoring programme to assess the associated environmental impact of planned and unplanned releases. For this purpose, the inspector may:

(a) Compare the release data with the established background conditions and data before operation commences;
(b) Compare the release data with the established action levels and annual limits;
(c) Review the arrangements for environmental monitoring of surface water, groundwater, soil and biota, as applicable.

II-11. FIRE AND CHEMICAL SAFETY

II-11.1. Fire safety

The purpose of an inspection in this area is to assess the adequacy and effectiveness of the arrangements for ensuring protection against fire and explosion in the facility. This includes the verification of compliance with applicable national requirements or standards (for conventional fire safety and fire safety relating to nuclear or radioactive material) related to fire safety. For this purpose, the following verifications may be done during the regulatory inspection.

(1) The inspector may, by monitoring and direct observation, by examination of procedures, records and documentation, assess the control of combustible materials and ignition sources in the facility. For this purpose, the inspector needs to review and assess the controls on both fixed and transient (e.g., during maintenance or hot work) materials and ignition sources.

(2) The inspector may, by examination of procedures, records, and documentation, and by discussions and interviews with operating personnel, assess the adequacy and effectiveness of programme for inspection, maintenance and testing of fire protection measures.

(3) The inspector may, by monitoring and direct observation, by discussions and interviews with operating personnel, and by examination of relevant procedures, records and documentation, assess the firefighting capabilities at the facility. The aspects that may be examined for this assessment include:

   (a) Availability and maintenance of fire detection and alarm systems;
   (b) Availability and maintenance of portable and fixed fire suppression systems;
   (c) Availability and deployment of personnel for firefighting;
   (d) Availability of emergency arrangements for firefighting that are commensurate with the size, complexity and diversity of the site and the hazard potential of the facility.

(4) The inspector may, by examination of relevant procedures, records and documentation, verify whether the assessment of the impact on fire safety has been done by the operating organization during the process of modifications in the facility.

(5) The inspector may, by examination of relevant procedures, records and documentation, and discussions and interviews with operating personnel, verify whether competent, trained, and qualified staff are available to perform any necessary work related to fire safety. The inspector may also verify the records related to the training of external fire fighters, as applicable.

(6) The inspector may, by monitoring and direct observation, by examination of procedures, records and documentation, or by discussions and interviews with operating personnel, verify that arrangements for fire safety are consistent with the arrangements for nuclear and radiation safety. For this purpose, the inspector may consider assessing the following:

   (a) The fire safety issues relating to radioactive material (e.g., radioactive organic liquids, metallic or other pyrophoric forms of uranium or plutonium);
   (b) The arrangements for firefighting in cases of fire with potential risk of release of radioactive material;
   (c) Radiation protection measures for firefighters;
   (d) Measures for management of radioactive releases to the environment in case of fire;

(e) Vulnerability of safety systems to fires (both internal and external) and inappropriate response to a fire or explosion (e.g., use of water for fire suppression may reduce the margin for criticality).

(7) The inspector may, by monitoring and direct observation, by examination of procedures, records, and documentation, or by discussions and interviews with operating personnel, assess the effectiveness of training, exercises and drills in firefighting.

(8) The inspector may, by general surveillance of the facility, assess the following:

(a) Condition of fire barriers (e.g., fire doors, fire dampers, fire seals);
(b) General housekeeping of the facility that may have impact on fire safety;
(c) Access to emergency exits, egress routes and firefighting equipment;
(d) Fire protection measures in non-safety-related areas to ensure that they have no adverse effects on the safety related areas of the facility.

(9) The inspector may, by examination of procedures, records and documentation related to reporting of fire incidents at the facility, ascertain the effectiveness of the response for fire incidents and preventive measures taken based on the review of the incidents.

(10) The inspector may, by monitoring and direct observation, by examination of procedures, records and documentation related to the self-assessment of the fire protection programme, and by discussions and interviews with operating personnel, assess the adequacy of the programme and management's attention to this area.

II-11.2. Chemical safety

The purpose of an inspection in this area is to assess the adequacy and effectiveness of the arrangements for controlling the risk of toxic chemical exposure to the personnel, public and the environment. This includes the verification of the arrangements for the planning, implementation, monitoring and review of the relevant preventive and protective measures, including the aspects related to procedures for ensuring confinement and control of toxic chemical exposures associated with radioactive material, detection systems, training, accident management and emergency preparedness. For this purpose, the following verifications may be done during the regulatory inspection.

