Safety Reports Series

No. 81

Development of a Regulatory Inspection Programme for a New Nuclear Power Plant Project

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DEVELOPMENT OF A REGULATORY INSPECTION PROGRAMME FOR A NEW NUCLEAR POWER PLANT PROJECT

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SAFETY REPORTS SERIES No. 81

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INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2014

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1400 Vienna, Austria
fax: +43 1 2600 29302
tel.: +43 1 2600 22417
email: sales.publications@iaea.org
http://www.iaea.org/books

Printed by the IAEA in Austria
February 2014
STI/PUB/1636

IAEA Library Cataloguing in Publication Data

Development of a regulatory inspection programme for a new nuclear power plant project. — Vienna : International Atomic Energy Agency, 2014.
p. ; 24 cm. — (Safety reports series, ISSN 1020–6450 ; no. 81)
STI/PUB/1636
ISBN 978–92–0–113513–1
Includes bibliographical references.

1. Nuclear power plants — Inspection. 2. Nuclear power plants Licences. 3. Nuclear energy — Law and legislation. I. International Atomic Energy Agency. II. Series.

IAEAL 14–00876

FOREWORD

With the recent interest in nuclear energy, many States have expressed an interest in developing nuclear programmes or expanding existing ones. Some of them have formally declared their intent to introduce nuclear power; others have even signed contracts to build nuclear power plants.

The IAEA identifies seven main stages in licensing within the lifetime of a nuclear facility: siting, design, construction, commissioning, operation, decommissioning and release from regulatory control. This Safety Report focuses on the development of a regulatory inspection programme for siting through to commissioning. In addition, it considers the transition to operation. The regulatory inspection programme provides a high level of assurance that licensed activities are conducted in accordance with regulatory requirements and in conformity with general safety objectives (e.g. the as-built configuration of structures, systems and components is in conformity with the licensing basis).

Construction and regulatory inspection of new construction projects are areas for which there are a limited number of requirements established in IAEA safety standards. Furthermore, the related IAEA Safety Guides address general regulatory functions, with limited emphasis on new construction projects or considerations for development of the inspection programme. This Safety Report identifies safety aspects from these requirements and recommendations, as well as key issues associated with initial programme development, and provides several examples from Member States.

The IAEA is grateful to all those who assisted in the drafting and review of this report. The IAEA officer responsible for this publication was S. Koenick of the Division of Nuclear Installation Safety.

EDITORIAL NOTE

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1. INTRODUCTION

1.1. BACKGROUND

With the recent interest in nuclear energy, many States have expressed an interest in developing nuclear programmes or expanding existing ones. This has highlighted the need for establishing appropriate regulatory oversight for new construction.

IAEA safety standards identify seven main stages in licensing within the lifetime of a nuclear facility: siting, design, construction, commissioning, operation, decommissioning and release from regulatory control. This Safety Report focuses on the development of a regulatory inspection programme for siting through to commissioning. In addition, it considers the transition to operation. The regulatory inspection programme provides a high level of assurance that licensed activities are conducted in accordance with regulatory requirements and in conformity with general safety objectives (e.g. the as-built configuration of structures, systems and components (SSCs) is in conformity with the licensing basis).

Aspects of regulatory inspection for the pre-operations licensing phases are addressed in several different IAEA Safety Requirements and Safety Guides. Principally, Requirement 27 of IAEA Safety Standards Series No. GSR Part 1, Governmental, Legal and Regulatory Framework for Safety [1], requires 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." Types and scope of inspections are provided in Requirements 28 and 29. Requirements 30 and 31 require the regulatory body to establish and to implement an enforcement policy within its legal framework and require corrective actions to be taken by authorized parties.

There are numerous other IAEA safety standards related to regulatory inspection and enforcement. IAEA Safety Standards Series No. GS-G-1.3, Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body [2], is the primary Safety Guide on this topic. The following also address elements of inspection and enforcement:

- — IAEA Safety Standards Series No. GS-G-1.1, Organization and Staffing of the Regulatory Body for Nuclear Facilities [3];
- — IAEA Safety Standards Series No. GS-G-1.2, Review and Assessment of Nuclear Facilities by the Regulatory Body [4];
- — IAEA Safety Standards Series No. GS-G-1.4, Documentation for Use in Regulating Nuclear Facilities [5];

— IAEA Safety Standards Series No. SSG-12, Licensing Process for Nuclear Installations [6].

As regulatory inspection and enforcement are considered key regulatory functions, they are regarded as processes within the regulatory body's management system. Additional guidance specific to management systems can be found in:

— IAEA Safety Standards Series No. GS-R-3, The Management System for Facilities and Activities [7];
— IAEA Safety Standards Series No. GS-G-3.1, Application of the Management System for Facilities and Activities [8];
— IAEA Safety Standards Series No. GS-G-3.5, The Management System for Nuclear Installations [9].

Guidance on construction of nuclear installations is under preparation, which will further elaborate the topic on construction in appendix V to IAEA Safety Standards Series No. GS-G-3.5 [9], as well as provide detail related to regulatory oversight during construction. IAEA Safety Standards Series No. SSR-2/1, Safety of Nuclear Power Plants: Design [10], and implementing Safety Guides provide the requirements and guidance related to the design of the nuclear power plant itself. The verification of these requirements is a primary objective of the regulatory inspection programme. IAEA Safety Standards Series No. SSR-2/2, Safety of Nuclear Power Plants: Commissioning and Operation [11], and IAEA Safety Standards Series No. NS-G-2.9, Commissioning for Nuclear Power Plants [12], identify the requirements and implementing guidance related to commissioning. In addition, IAEA Safety Standards Series No. GSR Part 4, Safety Assessment for Facilities and Activities [13], provides the requirements related to safety assessment. It should be noted that IAEA Safety Standards Series No. GS-G-1.3 [2] was published before these other relevant IAEA safety standards.

For States considering establishing a nuclear programme, the IAEA has developed IAEA Safety Standards Series No. SSG-16, Establishing the Safety Infrastructure for a Nuclear Power Programme [14]. This guide addresses the first three phases of the development of a nuclear programme. In relation to SSG-16, the contents of this Safety Report address phase 2 actions in establishing the basic regulatory framework on regulatory inspection with respect to the pre-operational licensing phases. This Safety Report also addresses phase 3 actions that implement those regulatory activities.

1.2. OBJECTIVE

The objectives of this Safety Report are:

(a) To provide information on key technical considerations and activities related to the development of a regulatory inspection programme by the regulatory body, in accordance with the phases of development in the Milestones approach;
(b) To identify, within one publication, relevant IAEA Safety Requirements and associated recommendations from IAEA Safety Guides related to the regulatory inspection programme of new nuclear facility projects;
(c) To support regulatory bodies in the development of their regulatory inspection programmes.

1.3. SCOPE

This Safety Report provides general principles, guidance and technical rationale for regulatory inspection of new nuclear power plant projects, and is based on the consideration of IAEA standards and experiences of Member States. It covers regulatory inspection during siting, design, construction and commissioning stages as well as the transition to operation. It takes into account approaches, practices and the experience of Member States recently involved in new nuclear facility projects, and it includes in Appendices I–VIII examples from Member States' regulatory inspection programmes and experiences. The principles of this Safety Report may be applicable to other nuclear facilities, such as:

— Enrichment and fuel manufacturing plants;
— Other reactors, such as research reactors and critical assemblies;
— Spent fuel reprocessing plants;
— Facilities for radioactive waste management (e.g. treatment, storage and disposal facilities).

However, some sections, primarily with regard to SSCs, focus more on nuclear power projects. These elements would have to be redefined for other facilities.

1.4. STRUCTURE

Section 2 introduces steps for developing a regulatory inspection programme consistent with SSG-16 [14]. Section 3 covers the objectives, legal authority and requirements for regulatory inspections. Section 4 describes the development of an inspection programme. Section 5 covers inspection areas during various licensing stages. Section 6 addresses specific elements of interest for the inspection programme. Section 7 deals with inspection programme implementation details, and Section 8 deals with enforcement.

Appendices I–VIII provide examples from Member States' regulatory inspection programmes for their nuclear power plants.

2. ESTABLISHING SAFETY INFRASTRUCTURE TO SUPPORT DEVELOPMENT OF A REGULATORY INSPECTION PROGRAMME

The sequence of steps in the development of a regulatory inspection programme is informed by the phases and actions contained in SSG-16 [14], which divides the lifetime of a nuclear power plant into five phases from a nuclear safety standpoint and provides indicative average durations for each phase. This Safety Report uses the same approach in considering phases 1, 2 and 3.

(a) Phase 1 is 'Safety infrastructure before deciding to launch a nuclear power programme' (average duration: 1–3 years).
(b) Phase 2 is 'Safety infrastructure preparatory work for construction of a nuclear power plant after a policy decision has been taken' (average duration: 3–7 years).
(c) Phase 3 is 'Safety infrastructure during implementation of the first nuclear power plant' (average duration: 7–10 years).
(d) Phase 4 is 'Safety infrastructure during the operation phase of a nuclear power plant' (average duration: 40–60 years).
(e) Phase 5 is 'Safety infrastructure during the decommissioning and waste management phases of a nuclear power plant' (average duration: from 20 to more than 100 years).

In phase 1, primarily the government is informed of the necessary safety infrastructure to introduce nuclear power safely. As part of this familiarization, the government should identify all the necessary elements of a legal framework for the safety infrastructure, and should plan how to structure it and to develop it — this includes consideration for inspection. It should begin to establish contact with other States and international organizations for advice on safety related matters. In addition, the government should identify competences required in the areas of nuclear safety and approximate the number of experts required.

The development of the infrastructure to support construction begins in phase 2. Here, the government should enact essential elements of the legal framework. SSG-16 [14] identifies a series of actions for the regulatory body, which should consider various regulatory approaches and then issue regulations and guides necessary for licensing and inspection. In addition, the regulatory body should specify safety requirements necessary for the bidding process. Lastly, the regulatory body should begin establishing a suitable working relationship with the operating organization. The regulatory body should start recruiting staff and commence education and training. It should also plan for the use of external support organizations. In phase 2, the regulatory body may be engaged in the review and assessment of the site evaluation report. There may be some corresponding need for inspection.

In phase 3, the regulatory body should establish and implement its programme for inspection and enforcement during construction, including, as applicable, the design and manufacture of safety related components. The regulatory body and external support organizations should ensure sufficient competent human resources at the appropriate time.

3. OBJECTIVES, LEGAL AUTHORITY AND REQUIREMENTS FOR REGULATORY INSPECTION AND ENFORCEMENT

3.1. OBJECTIVES OF REGULATORY INSPECTION AND ENFORCEMENT

The objectives for regulatory inspection and enforcement are provided in paras 4.49–4.60 of IAEA Safety Standards Series No. GSR Part 1 [1]. Some relevant aspects are that 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. Regulatory inspections shall cover all areas of regulatory body responsibility. The regulatory body shall have the authority to carry out independent inspections, and provision shall be made to regulatory inspectors for the free access to any facility or activity at any time.

The regulatory body shall record the results of inspections and take appropriate actions (including enforcement actions as necessary). The authorized party shall be held accountable for remedying non-compliances, for performing a thorough investigation in accordance with an agreed timetable and for taking all the measures necessary to prevent recurrence of non-compliance. Regulatory inspection and enforcement shall be applied in a graded approach.

Regulatory inspection cannot diminish the prime responsibility for the safety of the authorized party and cannot be a substitute for the control, supervision and verification activities conducted under the responsibility of the authorized party.

In essence, the underlying objective is about confirming the licensee does the right thing. The regulatory inspection programme should encourage this type of behaviour.

3.2. LEGAL AUTHORITY

3.2.1. National legal framework for inspections

The public expects activities associated with nuclear facilities to be managed at a high level of safety. Although the licensee has the primary responsibility in demonstrating this, the public expects the regulatory body to play an independent role in assuring that licensees are, in fact, doing what they claim to be doing to ensure safety. Within the regulatory framework, the regulatory body is expected to inspect the licensee's activities and facilities and to have the ability to enforce the licensee to comply with regulatory requirements. In order to conduct inspection and enforcement activities, the regulatory body needs sufficient legal authority.

One of the initial steps in the development of the overall nuclear programme is for the government to perform a complete assessment of the legislation and a regulatory framework required to support the safe operation and effective oversight and licensing of a nuclear power plant (para. 2.35 of SSG-16 [14]).

The assessment should include whether the regulatory body has sufficient provisions for conducting inspections and taking appropriate enforcement actions (para. 2.37(10) of SSG-16 [14]). IAEA Safety Standards Series No. GSR Part 1 [1], No. GS-G-1.3 [2] and No. SSG-16 [14] describe detailed requirements and recommendations on the roles and responsibilities of a nuclear regulatory body, including those of inspections. The assessment should consider whether the obligations, roles and responsibilities are clearly defined and that the regulatory body has the necessary authority, power and independence to fulfil its obligations.

With respect to the coordination of different authorities with responsibilities for safety, this assessment will also need to consider the existing legal framework for laws applicable to the nuclear programme. Examples include regulatory authorities that may be involved in the inspection of manufacturing facilities or pressure equipment, and interface with the judicial system. The assessment of the legislation should consider the functions, division of responsibilities and authority of various governmental bodies involved, how they interact and whether there is a process for settlement, should disputes arise.

The legal framework should clearly assign the prime responsibility for the safety of a nuclear power plant to the licensee — the regulatory activities do not relieve the licensee from its responsibility for safety. The regulatory body is responsible for developing the regulatory framework and for a nuclear power programme. It is responsible for granting authorizations and verifying compliance with applicable regulations. The legal framework should provide the regulatory body the necessary powers, including, but not limited to, the following (paras 2.7 and 2.9 of Safety Standards Series No. GS-G-1.3 [2]):

(a) Establishing regulations and issuing guidance which, among others, will serve as the basis for inspection;
(b) Entering the premises of any facility that is subject to any stage of the regulatory process or any related establishment at any time for the purposes of inspection;
(c) Requiring the preparation of, access to and submission of reports and documents from operators and their contractors when necessary;
(d) Seeking the cooperation and support of other governmental bodies and consultants with competences or qualifications relevant to regulatory inspections;
(e) Communicating information, findings, recommendations and conclusions from regulatory inspections to other governmental bodies or interested parties, including high level officials, as appropriate in view of the significance of the issue;
(f) Requiring the operator to take action to remedy deficiencies and to prevent their recurrence, curtailing activities or shutting down the facility when the results of a regulatory inspection or other regulatory assessment indicate that the protection of workers, the public and the environment might be inadequate;
(g) Imposing or recommending civil penalties or other sanctions for non-compliance with specified requirements.