(1) The inspector may, by examination of procedures, records and documentation related to training and qualification of operating personnel, assess whether:

(a) The training adequately emphasizes safety in handling of toxic chemicals and is commensurate with the hazard.
(b) The relevant operating personnel are suitable, qualified, and competent to deal with the chemical hazards.
(c) The workers, suppliers, contractors, and visitors are aware of, and appropriately trained in, chemical safety aspects including its interface with nuclear and radiation safety.

(2) The inspector may, by examination of procedures, records and documentation, discussions and interviews with operating personnel, and by monitoring and direct observation, assess on a sample basis, whether the activities related to handling of toxic materials are in compliance with the established safety rules and practices.

(3) The inspector may, by examination of records and by monitoring and direct observation, verify whether the concentration in air of hazardous gases (e.g., UF_6) is being maintained below the required limits, with an adequate margin.

(4) The inspector may, by examination of relevant procedures, records, and documentation, and by discussions and interviews with operating personnel, verify whether emergency drills related to handling of hazardous chemicals are being carried out periodically. The inspector may also review the findings of these drills to assess their effectiveness.

(5) The inspector may, by examination of procedures, records and documentation related to the accident management programme and by discussions and interviews with relevant operating personnel, verify whether:

(a) The accident management programme takes into account of chemical hazards associated with nuclear activities;
(b) The measures and guidelines for reducing the risk of release of hazardous chemicals are available and implemented;
(c) The instrumentation and equipment necessary for detection, monitoring, control, and mitigation of consequences of release of hazardous chemicals are available and are being maintained effectively, to ensure their availability when necessary;
(d) The operating personnel are trained in implementation of procedures to return the facility to a controlled state.

(6) The inspector may, by examination of relevant procedures, records, and documentation, by discussions and interviews with operating personnel, and by monitoring and direct observation, assess whether the following measures are implemented at the facility, following the hierarchy of prevention, control, and mitigation.

(a) The inspector may assess whether the inventories of toxic chemicals in the facility are minimized considering the operational requirements.
(b) The inspector may assess the safe transport, storage, use and disposal of hazardous process materials in the facility.
(c) The inspector may verify the configuration of the facility and assess the available controls over credible changes that might lead to the release of toxic materials.
(d) The inspector may verify the adequacy of the facility ventilation and the local ventilation.
(e) The inspector may assess the capability for detection and alarm systems for chemical or toxic releases.
(f) The inspector may verify the measures in place to prevent contact of incompatible chemicals or materials.
(g) The inspector may verify the availability and suitability of PPE to protect against exposures to chemical compounds or toxic materials.

(7) The inspector may, by examination of procedures and by direct monitoring verify whether packages, equipment and piping that may contain hazardous chemicals are suitably labelled.

(8) The inspectors may, by monitoring and direct observation, verify if there is undesired accumulation of chemicals in the facility.

II-12. EMERGENCY PREPAREDNESS

The objective of the regulatory inspection of this area is to ascertain the adequacy of emergency preparedness arrangements by the operating organization, including plans, staff, facilities and equipment, and effectiveness of coordination by the operating organization with the authorities responsible for emergency preparedness at local, regional, national and other levels as applicable. For this purpose, the following verifications may be done during the regulatory inspection.

(1) The inspector may review the emergency preparedness and response related documents, emergency plans, procedures, and records, discuss with operating personnel, and by monitoring and direct observation, verify whether:

   (a) The roles and responsibilities for preparedness and response for a nuclear or radiological emergency are clearly allocated, and the responsible persons are aware of their role and responsibilities.
   (b) In accordance with para. 4.26 of IAEA Safety Standards Series No. GSR Part 7, Preparedness and Response for a Nuclear or Radiological Emergency [II–3], "Operating organizations review appropriately and, as necessary, revise the emergency arrangements (a) prior to any changes in the facility or activity that affect the existing hazard assessment and (b) when new information becomes available that provides insights into the adequacy of the existing arrangements".
   (c) Arrangements are established for the timely identification and notification of a nuclear or radiological emergency as well as for the activation of an emergency response.
   (d) Arrangements are in place for taking mitigatory actions in a nuclear or radiological emergency to:

      (i) Prevent escalation of an emergency;
      (ii) Return the facility to a safe and stable state;
      (iii) Reduce the potential for, and mitigate the consequences of, radioactive releases or exposures.