The legal framework should also provide the necessary powers to the regulatory body for conducting inspections during all stages of the licensing process and all phases of the nuclear power plant including inspections of the licensee's contractors and subcontractors within the State as well as abroad, such as during equipment manufacturing outside the State.

The government should use the results of the assessment of its legislation and regulatory framework and should enact and implement essential elements in phase 2 (Action 22 of SSG-16 [14]).

3.2.2. Regulatory approach for inspection

The applicable IAEA safety standards describe the objectives of inspection. However, thresholds for what constitutes verification are determined by the States themselves. In determining the regulatory approach, SSG-16 [14] provides a wide range with respect to the scope and depth of inspection. The scope may include all SSCs classified as important to safety or may be limited at the discretion of the regulatory body. As to the depth of the review, the regulatory body in some States puts the main emphasis on the assessment and auditing of the management system and the operations of the operating organizations and their suppliers. In some States, it is the practice for the regulatory body to approve the various suppliers involved, following audits and inspections of their management systems. The decision on the regulatory approach should be based on the States' conditions to fulfil their legal responsibility. The approach should be communicated to the prospective applicant and other stakeholders. Appendices I–VIII provide Member State examples of the attributes of their construction inspection programmes.

3.2.3. National regulatory framework for inspection

During phase 2 and into phase 3, the regulatory body has to establish and to promulgate a regulatory framework for regulatory inspection, consistent with the legal provisions of the State. In most States, the basic regulatory framework for inspection and authorization processes is established in the form of regulations, whereas details are prescribed in management system documents, including programmes, procedures and manuals. States embarking on a nuclear power programme may consider the following in establishing their framework for inspection:

— Legal framework of the State;
— IAEA safety standards and security guidelines;

— Framework and practices of other States with established systems and processes;
— A combination of the above.

The regulatory framework should address:

(a) Powers and authority of inspectors;
(b) Scope of inspection;
(c) Provision for announced, unannounced, planned and reactive inspections;
(d) Inspections of contracted and subcontracted activities within and outside the State at the premises of contractors and subcontractors;
(e) Provision for technical and administrative inspections;
(f) Licensee responsibilities, such as those for providing unhindered[1] access and necessary information to the regulatory body staff and making its staff available for interviews and discussion;
(g) Reporting requirements (e.g. those for non-compliances and events).

The regulations need to be in place prior to the regulated activity in phase 3. Specific regulations that may influence the bidding process should be in place at the end of phase 2.

3.3. OTHER FACTORS

3.3.1. Licensee as the focus of the regulatory oversight programme

In IAEA Safety Standards Series No. SF-1, Fundamental Safety Principles [15], the first principle states that the licensee has the primary responsibility for safety, which cannot be delegated. The licensee is responsible for all activities, including those performed by contractors, vendors and suppliers. The licensee should ensure that the management system requirements, including quality assurance and safety culture, are implemented through the supply chain. The ultimate operating organization, along with the construction entity, should continuously monitor the construction of safety related SSCs, both at the site and at manufacturing facilities, to ensure that the construction is in accordance with the approved design (para. 2.78 of SSG-16 [14]).

[1] Unhindered means the licensee cannot impede the inspector’s access at any time. However, operational conditions that have safety concerns should be respected by the inspector, which may slow the inspector’s access. Security restrictions would also necessitate an inspector’s ‘need to know’ to gain access to security information.

The relationship between the licensee and the regulatory body should be open and based on professionalism. The regulatory body should perform its functions (e.g. verification through inspection) with an inquiring attitude. Hence, the regulatory inspection programme should verify effective implementation of a licensee's management system at all phases of a facility's life cycle, with a particular focus on the oversight of contractors involved in design, construction, commissioning and maintenance activities. The regulatory body should focus on all activities important to safety. It provides independent verification that requirements have been met, with the emphasis on making the licensee aware of its primary responsibility for safety during siting, design, construction, commissioning and transition to the operation phase of the facility.

For each project, it is also important to consider arrangements between the licensee, the vendor and other organizations involved and their experience performing in their respective roles. Experience can be used from previous projects of similar scope to inform the regulatory inspection programme.

The regulatory role in inspections of vendors and supply chains should also focus on verifying effective implementation of the vendors' management system. The regulatory framework should contain provisions for contractors and suppliers to report defects, and regulatory oversight should address these provisions.

3.3.2. Relationship between review and assessment and regulatory inspections

The regulatory processes of review and assessment and inspections have close interactions with one another. The output of one process is used as input for the other.

Generally, the review and assessment process occurs before the inspection process and the outcome of review and assessment — that is, the licence is verified during the inspection. However, the outcome of an inspection process may also be fed to the review and assessment process. This is especially the case for the progression of formal authorization or the use of hold points during construction and commissioning. In any case, the outcome of these processes may have a direct impact on the authorization process, as the overall objective of all regulatory processes is to verify compliance with the issued authorizations and documents that form the basis for the authorization, such as the safety analysis report. Figure 1 shows the interaction of these regulatory processes. Detailed information on authorization and documents that form the basis for authorization are provided in IAEA Safety Standards Series No. SSG-12 [6].

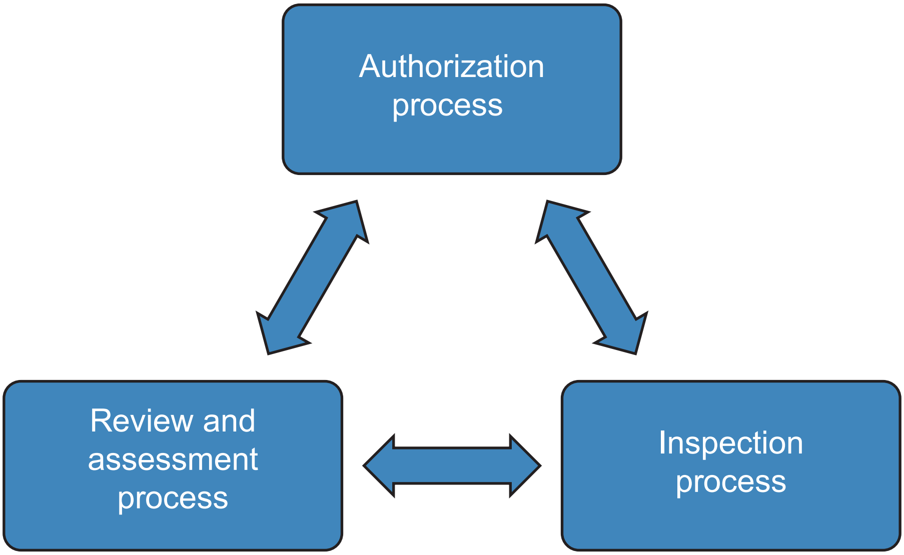

FIG. 1. Interaction of regulatory processes.

If separate hold points are, or will be, established as part of the licensing process for certain steps in design, manufacturing, construction and commissioning for the purpose of verifying the results of work and the preparedness to proceed, then the regulatory inspection programme will need to take these into account (para. 2.68 of SSG-16 [14]).

3.3.3. Cooperation with other regulatory bodies

Requirement 14 of IAEA Safety Standards Series No. GSR Part 1 [1] requires that: "The government shall fulfil its respective international obligations […] and promote international cooperation to enhance safety globally." Explaining further, GSR Part 1 [1] states in para. 3.2(e) that the features of global safety regime include, among others: "Multilateral and bilateral cooperation that enhances safety by means of harmonized approaches as well as increased quality and effectiveness of safety reviews and inspections."

At the State level, the government should establish mechanisms for bilateral and multilateral cooperation with other States to enhance safety globally and to provide a platform to nuclear regulatory bodies to enter into agreements and contracts or through other modes of collaboration with regulatory bodies of other States.

The regulatory body may look to establishing cooperation and collaboration with the regulatory bodies of States operating similar or reference plants, particularly the regulatory body of the vendor State, to learn from their experiences and practices. Various formal mechanisms, such as a memorandum of understanding, agreements and protocols, may be utilized for establishing such cooperation and collaboration.

The areas for cooperation and collaboration may include training regulatory body staff, providing support in the development of an inspection documentation system and providing consultancy services during inspections. Some regulatory bodies enter into agreement with the regulatory body of the vendor State to perform or to provide support in conducting inspections of vendor and equipment manufacturing in the vendor State. In such cases, arrangements should be made to ensure that the overall responsibility for inspections, reporting and decision making lies with the regulatory body of the State where the plant is to be installed and operated, and the responsibility cannot be delegated to the regulatory body of a vendor State.

4. DEVELOPMENT OF AN INSPECTION PROGRAMME

4.1. GENERAL FACTORS FOR DEVELOPING AN INSPECTION PROGRAMME

Some factors that may influence the scope and depth of the regulatory inspection are discussed in the following sections.

4.1.1. Regulatory body attributes that influence the inspection programme

The maturity of the regulatory body, its size, resources and availability of an existing inspection programme play important roles in developing the scope and depth of the programme.

The regulatory body may also consider the applicability of regulatory inspection programmes of other States that would minimize the time needed to develop its own programme. The programme being implemented needs to be consistent with the adoptee's legal framework and address any differences in requirements and authority granted. The adoptee State should have a strong ongoing working relationship with the 'donor' State to understand the background knowledge of the existing inspection programme and to receive experience feedback that will help in the revision of, and modifications to, the inspection programme. The type of licensing process and authorization will also be a factor in developing the inspection programme.

4.1.2. General attributes of the regulatory inspection programme

The inspection programme and implementing procedures necessary to conduct inspection activities should be established under the regulatory body's management system. The inspection programme should address:

(a) Inspection policy, objective and scope of the programme;
(b) Responsibilities and interfaces for the implementation of the programme;
(c) Interface and communication arrangements made with the licensee;
(d) Documentation system for the inspections, resource management, inspectors' qualifications, inspection methodology and techniques to be employed;
(e) Inspection planning considerations;
(f) Guidance for inspectors (as appropriate, i.e. guidance for inspection preparation, behaviour and precautions);
(g) Conduct and follow-up of inspections (including inspection closure and reporting inspection findings);
(h) Collection of feedback on the programme, assessment and evaluation of the effectiveness of the inspection programme.

Depending on the strategy, the regulatory body may establish one programme covering all facilities and phases or separate programmes for various phases and facilities.

Paragraph 4.53 of IAEA Safety Standards Series No. GSR Part 1 [1] identifies a number of aspects that the regulatory body is required to consider in conducting inspections:

— SSCs and materials important to safety;
— Management systems;
— Liaison with contractors and other service providers;
— Staff competency;
— Safety culture;
— Liaison with the relevant organization for joint inspections, where necessary.

IAEA Safety Standards Series No. GS-G-1.3 [2] provides general guidance related to the regulatory body's role in developing the programme considering the aspects defined in GSR Part 1 [1]. Specific responsibilities of the regulatory body for inspections include (para. 3.2 of GS-G-1.3 [2]):

(a) Conducting planned inspections at all stages of the authorization process;
(b) Carrying out reactive inspections, if appropriate, in response to events, incidents or accidents;
(c) Identifying and recommending necessary changes to the safety requirements approved by the regulatory body, specified in the authorization or contained in the regulations;
(d) Preparing reports to document inspection activities and findings of the regulatory body;
(e) Verifying the operator's compliance with regulatory requirements and otherwise confirming continuous adherence to safety objectives;
(f) Ensuring that the operator has adequate, comprehensive and up to date information on the status of the facility and for demonstrating its safety, and a procedure to maintain this information;
(g) Verifying that corrective actions have been undertaken by the operator to resolve safety issues identified previously;
(h) Tracking recurrent problems and non-compliance;
(i) Developing such procedures and directives as may be necessary for the effective conduct and administration of the inspection programme;
(j) Determining and recommending suitable corrective actions when non-conformance with requirements is identified.

Regulatory inspection programmes should be comprehensive and developed within the overall regulatory strategy. These programmes should be thorough enough to provide a high level of confidence that operators are in compliance with the regulatory requirements and are identifying and solving all actual and potential problems to ensure safety.

The regulatory inspection programme should include a review of the licensee's ability to address non-conformances (corrective actions) in licensing phases and when transitioning between phases (see IAEA-TECDOC-1335, Configuration Management in Nuclear Power Plants [16]). It is important to consider that the regulatory body's attention to major inspection areas does not begin and end at a single stage but continues with varying degrees of emphasis throughout the lifetime of the facility.

In developing the regulatory inspection programme, the regulatory body should coordinate with the licensee to obtain information on the schedule of the licensee's activities and to plan the inspections accordingly, so that the regulatory resource is available to inspect activities as they occur. If necessary, the regulatory body may use different regulatory measures — such as establishing hold points — to ensure there is sufficient time to inspect key activities before the licensee may proceed with the next phase of work.

To allow the regulatory body to plan regulatory inspection activities efficiently and to prioritize the resources needed for those activities, the licensee should be required to submit its schedule and periodic updates of construction, commissioning, inspection and testing, among others, to the regulatory body. In some Member States, the regulatory body attaches conditions to an authorization in which requirements are mentioned for the submission of the licensee's schedule of agreed or required SSCs. Furthermore, the regulatory body should inform the licensee of its inspection plan, including any hold and witness points, in advance, so that the licensee can incorporate these activities into its general schedule. Communication channels between the regulatory body and the licensee should be established and formalized and include details for timely notifications and confirmations.

For example, the regulatory bodies of some Member States require the licensee to submit notification and information pertaining to certain inspections a few weeks or days ahead of the inspection date. In some Member States, the regulatory inspections could be partly delegated to other accredited inspection organizations for which information is required well in advance. Past experience has shown that significant efficiencies can be realized by both parties when the regulatory body has the ability to observe the licensee's planning in real-time (i.e. access to the same software). For example, the regulatory body can use the licensee's schedule to map out the inspection programme and efficiently plan inspection activities.

4.2. ORGANIZATION FOR INSPECTION MANAGEMENT

Establishing an effective organizational framework is the first step by a regulatory body towards the development and implementation of an inspection programme. Roles, responsibilities and authority of various organizations and various units of the regulatory body, including arrangements for interfaces and communications, should be clearly established. Consideration should be given to assigning managerial responsibility to a single individual or organizational unit.

The process for exercising the legal authority delegated to the inspectors should be defined. In case the regulatory body hires outside consultants during the implementation of the inspection programme, roles and responsibilities of the consultants, including confidentiality undertaking, should be established. Arrangements for their access to the facility and information should be agreed with the licensee, and responsibility and process for evaluation of the work of consultants by regulatory body staff should be defined in advance. If legal provisions identify other organizations, such as authorized inspection agencies, then they should be consulted during the development and implementation of inspection programmes.

4.3. KEY PROCESSES IN A REGULATORY INSPECTION PROGRAMME

The regulatory body should establish an inspection programme, process description and procedures as part of its management system, in advance of the receipt of any licence application. This infrastructure will facilitate future development of the specific regulatory inspection programme, which can be finalized upon receiving the application. This infrastructure is necessary for a regulatory body to document the history of regulatory findings and decisions and demonstrate that activities were conducted in a systematic and auditable manner.

The regulatory inspection programme should be in place prior to the start of the licensed activity. To achieve this, the development of the programme should be done in parallel with the development of the licensing basis. It should be completed and communicated to the licensee, with sufficient lead time so the licensee can prepare itself for the inspection activities. The inspection programme should be reviewed regularly and revised, if needed, as experience or knowledge evolves.

The regulatory programme should promote identification and resolution of regulatory issues by the licensee, such as a corrective action programme.

4.3.1. Developing an inspection programme

The regulatory body's management system as applied to the inspection process should ensure that inspection activities are based on concepts and review criteria applied by the regulatory body in assessing the application for an authorization. The review criteria can also be applied to regulatory inspection activities of long lead time equipment and programmes[2]. Where submissions for the application demonstrated compliance with a specific standard, the inspection activity would verify compliance against the standard used for the review. The method for grouping inspection activities should also correlate to the method used for organizing the regulatory review and assessment of a licence application.

The planning of the inspection programme will also be influenced by the geographical location of the regulatory body in relation to the facility to be inspected. In particular, it will depend on whether inspectors are permanently posted at the facility site (resident inspectors) during one or more stages of the facility's lifetime.

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[2] An example of a long lead programme is the certified or authorized operator and maintainer training programme which typically has to begin well in advance of the construction licence application in order to have sufficient number of trained staff available for commissioning and operation activities.

The organizational structure of the regulatory inspection programme should be clearly defined — that is, the organization focusing on programmatic elements and the organization, or organizations, focusing on implementation. The structure will be largely dependent on the number of sites being regulated. Typically, headquarters emphasis is on programmatic areas, while the field office focuses on implementation. In a plan, the role of the regulators' head office could be to manage the programme and non-site-specific inspections (e.g. suppliers), and oversee communications with licensees and relevant stakeholders (e.g. the public). In addition, the programme identifies the communications between the programmatic organization and the implementing organizations (e.g. regulatory body's field office and technical support organization). These communications are in the context of providing necessary expertise as requested by the site or regional office for conducting inspections in specialized areas. The implementation office provides feedback on the inspection procedures to ensure that the plan can be achieved in a realistic manner. In addition, the results of the inspections should be representative of the regulatory body and not individual organizations. The following is a typical example of the division of responsibilities between the head office and the site office of the regulatory body. The responsibilities of the head office include, but are not limited to:

(a) Corporate oversight of the inspection programme implementation and effectiveness;
(b) Development and maintenance of inspection policy and programme;
(c) Establishing roles and responsibilities of site inspectors;
(d) Management of activities to coordinate the inspection programme with the review and assessment process;
(e) Assessment and evaluation of the inspection outcome for feedback to other regulatory processes, such as development of regulations and authorization;
(f) Dissemination of inspection information within the organization and sharing with other organizations and interested parties, as deemed appropriate;
(g) Providing feedback for the development and updating of the inspection plan;
(h) Management of inspection for manufacturing activities.

The responsibilities of the site or regional office include, but are not limited to:

— Management of inspections at facility sites (e.g. development and implementation of site inspection plan, procedures, guidelines and checklists);
— Determining and allocating resources for inspections;

— Determining additional support needed in implementation of the inspection programme and taking appropriate steps for arranging such resources (i.e. from the headquarters or technical support organization);
— Conducting site inspections and follow-up inspections;
— Ensuring that appropriate actions are taken by the licensee on the deficiencies indicated in inspection reports for safety improvements;
— Reporting inspection results to the headquarters;
— Maintaining inspection records, including follow-up and closure.

Communications between the licensee, regulatory body — internal and external — and authorized parties, as appropriate, should be formally defined and agreed prior to the start of the respective activities.

The scope of regulatory inspections should include the licensee's management system as well as technical areas covering activities of the authorization holder and contracted and subcontracted activities. The regulatory inspection should also cover cross-cutting areas (e.g. safety culture and human factors) and encapsulate the area of safeguard and security.

The inspection policy and strategy should include provisions for planned as well as reactive inspections. Since the regulatory body cannot, and should not, inspect all of the licensee's activities, it should use a systematic approach for sampling inspection activities (intelligent sampling). The regulatory body may perform announced and unannounced inspections.

4.3.2. Determining types of inspection

The inspection should employ a balanced approach between: monitoring and direct observation of activities and facilities; discussions and interviews with personnel of the licensee and its contractor; and examination of procedures, records and documentation. In addition, the regulatory body may also consider requesting the licensee to perform independent tests and measurements. Some regulatory agencies have the authority to perform their own independent tests. These methods are detailed in Methods of Inspection, paras 4.16–4.28 in IAEA Safety Standards Series No. GS-G-1.3 [2]. This process should start with the performance objectives and criteria for each inspection activity. This would assist in identifying the most suitable inspection method. In a performance based regulatory approach, performance objectives and criteria are used as inputs to the inspection types to be used. A prescriptive based regulatory approach may prescribe specific inspection types to be used under specific circumstances. The frequency of the activity should also be covered. A graded approach, based on the importance to safety and risk associated with the activity (e.g. safety classification and risk informed), should be used to optimize the regulatory inspection programme. Further information on the application of a graded approach is provided in Section 6.2.

4.3.3. Developing guidelines for inspections

The inspection plan should contain a framework for providing a consistent set of procedures. In some cases, the procedures may not be more than checklists, but in other cases more details would be required to tie the inspection tasks to the acceptance criteria. Inspection procedures and checklists should provide guidance on surveillance of activities beyond the technical aspects such as housekeeping, industrial hazards, material controls, identification, human factors, inspectors' behaviour and communication manners. Generally, the more precise the inspections, the more specific (or even prescriptive) the procedures need to be. In some Member States, these procedures are also provided to the licensee well before the execution of the inspection. This will help in the compliance of regulatory requirements and acceptance criteria.

4.3.4. Determining inspection resources

The determination of inspection resources is mainly influenced by the State specific legal framework and maturity of the nuclear programme. Since the amount of required human resources depends also on the project schedule of the nuclear facility, a specific estimation of inspection resources has to be done. The determination of the inspection resources should consider the following:

— Identification of inspection needs, scope and depth;
— Human resource development (e.g. number, skills and experience);
— Developing the inspection programme, the documentation system, plans, schedules, procedures, guidelines and checklists;
— Implementing the inspection programme, including follow-up and closure;
— Assessment of inspection programme effectiveness.

The performance objectives and criteria for each inspection activity should be used in conjunction with recognized project management tools and principles to identify the skills necessary, duration and size of team. The resource requirements are compared with the available resources and competences to determine the need for external support. If external support is used, the following should be addressed:

— Provide for necessary pre-qualification processes when a bidding process is to be used;

— Account for necessary lead times to establish contracts or agreements;
— Include the means by which to integrate the results of external consultants' findings from inspection into a regulatory conclusion or finding.

The size and specific competences of the workforce and available resources will influence the extent of obtaining external support to perform regulatory oversight activities. Types of external support are technical support organizations, inspection organizations and third party organizations. They are used for staff augmentation and specialized skills. The structure and scope of these organizations vary between Member States. The scope of activities, responsibilities and reporting should be controlled within the regulatory body's management system and needs to be prescribed by the regulatory inspection programme. Conflict of interest (e.g. external support organizations supporting simultaneously licensee and regulatory body) and independence of the external support need to be addressed.

The regulatory body needs to allow sufficient time to enable contractual arrangements to be put in place to define roles and responsibilities and the scope of support. IAEA Safety Standards Series No. GSG-4, Use of External Experts by the Regulatory Body [17], provides additional guidance on the use of external support to the regulatory body.

There are specific considerations that influence the inspection programme that is to be developed, such as:

— Number and type of new facilities (e.g. fuel cycle facility and nuclear power plant);
— Different designs (technology) to be built;
— Availability of detail design;
— Experience with the facilities (e.g. availability of reference plant);
— Organizational structure of the licensee.

These considerations are not mutually exclusive — a State may have several projects going on concurrently. This will not automatically force the regulatory body to have independent inspection teams. The regulatory body would have to plan and to coordinate efficiently with the projects so technical experts can cover multiple projects. If the State elects to construct multiple designs, then the regulatory body would likely have to customize some of the inspection procedures to tailor them, as necessary, to the respective design.

4.3.5. Management of inspection records

The filing system for records should comply with a recognized standard and correlate to the methods for grouping inspection activities and organizing the assessment of a licence application. The documentation system is part of the management and needs to be implemented for the life cycle of the facility.

4.3.6. Reporting inspection findings and determining regulatory actions

The process should point to procedures for analysing inspection results, writing reports and determining whether regulatory action is required. The process and procedures should also include methods by which results can be communicated in a timely manner to internal and external stakeholders (e.g. licensees, other agencies, other regulatory bodies, other departments with a technical interest, inspectors at similar facilities and members of the public).

4.3.7. Follow-up and tracking of regulatory actions

Records of all outstanding regulatory issues should be maintained to verify whether the necessary actions have been completed. This should be done in a systematic manner to allow auditing at any time. This process should account for any actions that are generated as a result of the following:

(a) Outstanding commitments by the licensee coming from the licensing process. For example, in some cases the licensee may not have certain key processes in place at the time of the licence application. However, the licence may be granted on the condition the licensee can demonstrate that the commitment(s) have been met. When a commitment is declared closed by a licensee, the regulatory body should be able to verify this.
(b) Findings from inspections, once analysed, may result in one or more actions that require follow-up by the licensee or regulatory body. This may result in further follow-up actions to be tracked.
(c) Operational experience information from other installations may result in the regulatory body imposing actions on the licensee which would need to be tracked.

4.3.8. Qualification and training of inspectors

Formal programmes for qualification and training of regulatory inspectors, combining classroom and on-the-job training, should be established and implemented. The regulatory body may consider Safety Reports Series No. 79, Managing Regulatory Body Competence [18], for training its staff. The objective of inspector training programmes is to ensure that the necessary knowledge, skills and attitudes are developed in the inspectors to implement the inspection programme successfully. The process should be consistent with the systematic approach to training (SAT), including an approval as a qualified inspector.

In addition, the regulatory body may consider mentoring programmes of, for example, vendor States' regulatory bodies. The regulatory body should ensure the inspectors' knowledge based on specific technical skills as well as, for instance, know-how in related fields such as management systems (holistic know-how). Another key factor which enhances the competency of the inspector and increases the effectiveness of the regulatory inspection is the good understanding of the design of the plant by the inspector or regulatory body.

4.3.9. Establishing acceptance criteria

The regulatory body should establish appropriate processes to ensure that the acceptance criteria are drawn from the licensing basis as defined in IAEA Safety Glossary: Terminology Used in Nuclear Safety and Radiation Protection (2007 Edition) [19]. These may include technical considerations, human factors, health and safety, procedural use and adherence, standards imposed by the licensee on its own organization (such as procedures for engineering change control, work control, documentation management and housekeeping).

4.3.10. Input for the enforcement process

The inspection programme should establish a process to link inspection outcomes with the enforcement process. The process should establish clear criteria to facilitate decision on whether an enforcement action is necessary and the level of the action.

4.3.11. Regulatory body's inspection programme: Self-assessment

Paragraph 6.2 of IAEA Safety Standards Series No. GS-R-3 [7] requires that: "Senior management and management at all other levels in the organization shall carry out self-assessment to evaluate the performance of work and the improvement of the safety culture". Self-assessment of the inspection programme should be conducted regularly (e.g. annually) to identify issues having an effect on the programme effectiveness, so that these can be corrected and continually improved. Self-assessment should also cover areas such as inspectors' knowledge and conduct, motivation, morale, safety culture, communication effectiveness and improvement in licensees' performance. The regulatory body may develop performance indicators as well as performance objectives and criteria, and assess the inspection programme with respect to these indicators, objectives and criteria.

4.3.12. Regulatory body's inspection programme: Independent assessment

IAEA Safety Standards Series No. GS-R-3 [7] also requires the use of independent assessment to — among other purposes — evaluate the effectiveness of processes in meeting and fulfilling goals, strategies, plans and objectives. This function may even be performed by an external organization. In this regard, peer review, such as the IAEA Integrated Regulatory Review Service (IRRS), is a very useful tool for an objective evaluation of the regulatory body against international safety standards. In addition, the regulatory body can use the peer review process as part of continuous improvement to understand different approaches and their possible benefits. The peer review process is particularly useful when adopting another regulatory body's programme.

5. INSPECTION AREAS DURING DIFFERENT LICENSING STAGES

Inspection Areas for Nuclear Facilities, an appendix to IAEA Safety Standards Series No. GS-G-1.3 [2], provides guidance on inspection areas that should receive close attention in the construction stage, primarily to ensure the licensee is detecting and correcting what could become latent[3] as-built flaws in the facility. Inspections during siting, design, construction and commissioning are important because of the difficulty of detecting and correcting deficiencies in these areas once fissile and radioactive material has been brought to the site and the facility enters active commissioning, including the mixing and placing of concrete and the installation of safety related components.

As discussed in IAEA Safety Standards Series No. SSG-12 [6], each step may be divided into substeps or merged depending on the specific State licensing process. It is important to recognize that the inspection programme will be directly influenced by the licensing steps of individual States. The following sections try to provide some practices related to the inspection of the pre-operating licence steps.

[3] An inherent weakness in SSC which, if not detected prior to installation and commissioning, may be aggravated by use, leading to an unanticipated failure.