   (e) Necessary on-site teams for mitigating the consequences of an emergency (e.g., damage control, firefighting) are available and are prepared to perform actions at the facility.
   (f) The equipment that are necessary for actions to be taken in manual response and recovery processes are placed at the suitable locations to ensure their availability at the time of need, and safe access to it would be available during postulated emergency conditions.
   (g) In accordance with para. 5.32 of GSR Part 7 [II–3], arrangements are in place to promptly assess and anticipate abnormal conditions at the facility; exposures and radioactive releases and releases of other hazardous material; radiological conditions on the site and, as appropriate, off the site; and any exposures or potential exposures of workers and the public and, as relevant, patients and helpers in an emergency.
   (h) In case of serious injury to the personnel, the first responders (e.g., medical) are aware of the precautions to take in giving first aid or in transporting an individual with possible contamination.

(i) As applicable, in accordance with Requirement 10 of GSR Part 7, "**arrangements are in place to provide the public who are affected or are potentially affected by a nuclear or radiological emergency with information that is necessary for their protection, to warn them promptly and to instruct them on actions to be taken.**"
(j) Necessary training has been provided for the workers expected to respond during an emergency and appropriate specialized protective equipment and monitoring equipment is available for their use.
(k) Appropriate numbers of suitably qualified personnel for emergency response positions are available at the facility. For a multi-facility site, whether an appropriate number of suitably qualified personnel are available to manage an emergency response at all facilities if each of the facilities is under emergency conditions simultaneously.
(l) Adequate tools, instruments, supplies, equipment, communication systems, facilities, and documentation (e.g., documentation of procedures, checklists, manuals, telephone numbers and email addresses), are available and are located or provided in a manner that allows their effective use under the emergency conditions postulated.

(2) The inspector may review the arrangements for coordination with response agencies at various levels (local, regional, national, as applicable) to ascertain whether the command and control system provides sufficient assurance for effective coordination of on-site and off-site response.

(3) The inspector may review procedures, records and documentation related to the training programme of the facility, and discuss with operating personnel, to ascertain whether the personnel assigned to positions with responsibilities in an emergency response, undergo the specified training and retraining as necessary.

(4) The inspector may review the documents, records and reports related to emergency exercises, monitor and directly observe the exercises, if possible, and discuss with relevant operating personnel to verify whether:

(a) The exercise programmes are developed and implemented to ensure that all specified functions that need to be performed for emergency response, and the organizational interfaces are tested at suitable intervals;
(b) The exercises are systematically evaluated and necessary corrective actions are taken. The conduct of exercises need be to evaluated against pre-established objectives of emergency response to demonstrate that identification, notification, activation and response actions can be performed effectively to achieve the goals of emergency response;
(c) The personnel responsible for critical response functions (including persons responsible for decision making on protective actions and for communication with public) participate in the exercises on a regular basis so as to ensure their ability to take their actions effectively.

(5) The inspector may review relevant documents and records related to management system and discuss with operating personnel to ascertain whether:

(a) In accordance with para. 6.34 of GSR Part 7 [II–3], the management system of the operating organization includes "a programme to ensure the availability and reliability of all supplies, equipment, communication systems and facilities, plans, procedures and other arrangements necessary to perform functions in a nuclear or radiological emergency";

(b) In accordance with para. 6.36 of GSR Part 7 [II-3], arrangements are made to "maintain, review and update emergency plans, procedures and other arrangements and to incorporate lessons from research, operating experience (such as in the response to emergencies) and emergency exercises";
(c) In accordance with para. 6.38 of GSR Part 7 [II–3], arrangements are made to "review and evaluate responses in actual events and in exercises, in order to record the areas in which improvements are necessary and to ensure that the necessary improvements are made".

REFERENCES TO ANNEX II

[II–1] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety of Nuclear Fuel Cycle Facilities, IAEA Safety Standards Series No. SSR-4, IAEA, Vienna (2017).

[II–2] INTERNATIONAL ATOMIC ENERGY AGENCY, Predisposal Management of Radioactive Waste, IAEA Safety Standards Series No. GSR Part 5, IAEA, Vienna (2009).