5.1. SITING AND SITE PREPARATION

The siting step of the licensing process of the nuclear power plant project presents several challenges. As stated in SSG-12 [6], there are two main steps: siting, followed by site evaluation. The siting process involves site survey, selection and assessment. This process is not a regulated process. As there is no application for a licence or site permit during siting, the regulatory body is not formally involved in a licensing or oversight role. The prospective owner may choose to engage the technical staff of the regulatory body for site visits during the assessment or other site related activities; however, this would not constitute any regulatory action for the licensing review process.

Most of the site characterization work occurs within the context of the applicant performing the site evaluation in preparation for a site licence or possibly as part of the construction licence. Relevant areas of the applicant's management system, including quality assurance measures, should be implemented for all activities that may influence safety or the derivation of parameters for the design basis for the site — see para. 6.6 of IAEA Safety Standards Series No. NS-R-3, Site Evaluation for Nuclear Installations [20]. The regulatory body is involved in the decision of the acceptability of the selected site as part of defined licensing process.

If the regulatory body were interested in observing any of these activities or observing how quality assurance measures were applied during this work, it would need to coordinate with the applicant in advance of any licensing reviews to obtain information about the siting activities and the schedule, so that regulatory inspections could be performed. Regarding site preparation, it is helpful if the regulatory body has defined the activities that can be undertaken prior to receipt of any authorization.

It is important to note that inspections during siting and site preparation may provide an indication, very early in a project, that the licensee is performing adequate oversight of licensed activities before the licensee takes on a significantly more complex phase, such as construction. For example, because during siting and site preparation, the licensee oversees a smaller number of contractors than during construction, there is an opportunity to observe the licensee's management system for oversight and allow the licensee to optimize its processes.

5.2. DESIGN

The development of a design of a nuclear power plant is a long process that starts in advance and independently of licensing activities and evolves throughout the life of the facility. Typically, a preliminary safety analysis report is submitted for regulatory review for the construction licence application review. Depending on the State's licensing steps, design information may be presented to the regulatory body as part of the site approval process — usually in the form of a generic (non-site-specific) conceptual design. In preparation for the construction licence, the applicant has to verify the adequacy of design parameters and site specific data in relation to safety criteria of the specified design basis. Following the issuance of a construction licence, the design will continue to evolve through commissioning and beyond, but should be subject to change control processes. Accordingly, the regulatory body should plan its inspection programme to cover the entire duration. The regulatory body should periodically perform inspections to verify effectiveness of the overall design management system of the licensee and its design organization, including the use of independent verification of the design and modifications. During the construction and commissioning stages, a number of field changes take place and the inspection programme should have provisions for inspections for verification of the effectiveness of the configuration management programme. The regulatory body may also conduct audits of design input, analysis and output documents. Major areas of attention during regulatory inspections include verification that:

— The design has met commitments made during the licensing reviews.
— Verified and validated tools have been employed.
— The results are correctly translated into the output documents.
— Design control measures are effective.

5.3. CONSTRUCTION

Construction of a nuclear power plant is a very complex endeavour. Various services, such as the licensee, vendor, designer and large number of contractors and subcontractors, are involved, and the effective coordination of their activities has a direct effect on the quality and performance of the plant and its SSCs. The inspection programme of the regulatory body should, therefore, be very carefully planned to focus on safety critical processes, items, activities, supply chain management and interfaces. The inspection programme may have provisions for the selection of hold, witness and record points as well as general site surveillance. The main areas of focus of the regulatory body's inspection programme should include:

Administrative areas

(a) Management system of the licensee, vendor, contractors, subcontractors and supply chain management;
(b) Readiness of contractors and subcontractors before starting the work (e.g. construction contractor before starting construction of structures important to safety or manufacturer of reactor pressure vessel before starting manufacturing activities);
(c) Transfer of responsibility of SSCs from one organization to another organization (e.g. transfer of structures from construction contractor to installation contractor or to commissioning contractor, or from equipment manufacturer to installation subcontractor), focusing on the effectiveness of the licensee's control during such transfer of responsibilities;
(d) Housekeeping;
(e) Qualification and training of contractor and subcontractor staff;
(f) Records.

Technical areas

(a) Site work, including authorized excavation and earthwork;
(b) Construction of civil structures important to plant safety (particularly the containment building), including reinforcement, concreting, prestressing, tests and examinations;
(c) Manufacturing and installation of safety class 1 and 2 mechanical equipment and systems (especially reactor coolant pressure boundary, reactor internals and engineered safety features), including forging, heat treatment, welding, destructive and non-destructive tests, functional and qualification tests, performance tests and pre-service inspections;
(d) Safety class electrical and instrumentation and control (I&C) equipment and systems (particularly reactor protection systems, engineered safety features actuation systems and emergency power supply systems), qualification tests (seismic and environmental), type tests and functional tests;
(e) Areas which become inaccessible after construction.

The regulatory body should also consider inspections that might need to be performed if the project is delayed for an extended period of time. For example, human resources and the state of SSCs with the risk that possible deterioration could result in a safety concern if construction were to continue.

5.4. COMMISSIONING

Activities associated with commissioning normally begin before the construction is completed, starting with single equipment functional tests and leading to full system integration tests with the reactor at full power. Commissioning is the final step before entering into the commercial operation phase of the plant; hence, its importance is manifold. The regulatory body conducts reviews and assessments to determine whether the commissioning programme is complete and includes the testing of all the SSCs important to safety to demonstrate that the nuclear power plant can operate safely in all modes for which it has been designed to operate. The inspection programme verifies that the commissioning activities are performed in accordance with the commissioning programme. The inspection programme for commissioning may include provisions for mandatory hold point inspections (i.e. hydrostatic tests of the reactor coolant system, containment/confinement integrity and leaktightness tests, and initial fuel loading and initial criticality) and provisions for witnessing other important tests.

During the commissioning phase, certain other activities also start, such as:

- Implementation of pre-service inspection programmes;
- Surveillance and maintenance programmes of commissioned equipment and systems;
- Radiation protection programmes;
- Environmental monitoring programmes;
- Emergency preparedness programmes.

The inspection programme for commissioning activities should cover these licensee activities. Because commissioning involves coordination between a number of organizations and complex interface arrangements, the regulatory body should focus on the effectiveness of the management system of these organizations. The main area of the inspection programme of the regulatory body may include:

Administrative areas

(a) Management system of the licensee, vendor, designer, contractors and subcontractors;
(b) Readiness of the licensee, vendor and commissioning organization (before the start of commissioning activities);
(c) Detailed interface procedures;

(d) Maintenance and surveillance procedures for commissioned items and systems;
(e) Operating procedures, including system operating procedures and procedures for normal, abnormal and emergency operation, and technical specifications;
(f) Transfer of responsibility as SSCs pass through construction to commissioning and then finally to operation under the operating organization;
(g) Exercises of emergency and physical protection plans, and fire protection;
(h) Radiation protection and environmental monitoring;
(i) Housekeeping;
(j) Records.

Commissioning tests

(a) The inspections of commissioning tests include the following main activities:
   (i) Examination of documented procedures to verify compliance with review, clear acceptance criteria and assessment conclusions;
   (ii) Review of the implementation of these procedures;
   (iii) Direct observation of the performance of certain key pre-operational tests;
   (iv) Examination of the results of selected tests.
(b) The inspection should focus on three broad areas of licensee’s activities:
   (i) Tests before fuel load:
      — Integrity of reactor coolant pressure boundary (e.g. hydrostatic and leakage tests);
      — Containment integrity and leaktightness;
      — Safety systems (e.g. engineered safety features and shutdown systems);
      — Reactor protection and engineered safety features actuation systems;
      — Susceptibility of structures and components to vibration;
      — Emergency power systems;
      — Communication capabilities;
      — Ventilation systems;
      — Fire protection systems;
      — Integrated cold and hot functional tests.

(ii) Initial fuel load and criticality:
   — Preparation for and actual loading of the nuclear fuel;
   — Fuel loading procedures;
   — Approach to criticality;
   — Core physics tests.

(iii) Power ascension testing.

This inspection area encompasses licensee's activities performed after achieving initial criticality, particularly the tests to demonstrate as far as possible that:

— The plant is being operated in accordance with the descriptions given in the safety analysis report (SAR).
— Systems respond to malfunctions in accordance with the claims made in the SAR.

5.5. INSPECTION OF VENDORS

In addition to inspections during different licensing stages, it is important to include inspections of vendors that may occur during each phase or stage of licensing. The regulatory body may choose to directly inspect vendor related activities (vendor inspections). However, vendor inspections performed by the regulatory body do not relieve the licensee of its responsibility to perform oversight of its vendors. A regulatory inspection programme should pay particular attention to the licensee's oversight of the vendor and the inspection of vendors supplying equipment and services to the licensee.

A vendor inspection programme should be implemented during all phases and should focus on the vendor's management system and associated quality assurance programme. The regulatory body should establish a methodology for the selection and periodicity of activities to be inspected.

International forums, such as the OECD Nuclear Energy Agency (NEA) Multinational Design Evaluation Programme (MDEP), have been created to develop innovative approaches to leverage the resources and knowledge of the national regulatory authorities which are currently, or will be, tasked with the review of new nuclear power plant designs. One of the MDEP working groups is the Vendor Inspection Co-operation Working Group (VICWG). This group encourages efficiency by coordinating vendor inspection activities between participating Member States.

6. SPECIFIC ELEMENTS OF INTEREST FOR INSPECTION PROGRAMMES

6.1. INSPECTION OF LICENSEES' MANAGEMENT SYSTEMS

One of the most important areas of the regulatory body's inspection programme is the inspection of the licensee's management system — in particular, oversight over contractors. Such inspections are conducted to verify the effectiveness of the licensee's management system and should be conducted both regularly and throughout the life cycle of the facility. The scope of such inspections may be expanded to the management system of vendors and suppliers with the purpose of determining the effectiveness of the licensee's management system control on their activities. Some of these inspections should cover the entire management system, whereas other such inspections may cover some parts of the management system. While conducting the inspections of vendors and suppliers, the regulatory body should recognize that the practices among different contractors to implement the management system — that is, contractual requirements specifying the level of reporting for non-conformance and corrective actions — may be unique and handled differently. However, the regulatory body's inspections should verify that not only are the individual organizations in compliance with requirements, but that the overall programme of the licensee is also in compliance.

The frequency of inspections covering the entire management system may vary from one to three years, depending on the licensing stage (e.g. during commissioning, the frequency may increase because comparatively the time span is less time than during other stages). The first comprehensive inspection of a licensee's management system processes in action should take place no later than one year into the activities under the first licence. This provides the licensee the opportunity to resolve process issues and demonstrate how corrective action feedback processes are functioning. In addition, the inspection programme should have provisions for more focused inspections of an aspect of the management system at a frequency commensurate with the importance of that aspect and the licensee's history of past performance. During these inspections, the regulatory body may select some part of the management system such as:

— Management responsibility;
— Management system documentation;
— Resource management;
— Measurement, assessment and monitoring;
— Management system processes.

It is emphasized that the licensee's responsibilities for oversight are independent of the contract type — that is, a turnkey project does not relieve the licensee of its oversight responsibility.

6.2. STRUCTURES, SYSTEMS AND COMPONENTS IMPORTANT TO SAFETY AND CONSIDERATIONS FOR APPLICATION OF THE GRADED APPROACH

SSCs important to safety are one of the main focus areas of the inspection programme of the regulatory body. However, the inspection programme may not give the same weighting to all SSCs, as it would require many resources and the process would also be inefficient. It should be noted that Requirement 29 of IAEA Safety Standards Series No. GSR Part 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." Furthermore, the IAEA Safety Glossary: Terminology Used in Nuclear Safety and Radiation Protection (2007 Edition) [19] definition of graded approach refers to the application of the system of control — in this case inspection activities — to be applied is commensurate, to the extent practicable, with the likelihood and possible consequences of, and the level of risk associated with, a loss of control (e.g. equipment failure).

The extent to which inspection is performed in the regulatory process will depend upon the potential magnitude and nature of the hazard associated with the facility or activity. Activities and processes of higher safety importance or higher risk require more attention and in-depth inspection by the regulatory body. Application of the graded approach enables valuable inspection resources and attention to be targeted at the processes and activities of higher safety significance. This can result in minimizing inspection costs while improving safety. Additional information on the graded approach is given in IAEA Safety Standards Series No. SSG-12 [6] and No. GS-G-3.1 [8]. Although there is no definitive means for implementation, the following subsections provide some means of implementation related to defining the scope and level of inspection of SSCs.

6.2.1. Taking into account safety classifications

One of the approaches is to select the SSCs based on safety classification — the higher the safety classification, the more attention it is given in the inspection programme. Guidance on the safety classification of SSCs in nuclear power plants is under preparation and provides four safety categories as well as the process used to classify SSCs. By its very nature, this classification process represents the underlying design requirements which can be verified through inspection, and the functional groups allow the regulatory body to define the scope and number of inspections to be performed.

6.2.2. Taking into account probabilistic safety assessments

The probabilistic safety assessment (PSA) results from the licensing process may be used as an input for the inspection programme by identifying the most risk significant SSCs. PSA results can also be used to define the frequency of the safety class components — that is, the frequency of the regulatory inspections may be increased for components which contribute more to risk. Regulatory inspection mainly focuses on the areas which fall under the category of important to safety. However, PSA insights can be used to identify non-safety components for regulatory inspection that contribute significantly to the risk or core damage frequency.

6.2.3. Other inspection attributes

The selection process may also include some construction activities that have a low risk and thus may be arbitrarily screened out of the inspection process if risk is the only aspect evaluated when determining the inspection scope and sample size. Other attributes may be used to determine the inspection scope and sample size, such as:

- Limited opportunity to verify by other means;
- Complexity of the construction activity;
- Licensee’s experience in the construction activity;
- Qualification of special construction processes;
- The need for, and extent of, inspection and test plans;
- The level of in-process controls and the need for hold or witness points;
- First of a kind activities;
- Risks associated with construction activities.

Additionally, the regulatory body should ensure that it selects a broad enough scope of inspection activities so that inspection results give an assessment of licensee’s performance for the entire construction project and are not limited to only safety significant construction activities. Examples include:

- Reinforcement bar placement: limited accessibility following the pouring of concrete;

— Operator training programme: timeliness to have competent plant operation personnel in time for plant operation.

6.3. TAKING INTO ACCOUNT LICENSEES' PERFORMANCE

The regulatory body may chart the licensee's performance based on the outcome of review and assessment activities and inspection results. The inspection programme may be optimized or modified based on the trend. Inspection efforts may be reduced in areas showing continuous improvement whereas inspection efforts and depth may be enhanced in areas showing declining trends.

6.4. USE OF DOMESTIC AND INTERNATIONAL EXPERIENCES

States embarking on a nuclear power programme (embarking States) may model their regulatory inspection programmes based on the regulatory inspection programmes of vendor States. In pursuing this approach, the embarking States may pursue a memorandum of understanding with relevant regulatory bodies for training, qualifications and technical assistance. This should fit within the legal framework of the embarking State and the vendor State.

To complement and to focus the inspection programme on areas important to safety, the regulatory body should establish a process to collect, evaluate and disseminate lessons learned from other projects and facilities, and evaluate them for changes to its inspection programme. This process should include both domestic and international experiences.

The regulatory body should establish multilateral and bilateral agreements or join regulatory forums with foreign regulators to share good practices, lessons learned and outcomes of inspection programmes. The benefit of sharing information is to use regulatory resources effectively and to improve the inspection programme continually.

There are several different international regulatory forums for exchanging construction experience:

(a) The MDEP was established for the exchange of information by regulators on reactor design. There are also subgroups based on thematic areas such as codes and standards, vendor inspections and digital I&C.
(b) The IAEA and the NEA have expanded the Incident Reporting System (IRS) for sharing construction experience and lessons learned, and the NEA has launched an effort to better focus on construction experience.

(c) There are several working groups on different reactor technologies:
   (i) Working groups under the NEA Committee on Nuclear Regulatory Activities (CNRA);
   (ii) CANDU Senior Regulators Group (CSRG);
   (iii) WWER Regulators' Forum;
   (iv) Network of Regulators of Countries with Small Nuclear Programmes (NERS);
   (v) Region based forums, such as the Asian Nuclear Safety Network (ANSN).

(d) The Regulatory Cooperation Forum (RCF).

6.5. CONSTRUCTION OF A NEW FACILITY IN CLOSE PROXIMITY TO AN EXISTING ONE

Paragraph 2.16 of IAEA Safety Standards Series No. NS-R-3 [20] requires that: "Foreseeable significant changes in land use shall be considered, such as the expansion of existing installations and human activities or the construction of high risk installations." Either the new facility, the existing facility or both should perform an evaluation to determine any risks to the safe operation of the existing facility posed by the construction and operation of the new facility, and identify measures to mitigate any risks. An evaluation of these risks, regardless of who performed it, should be included in the authorization process for the new facility. Possible risks are caused by, but not limited to, dredging, quarrying, excavation, blasting, piling, dust, transportation, and the lifting and creation of connections between the existing facilities and the construction site. Furthermore, construction activities and their impact on the existing facility need to be continuously monitored throughout construction to ensure that the safe operation of the existing facility is not affected. Additional guidance related to the construction of nuclear installations is under preparation.

In determining the regulatory inspection areas, the regulatory body should consider activities that present risks to the safe operation of the existing facility, for example:

(a) Monitoring the radiation dose to the construction workers from the existing facility;

(b) Integration of the emergency preparedness plan or modification of the operating site emergency plan to account for the increased activity on or near the site;

(c) Assessing the possible siting, construction and commissioning risks resulting from construction on shared or common SSCs (e.g. switchyard, intake structures and pipelines of the existing facility);
(d) Ensuring that emergency resources are sufficient for each site in case of site wide events (e.g. earthquakes and tsunamis).

6.6. INSPECTION OF LICENSEES' OPERATIONAL READINESS

Although regulatory inspections of a licensee's operational readiness preparations during construction and commissioning are not generally mandatory in many Member States, the regulatory body and the licensee can significantly reduce future regulatory issues and associated delays by reviewing these preparations well in advance of an application for an operating licence. For the regulatory body, supplemental inspections of specific areas discussed below will provide early insights on how the licensee will perform as an operator.

The licensee's overall preparation for eventual operation of the facility should begin as early as siting (involvement in early safety analysis) and involves a number of long lead activities that develop the capabilities of the operating organization to play a role in construction and commissioning. The early and timely implementation of these capabilities has been shown to contribute to safety in the long term and has the potential to reduce regulatory issues for when the licensee prepares its safety case to operate the plant.

Some of the long lead activities that begin years before operation include, but are not limited to, the verification of:

(a) Availability of qualified, trained and certified personnel for system commissioning and safe plant operation (e.g. shift crew, licensed operators and shift critical maintainers);
(b) Availability of operating procedures, including normal, abnormal and procedures used in emergencies (e.g. severe accident management guidelines);
(c) Demonstration of the emergency preparedness plan;
(d) Demonstration of physical security measures (before arrival of nuclear material at the plant site);
(e) Plant engineering change control processes for systems turned over to the operating organization;
(f) Work control systems;
(g) Licensees' configuration management programme and its connection to the licensees' safety classification programme and how the licensee is adhering to these programmes from early design activities;

(h) Availability of management system processes and procedures for radiation protection, waste management, environmental monitoring and firefighting.

6.7. SAFETY CULTURE

Promoting and maintaining good safety culture is highly important for the safety of nuclear installations. This has been recognized internationally and is also a focal point of IAEA safety standards. The inspection activities of the regulatory body for safety culture should not be limited to the licensee alone but should also examine how the licensee is ensuring that a strong safety culture is also present in equipment providers (vendors) and service providers (contractors).

The licensee should have a process for workers to report non-conformances and safety concerns to the contractor management, construction organization or itself. A good safety culture would encourage open reporting but some Member States have determined that it is good practice to include the capability of anonymous reporting. The workers should also be aware of the process for reporting safety concerns directly to the regulatory body.

The inspection programme of a regulatory body should give special attention to factors contributing to the safety culture. Openness, transparency, a questioning attitude, a no-blame culture, learning lessons from mistakes, sharing experiences such as those of near misses, and reporting safety concerns, mistakes and errors are some of the contributing factors. Special techniques have now been developed and practised by some regulatory bodies to inspect the safety culture of licensees. The regulatory bodies may learn from such practices and develop new ones for conducting special inspections of safety culture. Safety Reports Series No. 74, Safety Culture in Pre-operational Phases of Nuclear Power Plant Projects [21], may be used by the regulatory body in developing its procedures for the inspection of safety culture. Additional guidance regarding safety culture self-assessments is under preparation.

7. INSPECTION PROGRAMME IMPLEMENTATION DETAILS

7.1. INSPECTION PLANNING

Implementation of the inspection programme requires detailed planning by the regulatory body. Generally, a high level annual or biennial plan is prepared, which may be supplemented by more detailed quarterly, monthly and weekly plans. In addition, the inspection plan should include provisions for reactive inspections. In determining the intervals of inspections and the level of effort to be applied, the regulatory body takes into account the relative safety significance of the facility in each authorization stage and inspection area. Particular aspects that need to be considered in determining the intervals of inspections in various areas and the level of inspection effort to be applied include:

(a) Safety and risk significance — application of the graded approach;
(b) Inspection methods and approaches used (e.g. use of resident inspectors);
(c) Schedule of the licensee's activities;
(d) Extent of involvement of external support;
(e) Maturity, experience and effectiveness of the licensee's management system (including oversight);
(f) Performance record of the licensee, including the number of violations, deficiencies, incidents and problems encountered, and the number of reactive inspections required;
(g) Outcome of regulatory review and assessment;
(h) Type of facility;
(i) Resources available from the regulatory body;
(j) Results of previous inspections;
(k) National and international experience feedback;
(l) Insight from operator licensing examinations and interviews.

The inspection planning should not only focus on inspections at nuclear facility sites but also cover manufacturing activities at the vendors' premises. The regulatory body may conduct inspections of vendors supplying SSCs to the licensee. These inspections will generally be performed for the following reasons:

(a) To verify the effective implementation of vendor quality assurance programmes as a means of assuring the quality of materials, equipment and services supplied to the nuclear facility;
(b) To verify the effective implementation of commercial-grade dedication programmes for safety related materials, equipment and services;
(c) To ensure that vendors have an effective system for reporting defects and to obtain sufficient information to ensure that the root causes of reported vendor related problems are being identified and suitable corrective actions are developed and implemented;
(d) To provide input on instances involving substandard, suspected counterfeit or fraudulently marketed vendor products and to gather information to provide timely information to licensees and other users;

(e) To verify conformity of vendors' management systems with the licensees' management systems.

These inspections will be either routine or reactive. Reactive vendor inspections would typically be performed in response to a specific problem identified with the equipment or in response to allegations or other identified problems from outside sources. In addition, feedback from similar plants or base plants would also be used for reactive inspections.

Such inspections may be included in the overall plan of the facility or a separate plan for manufacturing activities may be developed. However, these plans should interact with each other for sharing information and executing the plans effectively under the overall inspection programme. Various regulatory bodies of different Member States manage the inspections of manufacturing activities differently (examples are given in Appendices I–VIII).

The inspection plans are reviewed periodically and adjusted as necessary. The licensee should be informed in advance of the inspection plan (except for unannounced inspections) and its revisions. The inspection plan is flexible enough to permit inspectors to respond to particular needs and situations. The regulatory body establishes a process of periodically evaluating inspection findings, identifying generic issues and making arrangements to enable inspectors from various plants, locations or projects to meet to exchange views and to discuss the findings and issues as well as to modify the inspection plan, if required.

7.2. PLANNING AND COORDINATION WITH LICENSEES' WORK SCHEDULES

Since implementation of the inspection plan and programme of the regulatory body is influenced by the schedule of licensees and their vendors' and contractors' activities, provisions are required for receiving the necessary information and updates about the licensee's work schedule. In addition, a large part of the regulatory inspection plan involves announced inspections, and it is necessary that information about them is provided to the licensee in advance. Accordingly, the regulatory body and the licensee should agree on the interface and communication arrangement for such information exchanges on a regular basis and any difficulty in the process needs to be resolved. In certain cases, the information is exchanged on a biannually, quarterly, monthly or weekly basis, with updates from a few days to a few hours in advance. In some Member States, such requirements are established in legal frameworks. Coordination meetings are held periodically between the regulatory body and the licensee to review the arrangement, discuss and resolve the difficulties, and to follow-up the inspection programme. The frequency of such meetings depends on the phase of the facility and the nature of the issues. Practices of some Member States are provided in Appendices I–VIII.

7.3. CONDUCTING INSPECTIONS AND FOLLOW-UP

While establishing requirements for the management system, para. 5.9 of IAEA Safety Standards Series No. GS-R-3 [7] requires that: "The work performed in each process shall be carried out…by using approved current procedures…that are periodically reviewed to ensure their adequacy and effectiveness." Accordingly, inspections should be performed using approved procedures supplemented by detailed checklists, which are periodically reviewed for adequacy and precision, and modified as required. The inspector or inspection team should reflect the scope, depth, technicalities and expertise involved (i.e. civil, mechanical, electrical, I&C, materials, management system and human factors).

In preparation for the inspection, the inspection team should review the relevant documentation (i.e. regulations, licence conditions, SARs, codes and standards), inspection procedures and checklists to be clear on the requirements and acceptance basis. While conducting the inspection, attention should be given to the effectiveness of the licensee's controls over the activity, use of valid documentation, precision and adequacy of the documentation, verification of performance requirements, qualification of personnel conducting the activity, environmental conditions and work control system.

Generally, the regulatory body should hold an entrance meeting with the licensee management to describe the purpose and scope of the inspection activity and its expectations from it. Upon completion of the inspection, the regulatory body should hold an exit meeting with the licensee management to apprise it of the major findings and issues highlighted during the course of the inspection. Afterwards, the regulatory body should prepare a report citing the inspection results along with the regulatory basis for the findings. Corrective actions should focus on system improvements to avoid repetition of similar problems in the future. The inspection report may also require the licensee to inform the regulatory body of its corrective action plan, which should be followed up for closure of the inspection finding. The inspection reports and follow-up actions should be shared with other inspectors for experience feedback.

7.4. PLANNED INSPECTIONS

Planned inspections are carried out in fulfilment of the preplanned baseline inspection programme developed for the facility or activity. Nuclear facility inspections should be planned using licensee schedules for the performance or completion of certain activities at all phases of the licensing process. These routine inspections provide an opportunity for the examination of the licensee's activities in order to confirm the licensee's performance and to identify potential problems at an early stage. Considerations in relation to performing routine inspections should include:

(a) Regulatory policies, requirements, regulations, guides and industrial standards;
(b) Safety significance of the areas to be inspected;
(c) Licensee's overall performance in the areas to be inspected;
(d) Operational experience and lessons learned from events or problems at other facilities or in other States.

During routine inspections, the observation and assessment of ongoing safety activities should be emphasized to assess the effectiveness of the licensee's performance. Inspections should also include interviews with licensee staff to confirm that they understand correct safety practices, and sufficient document reviews to verify that adequate records are being maintained.

Routine inspections at nuclear facilities should almost always be announced to the licensee beforehand. The main advantage of announcing inspections is that the inspector is able to discuss plans and needs with the licensee's personnel in advance to secure assurances that the necessary documentation will be available for inspection, personnel will be available for interviews and ongoing activities can be inspected as scheduled. The announcement of inspections will enhance their effectiveness and efficiency.

Some unannounced inspections, particularly at regulated materials facilities, may be advantageous from the standpoint that the actual state of the facility and the way in which it is being operated can be observed. Inspections may be carried out at any time of the day or night to provide a more complete picture of the situation at the facility.

The final inspection report for a routine inspection should be completed in appropriate time. There should be consistency between any message provided at the exit meeting and the final report. If inspection results change during the course of the review with management, the inspector needs to consider conducting a re-exit meeting with the licensee to communicate the final inspection results.

7.5. REACTIVE INSPECTIONS

Reactive inspections, by individuals or teams, are usually initiated at short notice in response to an unexpected, unplanned situation or incident to assess its significance and implications and the adequacy of corrective actions. A reactive inspection may be conducted as a result of an isolated incident or a series of lesser events that would indicate a potentially more serious problem. A reactive inspection may also be made in response to a generic problem encountered at another plant or identified by the regulatory body.