[II–3] FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL CIVIL AVIATION ORGANIZATION, INTERNATIONAL LABOUR ORGANIZATION, INTERNATIONAL MARITIME ORGANIZATION, INTERPOL, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, PREPARATORY COMMISSION FOR THE COMPREHENSIVE NUCLEAR-TEST-BAN TREATY ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, UNITED NATIONS OFFICE FOR THE COORDINATION OF HUMANITARIAN AFFAIRS, WORLD HEALTH ORGANIZATION, WORLD METEOROLOGICAL ORGANIZATION, Preparedness and Response for a Nuclear or Radiological Emergency, IAEA Safety Standards Series No. GSR Part 7, IAEA, Vienna (2015).

ANNEX III.

EXAMPLE OF A REGULATORY INSPECTION PROCESS

This Annex provides an example of a regulatory inspection process based on the practice of the Atomic Energy Regulatory Board (AERB) of India.

The AERB performs regulatory inspection of nuclear fuel cycle facilities (NFCFs) in India to ensure that the activities performed during all the phases of their lifetime (siting, construction, commissioning, operation, and decommissioning) are executed in compliance with the legal and regulatory requirements.

The regulatory inspections are carried out in accordance with the programme comprehensively developed in synchronization with other regulatory processes within the overall regulatory strategy to ensure that the facility complies with the regulatory requirements. The extent to which inspection is performed depends upon the potential, magnitude and nature of the hazard associated with the facility or type of activity.

III-1. PLANNING OF REGULATORY INSPECTIONS

The programme for regulatory inspection identifies various inspections to be conducted by the AERB and the broad scope of each of these inspections. The programme considers planned inspections (routine inspections and special inspections) and reactive inspections. The plan and a tentative schedule for routine inspections is prepared on annual basis, at the beginning of each calendar year. The need, scope and tentative schedule for special and reactive inspections is identified based on the outcomes of various regulatory processes, including the licensing, safety review and assessment, emergency preparedness and response, and regulatory inspection processes. The planning for each of these inspections includes finalization of inspection schedule and scope for each of these inspections, formation of inspection teams, and conduct of pre-inspection meeting within the regulatory body to deliberate on the specific points to be checked during inspection.

III-1.1. Finalization of scope, schedule, and composition of team for regulatory inspections

The scope of a routine inspections is broadly decided during planning of inspection based on the factors such as: objective of regulatory inspection; potential risk associated with facility or activity; stage of facility or activity; on-going activities; safety performance of the facility; inputs from resident inspectors or observers; nature, complexity, and safety significance of inspection areas; condition of structures, systems and components (SSCs); events, abnormal condition, or unforeseen situation; or issues of public concern. The various functional areas of the facility to be inspected, the number, qualifications and experience of inspectors, and duration of inspections are identified based on the potential hazard and complexity of the facility. The inspection areas of the facility may include plant management, operations, technical audit, maintenance (mechanical, electrical, control and instrumentation, civil), radiological safety, emergency preparedness, radioactive waste management, quality assurance (QA), in-service inspection, fire safety, occupational and industrial safety, or other areas decided by the regulatory body.

The scope, depth or rigor of inspection, duration of inspection, size and composition of inspection team are decided in accordance with a graded approach, primarily depending on the scope and objective of the inspection and the hazard potential of the facility. The inspections planned with the objective of verifying overall status and performance of a complex facility need dealing with wide range of technical areas with sample checks (i.e., horizontal slice) and may need a reasonably sized inspection team comprising of multi-disciplinary experts. The inspections with specific focus on an area of interest with deep diving (i.e., vertical slice) need an inspector with expertise in a particular field or a team of experts.

III-1.2. Formation of teams for conducting regulatory inspections

The regulatory inspections of the AERB are generally conducted by its staff who are specifically authorized as 'Inspectors'. In certain cases, the AERB may utilize the services of external experts for inspection of specific area or aspects during the regulatory inspections. While these external experts participate in the inspection as team members for their areas of expertise, the leader of the inspection team is one of the inspectors of the AERB. In addition to the minimum number of inspectors as identified in the inspection programme, the inspection team may also have one or more staff, who are in the process of obtaining authorization as an inspector, to gain experience in the regulatory inspection process. These officers do not conduct inspection independently but participate in the inspection under guidance of the authorized inspector.

III-1.3. Pre-regulatory inspection meeting

Before the conduct of inspection, inspectors need to be thoroughly prepared for the inspection. To this end, a meeting is organized by the inspection team leader and is attended by other inspection team members and the representative involved in the safety review and assessment of the facility. As a guidance to inspectors, guidelines in the form of procedures and checklists for conduct of inspections are available. In addition to the established procedures and checklists, the availability of information on the relevant and latest inputs from various regulatory processes with the inspectors is key to the efficient and effective conduct of any type of inspection (routine, special, as well as reactive). The specific points that need to be checked during routine inspections based on outcomes of other regulatory processes are informed to the inspectors.