Although specific reactive inspections cannot be anticipated, the potential resource need for conducting these inspections should be anticipated. A graded approach in responding to unforeseen circumstances is necessary because all available resources may be required in responding to a serious event, whereas in the simplest of cases only one inspector may be needed.

The need for a reactive inspection may be identified as a result of an ongoing inspection. However, the primary basis for identifying the need for these inspections will likely be licensee event notifications or allegations by workers or the public about items such as:

- Deficiencies in siting, construction and manufacturing, and non-compliances in design;
- Abnormal test results;
- Unplanned releases of radioactivity;
- Violations of licensing limits and conditions;
- Unexpected radioactive exposure of personnel;
- Inoperability of safety related equipment;
- Any other situation giving rise to potential hazards for workers, the public or the environment.

Details regarding different types of inspection can also be found under section 3 of IAEA Safety Standards Series No. GS-G-1.3 [2].

7.6. TRANSPARENCY AND COMMUNICATION WITH STAKEHOLDERS

Requirement 36 of IAEA Safety Standards Series No. GSR Part 1 [1] deals with the communication and consultation of the regulatory body with interested parties. It states that:

> "The regulatory body shall promote the establishment of appropriate means of informing and consulting interested parties and the public about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body."

Hence, the management system of the regulatory body should have provisions for sharing and communicating inspection programme status, issues and resolutions with the interested parties. Aware of the issues raised by the nuclear industry in respect of health, safety and the environment, and desiring that decisions leading to the potential development of nuclear power be grounded in the trust and acceptance of its citizens, the State should consider taking the steps necessary to ensure effective public information and engagement. Transparent communication vis-à-vis the general public would also be bolstered by effective communication with governmental and appropriate expert organizations, neighbouring States and the larger international community. The channels of communication with the citizens of the State should also be established in the process of evaluating nuclear power option.

The above commitments with regard to open communication and transparency would not extend to security related measures and plans developed to ensure the physical security of any nuclear facility, equipment or materials within the State. Such measures and plans would be treated as sensitive information and afforded appropriate protection to ensure the physical security of the facilities, equipment and materials.

It is advisable that regulatory bodies of States establish some mechanism suitable to their culture and society for sharing information on inspection activities with the public, interested parties and the international community.

8. ENFORCEMENT ACTIONS

In order to fulfil its regulatory mandate, the regulatory body should have statutory enforcement powers specified in the State's legal framework. These statutory powers should include the authority to address non-conformances by requiring a licensee to modify, correct or to curtail any aspect of the activities authorized by the regulatory body. Furthermore, guidance beyond IAEA Safety Standards Series No. GS-G-1.3 [2] with respect to implementation of the enforcement process is dependent on the individual State's legal framework.

It is internationally recognized that there are some specificities, particularly during construction, that are not present in the operational phase and should be taken into account by the regulatory body in the licensing phases leading up to operation, such as a complex management system of a large supply chain. When considering enforcement actions as a result of findings based on inspection activities, the regulatory body should not only consider the risks and consequences to health, safety, security and the environment under the current authorization, but also consider the consequences to operation had the non-conformance not been addressed [22]. Taking consideration of international construction experience, examples of inspection findings that required enforcement actions by the regulatory body include:

- Lack of quality of liner welds due to improper training;
- Concrete slab cracks due to improper water cement mixture according to procedure;
- Manufacturing defects on main components (e.g. steam generators and reactor coolant system piping);
- Impact of environmental qualification of cables for radiation and temperature.

It should be well understood that, while an enforcement process is needed to ensure compliance with the legal framework, the regulatory body should acknowledge that the ultimate goal, with a graded approach enforcement process, is that the licensee operates safely and takes appropriate actions to address non-conformance. An enforcement action is required to ensure enhancement of the safety culture and may, if necessary, mean punitive actions (e.g. graduated enforcement).

A Member State (i.e. Pakistan) example of enforcement activities is included in Appendix V.

Appendix I

EXAMPLES FROM MEMBER STATE INSPECTION PROGRAMMES: ROMANIA

Sections of Appendix I have been adapted from the National Report under the Convention on Nuclear Safety [23].

I.1. ROMANIAN NATIONAL COMMISSION FOR NUCLEAR ACTIVITIES CONTROL

Cernavodă is the only nuclear power plant in Romania, with five units, pressurized heavy water reactors (PHWRs) of the CANDU 6 design (700 MW/unit). The construction of all the units started in the 1980s. Unit 1 started commercial operation in 1996 and Unit 2 was commissioned and started commercial operation in 2007. The construction of the other three units on the site was stopped at different stages, and these units are currently under preservation.

It is expected that in the next two years the construction of Units 3 and 4 will be restarted. The licensing basis documents for Units 3 and 4 have already been submitted to the National Commission for Nuclear Activities Control (Comisia Naţională pentru Controlul Activităţilor Nucleare, CNCAN) for approval, as part of the prelicensing activities, and the inspection of existing structures and buildings has already started, based on a contract between EnergoNuclear (the company in charge of the project for completion of Units 3 and 4) and Atomic Energy of Canada Limited (AECL) — the designer and vendor of CANDU 6 reactors. There are currently no plans for resuming construction of Unit 5. The Elements of Energy Strategy for 2011–2035 [24] includes plans for a new nuclear power plant to be constructed at a new site, delivering 1000–1600 MW, beginning in 2021.

With regard to the research reactors' status, Romania has one TRIGA research reactor in operation, located near Piteşti, recently refurbished and recommissioned in 2010, and a VVR-S research reactor, located near Bucharest, under the first stage of decommissioning.

Based on the recent construction and commissioning experience and considering the future challenges, the CNCAN is ready to use the experience feedback in the regulatory oversight of the construction activities for Units 3 and 4 of Cernavodă nuclear power plant and of the activities to be performed for the selection and preparation of a new nuclear power plant site.

I.2. LEGAL AUTHORITY, OBJECTIVES FOR REGULATORY OVERSIGHT AND REQUIREMENTS

The legal basis for the nuclear regulatory framework is established by the Nuclear Act (Law No. 111/1996 on the safe deployment, regulation, authorization and control of nuclear activities), last revised and re-issued in 2006. The legal provisions stated in the Nuclear Act empower the CNCAN to carry out inspections on the licence holders as well as on the applicants for a licence, and to control the application of the relevant regulatory requirements.

CNCAN inspectors are empowered to perform the necessary control activities at the site where the activities subject to licensing are deployed, as well as at any other location which may be connected to these activities, including the home or other location of any natural or legal person that may carry out activities related to nuclear and radiological installations or have possession of any nuclear or radiological materials, including related information. The control activities are performed for any of the following situations:

(a) Before granting the licence for which an application has been submitted;
(b) For the whole period of validity of the licence (periodic, as well as unscheduled or unannounced inspections);
(c) Based on a notification or request made by the licence holder;
(d) For cases when it is suspected that installations, devices, materials, information and activities, among others, that are under the scope of the Nuclear Act, exist or are performed without having been registered and subjected to the licensing or authorisation process.

Following the control, the CNCAN may order, if deemed necessary, the suspension of the activities and cease of operation or use of the respective installations, devices, equipment, materials and information, among others, that are possessed, operated or used without a licence or the operation or possession of which could pose a threat. In exercising the control mandate, CNCAN representatives are empowered to:

(a) Access any place in which activities subject to the control may be deployed;
(b) Carry out measurements and install the necessary surveillance equipment;
(c) Request the taking or receiving of samples from the materials or products directly or indirectly subject to the control;
(d) Compel the controlled natural or legal person to ensure the fulfilment of the provisions mentioned under points (a)–(c) and to mediate the extension of the control to the suppliers of products and services or to their subcontractors;

(e) Have access to all the information necessary for achieving the objectives of the control, including technical and contractual data, in any form, with observance of confidentiality if the holder makes explicit requests;
(f) Compel the licence holder to transmit reports, information and notifications in the form required by regulations;
(g) Compel the licence holder to keep records, in the form required by regulations, of materials, other sources and activities subject to the control, and to check these records;
(h) Receive the necessary protective equipment, which the applicant, or licence holder, arranges.

For the whole duration of the control activities, CNCAN representatives have the obligation to observe the applicable licensing conditions as imposed upon the personnel of the licence holder. CNCAN representatives have the following powers, to be exercised after conclusion of the inspection or control activity:

(a) Draw up a report stating the results of the control, the corrective actions requested and the deadlines for their implementation;
(b) Propose the suspension or withdrawal of the licence or practice permit, under the terms of the Nuclear Act;
(c) Propose the information of the legal prosecution bodies in the cases and for the violations specified under the Nuclear Act;
(d) Request that the licence holder applies disciplinary sanctions to personnel guilty of violations specified in the Nuclear Act;
(e) Apply sanctions for contraventions, as specified in the Nuclear Act, to persons vested with the statutory responsibility of representing the licence holder in dealings with the public authorities;
(f) Apply sanctions for contraventions, under the terms of the Nuclear Act, to personnel guilty of the violations.

I.3. DEVELOPMENT OF THE OVERSIGHT PROGRAMME

According to provisions of IAEA Safety Standards Series No. GS-R-3 [7], the CNCAN developed inside its own organization a management by process approach. The management system processes of the CNCAN fall into three main categories: management processes, core processes and support processes. The subdivision of the core processes are: development of regulations and guides; licensing; review and assessment; and inspection and enforcement. The key objective of the CNCAN inspection programme is to monitor compliance with the legal, regulatory and licensing requirements and to take enforcement actions in the event of non-compliance. The regulation, review and assessment, and inspection and enforcement processes each provide input to the licensing process (see Fig. 2).

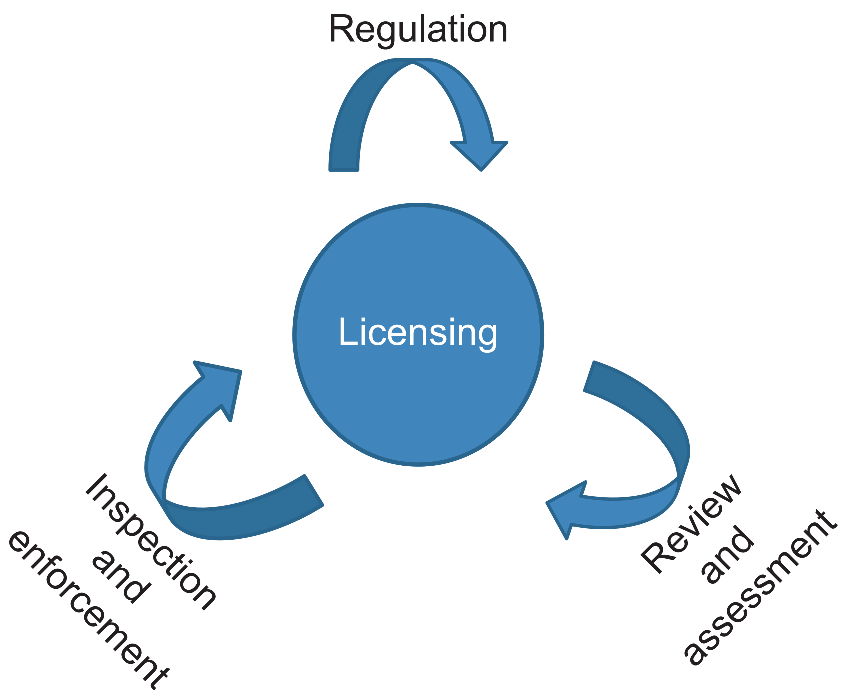

FIG. 2. Relationship of CNCAN regulatory processes.

The inspections performed by the CNCAN include:

(a) Scheduled inspections, planned and performed either by each of the technical divisions, or jointly, on the occasion of major licensing milestones;
(b) Unscheduled or unannounced inspections, some of which are reactive inspections in response to incidents;
(c) Routine and daily observations performed by the resident inspectors.

The various interfaces required to support the continuous communication between the licensee and the regulatory body are well established and described in specific procedures for all the safety related activities of the plant, which are subject to licensing, require approval from or notification to the CNCAN, or which are under regulatory surveillance.

I.4. OVERSIGHT FOR DIFFERENT LICENSING STAGES

I.4.1. Siting

During the siting stage, the activities performed and the companies involved on the site are generally limited. The evaluations and audits of the management systems and the technical inspections of the companies involved will be subject to a CNCAN inspection programme to verify compliance with the regulations in force. Qualified CNCAN specialists will be asked to inspect the collecting of data, computer modelling, assessment and confirmation of site location. Additional inspections need to be planned to check the preparation of field activities. As an important part of this stage, the CNCAN will conduct audits of the management systems of the licensee, designer and other companies that are to be involved in the construction of the nuclear power plant.

I.4.2. Design

A detailed checklist on design capability and experience and management system documentation is required to be submitted to the CNCAN by the architect designer company. The management system of the designer company is licensed by the CNCAN for the period it is involved in the construction project. The licence is issued by the CNCAN after an audit is conducted to verify the design capability and the fulfilment of the requirements on management systems for nuclear activities, as outlined in the regulations in force. The licence is issued for two years.

Additional information is collected by the CNCAN during the construction stage from the nuclear power plant site through measuring the performance in controlling the design completion and changes.

I.4.3. Construction

Through the entire construction phase, CNCAN inspectors perform audits and inspections in accordance with the regulatory inspections programme, and periodic licensing meetings are also held to discuss the progress of the project and any outstanding issues and significant findings with the licensee's representatives. Comprehensive assessments and inspections are performed, especially on the occasion of the licensing milestones. For each of the licensing milestones, a formal approval or authorization is granted by the CNCAN to the licensee to proceed further with the work, provided that all the specific requirements and conditions have been fulfilled. For example, prior to granting the approval for heavy water loading into the moderator system, one of the conditions is for the licensee to demonstrate that all construction activities related to the plant systems required for that milestone have been completed, that the necessary verifications and tests have been performed with acceptable results and also that all the required documentation is available and adequate.

For each activity to be performed, the responsible company submits the quality plan to the CNCAN to establish regulatory hold and witness points. The requirement is valid for all companies participating in the construction activity: main constructor, subconstructors, and providers of services, equipment and components. These three elements represent the basis of the annual CNCAN inspection programme. The inspection programme is based on the management system approach and is supported by nuclear safety criteria and the background of CNCAN technical specialists. Applying the Romanian regulatory requirements on management systems for nuclear activities and facilities, all participants involved in activities related to safety are licensed from the management system point of view prior to performing the respective activity. Hence, the CNCAN regulatory control is extended to nuclear licensees, investors, vendors, constructors, manufacturing facilities, main suppliers and contractors.