Special inspections may be carried out for witnessing certain tests or activities, or to consider specific issues that may be of interest to the AERB, such as, new research and development findings and experience at other facilities. Reactive inspections are conducted by the AERB in response to an unexpected or unplanned, or unusual situation or event, to review its significance and implications, and the adequacy of corrective actions. During the pre-inspection meetings, the objectives for conducting these inspections are conveyed to the inspectors, along with the specific points to be checked based on the review of information available with various regulatory processes. The inspection team may prepare a checklist to list out specific points that are to be checked during the inspection. During the pre-inspection meeting, the methods to be employed for checking specific issues during the inspection may also be deliberated.

III-2. CONDUCT OF REGULATORY INSPECTION

The inspection team conducts inspection at the NFCF site as per the objective and scope of the inspection. The inspection is carried out to check compliance with legal and regulatory requirements related to the areas as identified in the scope of the inspection. The pre-established

checklist and the deliberations during pre-inspection meetings serve as guidance to inspectors to focus on the specific issues to be checked during inspection. Major steps related to conduct of regulatory inspection and associated inspection activities at the facility are detailed in the subsections below.

III-2.1. Introductory meeting with the licensee

Before the start of the inspection, an introductory meeting is conducted by the inspection team with the licensee. The purpose of this meeting is to ensure that the inspection team and the facility have a common understanding of the purpose and scope of the inspection. The inspection team may brief the facility personnel on the approach for the inspection; activities to be observed; records to be evaluated and personnel to be interacted with. The team may also seek brief information on the current issues related to the inspection areas and the ongoing plant activities that may impact the scope or approach of the inspection, if any.

III-2.2. Inspection of identified areas

The inspection team carries out inspection as per the predefined objective and scope. However, the scope may be extended to other areas based on the specific observations made during the inspection.

III-2.2.1. Time management

The inspectors plan their activity based on the importance and nature of inspection. The time spent by an inspector during the inspection is managed and divided accordingly considering the time necessary for the following activities:

- Field visits including tests or examinations to be conducted;
- Review of documents;
- Interview of plant personnel;
- Consolidation of the findings and report preparation.

The inspectors identify the SSCs that are to be inspected and the tests and activities that are to be observed during the inspection and convey the same to the facility at the beginning of inspection to make necessary arrangements.

III-2.2.2. Inspection methods

The methods for obtaining information during an inspection include monitoring and direct observation; discussions and interviews; document evaluation; and independent tests and measurements. Depending on the type of inspection being performed, the inspector determines the method, or methods that would be suitable to gather and evaluate the necessary information and data.

III-2.3. Reporting of regulatory inspection findings

The results of all regulatory inspections are documented and submitted as an inspection report to:

- Document and record an assessment of the facility status and licensee’s safety activities;
- Record the information gathered during the inspection;
- Record any findings or conclusions of the inspectors;

- Record the deviations, if any, for future actions by the licensee or the regulatory body;
- Provide a basis for notifying the licensee of the inspection findings, and of any requirements to be complied with;
- Highlight any non-compliance, deficiencies, or violations for immediate corrective actions, if any.

III-2.4. Exit meeting with the facility management

At the end of the inspection, when a draft of the inspection report is ready, an exit meeting with the facility management is conducted. The purpose of this meeting is to brief the important findings to the management and to get additional information, if any, from the management, to finalize the observations and recommendations made in the inspection report. The draft inspection report is given to the facility prior to start of the feedback or exit meeting.

During the meeting, the inspectors briefly restate the inspection scope; present overall conclusions; discuss any violations, including a description of the findings and the requirement that was not met.

The meeting provides an opportunity to the facility to respond to the observations of the inspectors. When the management response is convincing, the team may accept it, and appropriately modify the relevant portions of the report.

Inspection team may also seek feedback from the facility about the conduct of inspections in exit meeting.

III-3. FINALIZATION AND ISSUANCE OF REGULATORY INSPECTION REPORT

The inspection team finalizes the inspection report at AERB headquarters. To facilitate follow-up review, enforcement and corrective actions, the reported deviations are categorized based on their safety significance and follow-up of the necessary measures. The categorization helps the facility in submitting appropriately detailed responses considering the category level. The team leader of the regulatory inspection, in consultation with the inspection team members categorizes the reported deviations in a graded manner as ‘white’, ‘grey’, ‘orange’ or ‘red’ in an increasing order of safety significance.

The inspection report is then harmonized by the Division of Regulatory Inspection (DRI) in consultation with inspection team and representative of the division responsible for safety review and assessment. The harmonization process is aimed to maintain uniformity in the reporting and categorization of similar observation in the inspection reports of various facilities. After the harmonization, the inspection report is issued within a specified time frame after completion of the regulatory inspection. The inspection report is sent to the licensee for necessary corrective actions.

III-4. RESPONSE TO REGULATORY INSPECTION REPORT FROM FACILITY

The facility is expected to correct all the deviations reported during regulatory inspections and submit response for observations informing the actions taken for resolution of the deviations or giving the proposed target date(s) for completion of necessary actions. The response needs to be submitted within the specified period after issuance of inspection report. However, in case an early review is necessary or planned within the AERB for one or more observations, the facility may be asked to submitted response within a shorter period. No formal response needs

to be submitted for 'white' deviations (lowest safety significance). However, the facility is expected to correct the deviations and maintain internal action taken reports which may be checked during subsequent regulatory inspections.

In case of delay in receipt of the facility response, a reminder is sent to the facility. In case of non-submission of response even after the reminder an appropriate enforcement action may be initiated.

III-5. REVIEW AND FOLLOW-UP

The facility's response to the regulatory inspection report is initially reviewed in consultation with inspection team leader and members, and representatives from the concerned safety review division of the AERB. Based on this review, the follow-up actions for the reported deviations and observations needing safety review are identified, which may be as follows:

a) The observations on which satisfactorily action has been taken by facility are closed.
b) The observations for which facility response is satisfactory but an on-site verification is to be done by AERB before closure of the observation are identified as 'Pending for Verification'. These observations are closed after on-site verification of the action taken by the facility during forthcoming regulatory inspection or by the resident inspectors or observers, if available.
c) The observations which need further review by the AERB are forwarded to respective safety review division. Based on the review, the concerned safety review division may either accept the facility's response or initiate appropriate enforcement action. The observation is closed after satisfactory resolution of the observation through the concerned safety review division.
d) The observations for which action or submission by facility are marked 'Pending'. Facility is asked to submit additional information and provide updated status after completion of identified actions.

Based on this initial review, the regulatory follow-up actions are decided and communicated to the facility through a review report on the facility response. The status of all the pending observations (incl. those pending for verification) is checked during subsequent regulatory inspections.

III-6. SELF-ASSESSMENT OF REGULATORY INSPECTION PROCESS

With an aim to continually improve the regulatory inspection process and its effectiveness to ensure safety, self-assessment is conducted periodically to identify areas for improvement. Reference documents used for the assessment are the approved policies, and procedures under the integrated management system of the AERB.

III-6.1. Conduct of self-assessment

Self-assessment is planned based on the calendar of activities and is generally once in three years. The process owner (Head, DRI) identifies the assessment team from DRI for conducting the self-assessment. The officers for conducting the self-assessment are preferably selected from the officers involved in process of regulatory inspection of the facilities in the block period of three years.

Self-assessment questionnaires and forms (see Annex III-6.2) on the various sub-processes of the inspection process are used to obtain the assessment inputs. Based on the data analysis,

group discussions and brain storming sessions, the outcomes along with corrective actions, if any are recorded.

During the self-assessment, the assessment team needs to identify performance metrics from the reference documents (e.g., policies, procedures) and deploy various methods of self-assessment for conducting the evaluation. The self-assessment needs to cover:

(a) Compliance with approved policies and procedures;
(b) Effectiveness in meeting the process objectives;
(c) Effectiveness of coordination with various core and associated processes;
(d) Staff competence;
(e) Adequacy and optimization of resources;
(f) Effectiveness of corrective actions identified during earlier assessments;
(g) Adequacy of documentation and record keeping.

The following methods, may be applied for conducting the self-assessment:

(a) Group discussions among the responsible persons of the process;
(b) Collection and analysis of available records;
(c) Collection and analysis of performance data (e.g. for identification of trends);
(d) Internal benchmarking (within the regulatory body with performance of other divisions) and external benchmarking (with other national or international regulatory bodies) of regulatory processes and activities;
(e) Lessons learned by the process performers during execution of the regulatory inspection process;
(f) Comparison with international standards, such as the IAEA Safety Standards;
(g) Individual feedback from internal staff of the AERB (from other processes).