The regulatory inspections are normally focused on areas which may pose a significant risk or for which a poor performance has been recorded. If an assessment finds good performance in an area, the results may be used to reduce the frequency and depth of future inspections.

Periodical meetings are organized between the CNCAN, the licensee and the participants involved in the construction process to summarize the main regulatory issues. The assessment and inspection activities performed by CNCAN staff are documented by one of the following means:

- Assessment reports;
- Inspection reports;
- Written minutes of the meetings with licensees' representatives.

These documents are also distributed to the licensee, in addition to the regulatory letters, which summarize the main regulatory requirements and dispositions based on findings arising from the review process.

The daily surveillance of construction activities is performed by resident inspectors. The staff from the CNCAN head office participate in team inspections and specialized inspections. Qualified CNCAN specialists in appropriate areas participate in hold and witness points.

During the two year period for which a licence is issued, each process of the licensee and constructor company is the subject of a management system audit. Specially focused inspections are organized between participants, handling of non-conformities, control of design, issuing and maintaining of specific records, planning and supervising of performed work, and control of procurement activity. Databases on inspection findings ensure the main feedback experience in reviewing the CNCAN inspection programme.

During the construction of the first CANDU 6 unit in Romania, a contract with the Canadian Nuclear Safety Commission (CNSC) was in place to ensure appropriate training for CNCAN staff and to provide regulatory assistance at the construction and commissioning stage.

In 1990, the owner decided to stop the construction of all five units due to lack of financial resources. At that time, the major equipment of Unit 2 was installed or stored on-site. The owner started the preservation phase. The CNCAN performed inspections to verify how the appropriate preservation conditions were established and maintained for each type of equipment. After more than ten years of preservation, the licensee resumed construction of Unit 2. The CNCAN focused the inspection programme on the activities related to the evaluation of equipment readiness for installation after a long period of preservation. Other management system changes (e.g. electronic and 3-D design, and change of record support) were also carefully inspected by the CNCAN.

Regular training of inspectors consisted of a basic knowledge of CANDU 6 technology, the application of CNCAN inspection procedures, and audit courses and qualifications. All inspectors have their initial qualification from different engineering backgrounds.

I.4.4. Manufacturing

The management system authorization requirement is extended to suppliers of products and services classified as important for nuclear safety. The management system and technical capability are evaluated by the CNCAN through the audit process. The CNCAN oversight is extended to the manufacturing activity through hold and witness points established in quality plans submitted prior to starting the contracted activity. On-the-job training is used to develop inspection skills.

I.4.5. Commissioning

Compared to the construction stage, commissioning requires much more effort for a short time period. The document Commissioning Safety Objectives, submitted by the licensee and agreed by the CNCAN, links the safety requirements to the appropriate commissioning test. Available and appropriate CNCAN staff join the task force team designated by the project manager responsible for each safety related and complex test. They assess the commissioning accomplishment reports, witness the commissioning tests and perform adequate inspections, verifying how the nuclear safety objectives are fulfilled.

In addition to the inspectors qualified for the construction stage, the designated staff are trained in specific CNCAN procedure for inspections during commissioning. Construction and commissioning inspections also represent a good opportunity to train CNCAN staff for regulatory inspections of operational activities.

General regulatory provisions, focused on the quality management of the commissioning activities, are given in Norms Regarding Specific Requirements for the Quality Management Systems Applied to the Commissioning Activities of Nuclear Objectives [25].

The commissioning programme for Cernavodă nuclear power plant was conducted on a milestone basis in parallel with the licensing programme agreed with the CNCAN. Each milestone was achieved, and documented processes were set in place to demonstrate that:

(a) The testing activities were well defined and clearly detailed and the objectives of the tests were well established — in such a manner that the equipment and systems are placed in service, design specifications confirmed and safety assumptions validated.
(b) The testing activities were scheduled, reviewed and performed without jeopardizing plant safety at any time, and the status of the plant was appropriate for the corresponding commissioning activities.
(c) The process of test results evaluation provided assurance that all the applicable assumptions and conclusions included in the safety documentation were adequately demonstrated.
(d) All the required operating documentation, including baseline data collection forms for systems and components, was prepared and available to the operating personnel.
(e) Test records essential to demonstrate that commissioning activities had been performed in accordance with specified requirements were collected, assembled, validated and filed to storage by the Operations Document Control Centre, as a part of the individual system commissioning packages.
(f) The commissioning test results together with the process in place to review, evaluate and to approve them — referred to as Commissioning Completion Assurance (CCA) — were used to obtain approval to proceed beyond the licensing milestones and release hold points agreed with the CNCAN.

All of the above were sustained by a framework of processes described within the following procedures:

— System commissioning procedures;
— Standard commissioning procedures;
— Commissioning records, files and reports;
— Transfer of operating control to shift crews;
— CCA;
— Commissioning technical process;
— Commissioning planning process;
— Commissioning specifications and objectives;
— Work permit and equipment guarantee system during commissioning;
— Temporary modifications during commissioning prior to fuel load;
— Temporary modifications during commissioning after fuel load;
— Commissioning execution process;
— Operating manual tests;
— Work request system;
— Work plans;
— Operating flowsheet preparation;
— Operating manuals;
— Commissioning temporary operating procedures;
— Preparing, issuing and revising commissioning programme documents and directives;
— Document and template management;
— Commissioning/management team engineering interface;
— Integrated commissioning tests coordination;
— Commissioning unplanned event reports.

The detailed programme for tests to be performed on a system by system basis and for integrated tests for all phases has been elaborated by the licensee and submitted to the CNCAN for review and approval. The programme, including specific safety objectives and acceptance criteria, has been reviewed for compliance with design intent and safety analyses and approved by the CNCAN. From this programme, safety relevant tests have been selected to be witnessed by CNCAN inspectors and included in the regulatory surveillance programme. The CNCAN inspection programme was provided to the licensee to ensure the coordination of the direct necessary interfaces. The inspectors verified the completeness of construction and commissioning stages and the transfer of systems and responsibilities from constructor/commissioning to commissioning/operating organization.

The CNCAN programme for surveillance of the commissioning activities for Unit 2 included more than 180 witness points for all the phases of the commissioning programme. The hold points coincided with the licensing milestones.

During the commissioning stage, the regulatory authority granted the following permits and approvals:

- — Permit to load fuel;
- — Permit to load D_2O in the primary heat transport system;
- — Permit for the first criticality;
- — Permit for power increase up to 5% full power operation;
- — Permits for power increase in stages, up to 100% full power operation.

Before granting each of these permits, CNCAN inspectors performed comprehensive inspections and verification of documentation related to the status of construction and commissioning activities for systems important for safety, as well as verification of results of important tests.

For example, with regard to the assessment of the project status for the first criticality, the licensee submitted to the CNCAN, in compliance with the commissioning licence conditions, a report regarding the plant status. It contained a detailed review of the entire scope of work that had an impact on the plant readiness for criticality. The results of the review had to demonstrate that the activities had been completed as required to ensure safe and reliable plant operation. This report was submitted to the CNCAN in support of the application for the permit to reach first criticality. It took into consideration the following activities:

- — Systems, structures and equipment turnover from the construction department to the commissioning department, clarification of deficiencies, and completeness of as-built documentation;
- — Systems, structures and equipment turnover from the commissioning department to the execution and operations department;
- — Commissioning activities;
- — Design changes;
- — Radiation protection programme (procedures, preparation and equipment);
- — Reference documents and station instructions;
- — Personnel training (based on minimum training requirements);
- — Training manuals (elaboration and approval for use);
- — Chemical control (safety related systems);
- — Quality management system;
- — Physical protection;
- — Operating manuals (preparation, approval and acknowledgement);
- — Operational flowsheets (revised);
- — Operating manual tests (preparation, approval and acknowledgement);
- — Call-ups and routines (elaboration, approval and acknowledgement);

— Maintenance programmes and procedures (elaboration, approval and acknowledgement);
— Housekeeping and housecleaning (equipment, systems, buildings and site).

The adequacy of the commissioning tests was judged based on the review of the test results, which had to demonstrate that all the relevant requirements and procedures had been observed and that safety objectives and acceptance criteria had been met. The review of acceptance criteria formed part of the review of the document containing specific commissioning safety objectives and acceptance criteria for all safety related systems, which has been approved by the CNCAN well in advance of the actual test performance. The commissioning test results were listed in the CCA reports containing a comparison to the acceptance criteria.

The regulatory surveillance plan enabled the CNCAN to effectively control the commissioning process step by step to verify that the plant, as built, meets the design safety requirements.

Appendix II

EXAMPLES FROM MEMBER STATE INSPECTION PROGRAMMES: FINLAND

Sections of Appendix II have been adapted from Guide YVL 2.5, The Commissioning of a Nuclear Power Plant [26].

II.1. FINNISH RADIATION AND NUCLEAR SAFETY AUTHORITY

The Finnish Radiation and Nuclear Safety Authority (Säteilyturvakeskus, STUK) can rely on its own in-house competence for conducting inspections of structures and components. STUK's unique regulatory approach including review of design documentation for structures and components had already been developed in the 1970s, when it conducted regulatory oversight of the Russian supplied components to Loviisa nuclear power plant. The regulatory approach is documented in the national legislation and regulatory guides on nuclear safety (YVL) issued by STUK.

STUK authorizes inspection organizations which are accredited by the Fuel Incident Notification and Analysis System (FINAS). STUK participates to the accreditation process as an expert. Accreditation is based on the standard EN ISO/IEC 17020, Type A. Licensee contracts the inspection organization, which is authorized by STUK.

II.2. REGULATORY INSPECTIONS DURING CONSTRUCTION

Review of design basis and commissioning inspections are on STUK's responsibility in safety class (SC) 1, 2 and 3. SC 1 is solely STUK's responsibility. Inspection organizations are used for regulatory inspections for components' supervision and inspections mainly in SC 3 and in SC 2, inspection organizations depending on equipment's safety significance. SC 2 steel and concrete structures and SC 3 concrete structures are STUK's responsibility. Regulatory inspections of SC 3 steel structures are the inspection organization's responsibility. Comprehensive technical control is used and hold points are predefined.

STUK reviews and approves detailed design documentation (e.g. construction plans) for SSCs before the start of construction and manufacturing. STUK develops inspection programmes based on this detailed design review. Final safety analysis report documentation is submitted to the regulatory body at least one year prior to operational licence approval. Detailed design review is focused on SC 1, 2 and 3 SSCs. Inspections during and at the end of manufacturing verify that the manufacturer, vendor and licensee have implemented their oversight as presented in the manufacturing documents and that the results are acceptable (within the predefined and approved acceptance criteria). STUK does not perform its own inspections, tests or analyses other than in very specific cases. STUK will carry out inspections on SC 1 and 2 components and has delegated lower safety class inspections to the inspection organizations. The licensee is responsible for preparing inspections and for inviting STUK to the inspection at the correct time. STUK issues a protocol to the licensee as a result of the inspection.

For civil constructions, STUK carries out the following concreting readiness inspections:

(a) First phase concreting readiness inspections only for large SC 2 structures. In the first phase, concreting readiness inspections are to verify that tasks, responsibilities and cooperation are clearly defined and known to all involved organizations.
(b) Second phase concreting readiness inspections are to verify that the constructor, vendor and licensee have implemented their oversight and inspections as presented in the concreting documents and that the results are acceptable.

STUK also carries out oversight of SC 2 structures during the concreting to follow concreting activities to verify the quality of concreting activities and the adequacy of constructor, vendor and licensee oversight activities on-site. STUK has delegated SC 3 structure oversight to the inspection organizations.

In Finland, STUK carries out inspections on licensee's performance within the construction inspection programme to verify performance conformity and to verify that the licensee bears the responsibility on safety. Licensee performance inspections performed by STUK assess:

— Adequacy of project and safety management;
— Quality management;
— Quality control (e.g. construction and manufacturing) design review and approval process on process systems and pressure equipment;
— I&C systems;
— Electrical systems;
— Layout;
— Civil construction;
— Training (operators and project staff);

— Use of probabilistic risk assessment;
— Radiation safety;
— Waste management;
— Physical protection and emergency preparedness.

II.3. REGULATORY INSPECTIONS DURING COMMISSIONING

STUK inspects the commissioning plan of a nuclear power plant as part of the preliminary safety analysis report. In addition, STUK controls the licence holder's functions during the construction and commissioning in the manner and within the scope described in the relevant YVL guides to ensure the safe commissioning of the plant.

The licence holder requests STUK's approval for all test programmes that involve systems belonging to SC 1, 2 and 3. Of the systems belonging to SC 4, STUK determines, on the basis of the plant testing programme, those system tests whose programmes the licence holder submits to STUK for approval. Other test programmes of the systems belonging to SC 4 should be submitted to STUK for information. The test programmes of compatibility tests of the main and auxiliary systems should also be submitted to STUK for approval.

If a test programme is subject to STUK's approval, it may only begin upon receipt of the approval. Beginning the test means the first measure aimed to demonstrate the performance of the tested item and whose results are documented for use during the acceptance procedure. However, inspections and tunings of the automation equipment, flushing of the pipe work and other preparatory measures can be carried out before beginning the test programme.

II.4. REGULATORY INSPECTIONS DURING OPERATION

In Finland, the operation of a nuclear power plant is considered to begin when the loading of nuclear fuel into the reactor starts. Loading the reactor may begin after the plant has been granted an operating licence and STUK has accepted the application concerning fuel loading and the reports on the reactor and fuel behaviour in the first operating cycle. To ensure that the plant fulfils the requirements set for it, STUK carries out an inspection in accordance with Section 20 of the Nuclear Energy Act (990/1978) before fuel loading. Guide YVL 1.1, Regulatory Control of Safety at Nuclear Facilities [27] describes the contents of the inspection.

STUK oversees the fuel loading and inspects, upon its completion, whether the loading has been performed in accordance with the loading plan and that compliance of the loading with the plans has been verified in the manner required by the licence holder's quality management system. The closing of the primary circuit and pre-criticality tests of the reactor systems may begin after STUK has inspected the loading pattern of the fuel assemblies and approved the pre-criticality test programmes. STUK supervises pre-criticality tests of the reactor systems, as it deems necessary.