The assessment activities are completed as per the plan and assessment report is submitted by the assessment team to the process owner. The assessment report needs to clearly bring out the outcomes of the assessment, and areas for improvement. The assessment report is communicated to all the responsible persons of the process and is used to develop an action plan for improvement. The process owner allocates responsibilities for monitoring the action plan till corrective actions are completed.

III-6.2. Sample questionnaires for self-assessment of inspection process

A sample self-assessment questionnaire for the development of an annual baseline inspection programme is given in Table III-1.

TABLE III-1. SAMPLE SELF-ASSESSMENT QUESTIONNAIRE FOR THE DEVELOPMENT OF AN ANNUAL BASELINE INSPECTION PROGRAMME

#	Questionnaire	Yes/No	Remarks
1.	Are different inputs as envisaged for the development of the annual baseline inspection programme taken into consideration during development?		
2.	Are all the inputs available to the DRI for programme development?		
3.	Is the annual baseline inspection programme approved and issued in time?		
4.	Is the annual baseline inspection calendar communicated to the licensee well in advance?		

A sample self-assessment questionnaire for regulatory inspection programme implementation is given in Table III-2.

TABLE III-2. SAMPLE SELF-ASSESSMENT QUESTIONNAIRE FOR REGULATORY INSPECTION PROGRAMME IMPLEMENTATION

#	Questionnaire	Yes/No	Remarks
1.	Is sufficient time available to the licensee and inspectors for the preparation of the inspection?		
2.	Are inspectors with the necessary specialization conducting the inspections?		
3.	Are inspectors in the process of obtaining authorization included in the regulatory inspection as a team member for gaining experience?		
4.	Is the team leader communicating with the licensee and team members with respect to logistics and pre-regulatory inspection activities?		
5.	Are pre-regulatory inspection meetings conducted by the team leader with participation from safety review division and the DRI?		
6.	Are specific inputs for an inspection provided by the safety review division representatives? Are operating experience feedback inputs available? Is facility specific data available for the regulatory inspection team?		
7.	Are inputs from previous regulatory inspections made available to the inspection team?		
8.	Is logistics support available to the regulatory inspection team from the AERB?		

A sample self-assessment questionnaire for the conduct of regulatory inspection is given in Table III-3.

TABLE III-3. SAMPLE SELF-ASSESSMENT QUESTIONNAIRE FOR THE CONDUCT OF REGULATORY INSPECTION

#	Questionnaire	Yes/No	Remarks
1.	Is the regulatory inspection team briefing the facility management on the scope and coverage of the inspection?		
2.	Is sufficient time spent by the regulatory inspection team in the field (of the total regulatory inspection duration) for physical verification and field observations?		
3.	Is any difficulty faced by the regulatory inspection team with respect to the availability of documents or records, or coordination for field visits?		
4.	Is the duration of inspection sufficient for the planned activities, document review, and field visits?		
5.	Is the regulatory inspection team able to plan and witness the scheduled activities during the regulatory inspection?		
6.	Is sufficient knowledge and expertise available within the regulatory inspection team for follow up of previous regulatory inspection deviations and specific inputs provided? (e.g., by the safety review division with respect to the licensing conditions, safety committee issues, other divisional reviews)		

TABLE III-3. SAMPLE SELF-ASSESSMENT QUESTIONNAIRE FOR THE CONDUCT OF REGULATORY INSPECTION (cont.)

#	Questionnaire	Yes/No	Remarks
7.	Is the necessary infrastructure available at the temporary stay (e.g., at hotel, guest house) for the regulatory inspection team to prepare reports and discuss issues?		
8.	Are designated (by the licensee) coordinators available to coordinate with the inspectors for the assigned functional areas of regulatory inspection?		
9.	Is any difficulty faced by the team leader in compilation and understanding of observations or deviations noted by other inspectors of the team?		
10.	Are important observations and deviations briefed to the facility management at the end of the inspection? Are there any difficulties with respect to these discussions?		

A sample self-assessment questionnaire for the finalization of the regulatory inspection report is given in Table III-4.

TABLE III-4. SAMPLE SELF-ASSESSMENT QUESTIONNAIRE FOR THE FINALIZATION OF THE REGULATORY INSPECTION REPORT

#	Questionnaire	Yes/No	Remarks
1.	Has the team leader provided information to Head, DRI on the major observations and deviations (warranting enforcement or other regulatory actions) reported during the regulatory inspection after returning from the site?		
2.	Have all the points or issues identified and documented during the pre-regulatory inspection meetings been addressed in the inspection report?		
3.	Was sufficient time available for the regulatory inspection team to finalize the draft inspection report after returning from the site?		
4.	Was the regulatory inspection team able to submit the first draft of the inspection report to DRI within the stipulated time period (7 days after completion of the inspection)? If not, the reason for delay.		
5.	Was the team leader able to conduct the harmonization meeting with proper participation of representatives from DRI and safety review division and regulatory inspection team members?		
6.	Was the regulatory inspection team able to find relevant requirements in regulatory documents to report deviations? Is the concept of 'Significant Observation' understood by the inspectors?		
7.	Do the inspectors have sufficient understanding of the categorization of deviations? Problems faced, if any, while categorizing the deviations.		
8.	Are the team members, representing the safety review division and DRI, able to come to a consensus during harmonization of the regulatory inspection report? Problems faced, if any, during the harmonization.		
9.	Are regulatory inspection reports being issued within the stipulated time period (within 21 days)? Reasons for delay in issuance of report, if any.		
10.	Are regulatory inspection findings archived in the central database after issuance of the inspection reports?		

A sample self-assessment questionnaire for review of the facility's response and follow-up is given in Table III-5.

TABLE III-5. SAMPLE SELF-ASSESSMENT QUESTIONNAIRE FOR REVIEW OF THE FACILITY'S RESPONSE AND FOLLOW-UP

#	Questionnaire	Yes/No	Remarks
1.	Is the response to the regulatory inspection report being received within the stipulated time period (30 days) from the facilities? Do reminders need to be sent to the licensee for submission of responses?		
2.	Is the response to the regulatory inspection report being reviewed within the stipulated time? Is the review being made after discussions with the concerned officials from the safety review division and regulatory inspection team members?		
3.	Is the facility taking necessary corrective actions for addressing 'white' category deviations and keeping proper records?		
4.	Is the safety review division taking up the issues identified during review of facility's response and submitting necessary information for closure of these issues?		
5.	Is an inspection findings trend analysis conducted to identify generic issues?		
6.	Are inspection findings trend analysis results disseminated to appropriate agencies (e.g., the divisions responsible for safety review and assessment, licensees)		

III-6.2.1. Lessons learnt during regulatory inspection and suggestion for improvements

A sample form for collection of lessons learnt during regulatory inspection and suggestions for improvement from the inspection team, is given in Table III-6.

TABLE III-6. SAMPLE FORM FOR COLLECTION OF LESSONS LEARNT DURING REGULATORY INSPECTION AND SUGGESTIONS FOR IMPROVEMENT

#	Regulatory inspection **attributes**	Lessons learnt	Suggestions
1.	**Pre-regulatory inspection activities:** (a) Study of safety review inputs, routine submissions from licensee, feedback from previous regulatory inspections etc.; (b) Communication with team members; (c) Communication with licensee with respect to the logistics (e.g., travel plan, accommodation).		
2.	**Conduct of regulatory inspection:** (a) Discussions with licensee's management; (b) Field visits including independent tests and examinations; (c) Review of documents; (d) Interviews with facility personnel; (e) Logistics and support from licensee.		
3.	**Post-regulatory inspection activities:** (a) Finalization of regulatory inspection report; (b) Regulatory requirements with respect to the observed deviations or findings; (c) Interaction with safety review division.		

LIST OF ABBREVIATIONS

AERB	Atomic Energy Regulatory Board (India)
CNSC	Canadian Nuclear Safety Commission
DRI	Division of Regulatory Inspection (AERB)
DNCFR	Directorate of Nuclear Cycle and Facilities Regulation (CNSC)
FINAS	Fuel Incident Notification and Analysis System
NEA	Nuclear Energy Agency of the OECD
NFCF	nuclear fuel cycle facility
MOX	mixed oxide
NSCA	Nuclear Safety and Control Act
OECD	Organization for Economic Co-operation and Development
PPE	personal protective equipment
QA	quality assurance
SCA	safety and control area
SSC	structures, systems and components

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