When results that meet the acceptance criteria have been achieved in the pre-criticality tests of the reactor systems, STUK's permission may be requested to make the reactor critical and to perform the low power tests at the power specified in the application. Preliminary results of the preceding tests, which have been inspected by the testing organization, are submitted as part of the application within the scope necessary to prove that the acceptance criteria have been met.

Since the operating licence is delivered, technical specifications are relevant, so the testing procedures should take this into account. Some inspections could be performed to verify the correct identification of technical specifications and the process of authorization.

Making the reactor critical may be begun after STUK has taken a decision to approve the programme that describes the measures concerned. The same decision may also apply to low power tests provided that the related programmes have been approved. STUK supervises the making of the reactor critical, low power tests and power tests, as it deems necessary.

When results that meet the acceptance criteria have been achieved in the low power tests, STUK's permission may be requested to perform the power tests at the power specified in the application. Preliminary results of the preceding tests, which have been inspected by the testing organization, are submitted as part of the application within the scope necessary to prove that the acceptance criteria have been met.

When results that meet the acceptance criteria have been achieved at the specified power level, STUK's approval may be requested for the use of a higher power. The application contains preliminary results of the tests conducted at the previous power, which have been inspected by the testing organization, within the scope necessary to prove that the acceptance criteria have been met. The power may be raised to a new, higher level after STUK has preliminarily inspected the results of the tests conducted at the previous power level and taken a decision to approve the programmes of the tests to be carried out at the new power level.

Appendix III

EXAMPLES FROM MEMBER STATE INSPECTION PROGRAMMES: FRANCE

Sections of Appendix III have been adapted from Nuclear Safety and Radiation Protection in France in 2011 [28].

III.1. FRENCH NUCLEAR SAFETY AUTHORITY

The French Nuclear Safety Authority (Autorité de sûreté nucléaire, ASN) inspection aims to detect:

— Any deviations revealing a potential deterioration in facility safety or the protection of individuals;
— Any non-compliance with the legislative and regulatory requirements the licensee is bound to apply.

The inspection (frequency and depth) is proportionate to the level of risk presented by the facility or activity. Hence, the inspection is neither systematic nor exhaustive. It is based on sampling and focuses on subjects for which the stakes are highest. However, to avoid ignoring activities of lesser significance, a part of the inspection programme is devoted to them through targeted actions.

The ASN has no resident inspector at nuclear facilities: it considers that its inspectors must work within a structure large enough to allow the sharing of experience and that they must take part in inspections of different licensees and facilities. This also avoids confusion of responsibilities.

To ensure greater efficiency, the ASN's action is organized on the following basis:

— Inspections, according to a predetermined frequency, of nuclear activities and topics of particular health and environmental significance;
— Inspections, on a sampling basis, of installations representative of other nuclear activities;
— Systematic technical inspections of all facilities by approved organizations.

Although the activities with the least implications are checked by approved organizations, they can also be the subject of targeted inspections by the ASN.

III.2. ASN INSPECTION PRACTICES

The inspections may be unannounced or notified to the licensee a few weeks before the visit. They take place mainly on the site or during the course of the relevant activities (work and transport operations). They may also concern the head office departments or design and engineering departments at the major licensees, the workshops or engineering offices of the subcontractors, and the construction sites, plants or workshops manufacturing the various safety related components. The ASN uses various types of inspection:

(a) Standard inspections, which are performed during one day by two ASN inspectors.
(b) In-depth inspections, which take place over several days and mobilize about ten inspectors. Their purpose is to carry out detailed examinations and they are overseen by senior inspectors.
(c) Inspections with sampling and measurements — for construction activities, it can be concrete sampling to realize some independent checks.
(d) Inspections which are carried out owing to a particularly significant event, shortly after it is reported to the ASN.
(e) Worksite inspections, which ensure a significant ASN presence on the sites on the occasion of reactor outages or particular work.

Each year, the ASN establishes a national inspection programme:

(a) Beginning of summer: definition of priorities (topics) for next year's inspection.
(b) September–October: preliminary national inspection programme; for a new nuclear power plant, topic may not be defined clearly enough to allow the construction progress to be adapted.
(c) November–December: finalization of the national inspection programme (definition of nuclear site/topic/inspection team).

The inspection programme is endorsed by the ASN director general in December, but, depending on events, the programme may evolve during the year. Each inspection of a nuclear facility results in[4]:

[4] See http://www.iaea.org/NuclearPower/Downloads/Technology/meetings/2011-Dec-12-16-WS-Paris/2.04-F.FERON-ASN.pdf.

(a) At the end of the inspection, a factual record of major negative findings (signed by the inspectors and the licensee's representative).
(b) A few weeks after the inspection (around three weeks):
   (i) A follow-up letter to the licensee stating, in addition to an overall synthesis of the main positive and negative findings:
      — Anomalies in the facility or aspects warranting additional justifications;
      — Deviations between the situation observed during the inspection and the regulations or documents produced by the licensee pursuant to the regulations;
      — ASN requirements to correct, within a fixed period of time, the deviations or non-compliances observed by the inspectors or to improve the situation.
   (ii) An inspection report which is restricted to the ASN.

Inspection follow-up letters are available on the ASN web site.

III.3. ASN INSPECTION RESOURCES

The ASN employs inspectors chosen for their professional experience and for their legal and technical expertise. It gives them the practical tools they need to carry out their inspections, which are performed under the authority of the ASN director general. They are sworn in and bound by professional secrecy. They are appointed and qualified once they have acquired the necessary competence through their professional experience, tutoring and appropriate training. To ensure constant progress:

(a) The ASN has defined a system of qualification for its inspectors, based on recognition of their technical competence.
(b) The ASN has adopted a number of foreign practices identified during the course of inspector exchanges between regulatory authorities.
(c) The ASN encourages an open-minded attitude to other regulatory practices on the part of its inspectors, and it encourages its departments to take on inspectors from other regulatory bodies. It also proposes organizing joint inspections with these bodies concerning the activities falling within its scope of expertise. In order to identify other methods for risk management by the licensees, ASN inspectors may also observe inspections on specialized subjects in facilities which do not fall within their field of expertise.

(d) It aims to ensure the uniformity of its practices. It encourages participation by its staff in inspections on different subjects, and in different regions and sectors.

For inspectors involved in construction inspection, additional training is scheduled to obtain knowledge which is more focused on construction activities and according to the ongoing construction schedule. For instance, some training dedicated to civil works and mechanical installation is performed by experts from the ASN's main technical support organization, the French Institute for Radiological Protection and Nuclear Safety (Institut de radioprotection et de sûreté nucléaire, IRSN).

To help inspectors with the performance of their duties, the ASN provides its inspectors with inspection guides and tools to help them to decide the follow-up to any deviations observed. These guides are regularly updated to take account of changes to regulations and techniques. Some guides related to construction activities are drafted on the basis of current construction projects.

Some inspections are carried out with the support of an IRSN representative specialized in the facility visited or the topic of the inspection.

III.4. ASN CONSTRUCTION INSPECTION PROGRAMME FOR OVERSIGHT OF NEW NUCLEAR POWER PLANTS

The ASN objective[5] during the construction of a nuclear power plant is:

— To ensure that the plant operator and the pressure nuclear system manufacturers exercise their responsibilities, as defined by the law;
— To review the reactor construction to appreciate the safety level of the construction activities.

The ASN inspection scope includes:

(a) On-site preparation and activities;
(b) Manufacture, construction, qualification (certification), and installation of equipment and SSCs;

[5] See http://www.iaea.org/NuclearPower/Downloads/Technology/meetings/2011-Dec-12-16-WS-Paris/2.04-F.FERON-ASN.pdf.

(c) Consideration of the hazards that the construction may induce on the adjacent operating nuclear plants and vice versa;
(d) Industrial safety inspections (safety of workers).

Due to the graded approach, the ASN selects topics of inspection in accordance with the safety, radiation protection or environmental importance of the topics. Some exhaustive inspections are dedicated to some nuclear pressurized components. Figure 3 describes the various inputs used by the ASN to develop and to implement a construction inspection programme.[6]

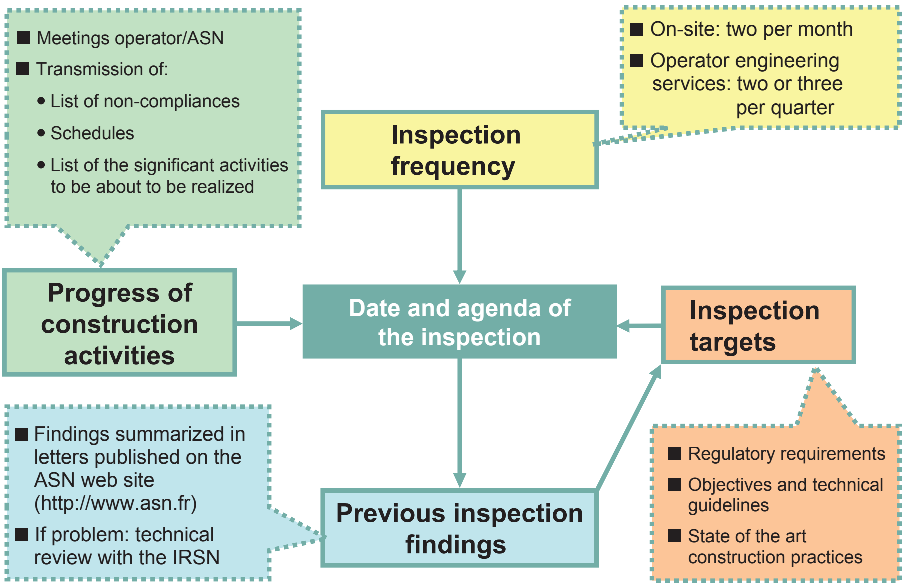

FIG. 3. Inputs into the development of the ASN construction inspection programme.

III.4.1. Inspection frequency

The inspection frequency may be adjusted depending on the volume and diversity of the activities at the site and manufacturer works and in light of findings of completed inspections. The current ASN inspection frequency is around two on-site inspections per month.

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[6] Figure 3 is adapted from http://www.iaea.org/NuclearPower/Downloads/Technology/meetings/2011-Dec-12-16-WS-Paris/2.04-F.FERON-ASN.pdf.

III.4.2. Progress of construction activities

The ASN has frequent contacts with the operator (on-site and at the engineering department level) to be well informed of the progress of current and future planned activities for the site. The operator is also required to report significant events directly to the ASN (including non-nuclear events during construction).

The ASN introduced a 'point de notification' (reporting point) system to allow the ASN to inspect or to observe significant site activities which have been identified by the ASN on the basis of the work schedule submitted by the licensee as required by a licence condition. The operator cannot start an activity which is a point de notification before the date specified to the ASN. The ASN may decide not to inspect or witness a point de notification activity. For the regulation of pressure systems, points de notification are hold points.

There is no predefined hold point: conclusion of assessment of detailed design can be available after construction and manufacture (industrial risk). In case the ASN finds or is informed of significant non-compliances, a hold point may be imposed by the ASN. An ASN agreement is required for the operator to progress activities beyond the hold point.

III.4.3. Inspections targets

On the basis of the major tasks scheduled on Flamanville 3, the ASN uses IRSN input to identify the main relevant safety activities. Moreover, the ASN performs some inspections on operator or manufacturer engineering services to check the detailed design activities process. On-site inspection targets can be:

(a) Civil engineering, including activities relating to reinforcement, concreting and welding, construction joint and pre-stressing system.
(b) Mechanical assembly activities, including initial pipe welding and the tank manufacture activities.
(c) Electrical system assembly activities.
(d) Non-destructive testing and occupational radiation protection.
(e) Organization and management of safety on the construction site and within the operating team for the future nuclear power plant: an inspection target can be the French ministerial order concerning quality management at nuclear facilities, published in 1984.
(f) Impact of the construction site on the safety of the adjacent operating nuclear power plants.
(g) Environmental impact of the construction site.
(h) Emergency response organization and resources.

Regarding SSCs — except nuclear pressure equipment (for which specific regulations apply) — some inspection targets can be the manufacture of components of particular importance for safety, such as the accumulators of the safety injection system (SIS) or components specific to the new nuclear power plant, but also the manufacture of items considered to be more 'conventional' with respect to the nuclear power plants in operation (flow restrictors, diaphragms or electrical cables). During this kind of inspection, the ASN checks the licensee management of the supervision of subcontractors. The inspection takes the form of document reviews, visits to the workshops of the subcontractors and interviews with employees of both the licensee and its subcontractors.

Regarding nuclear pressure equipment construction, the ASN must ensure that conformance to technical documentation during manufacturing meets the requirements in the manufacturer's and the subcontractors' workshops. Before manufacturing begins, the ASN defines an inspection programme for each equipment based on requirements established in ASN Guide No. 8 (regarding conformity assessments) [29]. The ASN can mandate third party bodies to perform inspections.

III.4.4. Inspection findings

Inspection findings are used to assist the inspection planning process and to identify areas where improvements in compliance are desirable or necessary. The IRSN may be required to undertake further technical reviews of findings arising from an inspection.

A database is developed to manage the inspection findings and follow-up. Some inspections are carried out on the basis of this database to ensure that operator commitments are indeed implemented.

III.5. ASN COMMISSIONING INSPECTION PROGRAMME

With regard to the commissioning period, there is no specific requirement in force. Hence, the ASN intends to establish licence conditions related to the preparation and performance of commissioning. Today, the ASN drafts licence conditions to regulate the preparation of commissioning tests and commissioning tests performed before fuel arrival and to set some hold points. Those licence conditions will give a legal basis of activities to be checked during ASN inspections.

The operating licence is required to allow the licensee to introduce fuel in the vessel. In the operating licence, the ASN can set hold points during these commissioning tests. Based on this legal framework, the ASN will perform inspections to:

- Evaluate the process of the testing programme and testing procedures;
- Verify that tests are conducted in compliance with the test procedures and, if required, the general operating rules;
- Verify the safety management system settled by the licensee to go to the next step of the commissioning programme;
- Verify how non-conformances are handled.

Appendix IV

EXAMPLES FROM MEMBER STATE INSPECTION PROGRAMMES: REPUBLIC OF KOREA

Sections of Appendix IV have been adapted from the Notice of the Minister of Science and Technology No. 2001-46 (MOST.reactor.003), Standard Format and Content of Technical Specifications for Operation [30].

IV.1. INSPECTION PROGRAMME FOR A NEW REACTOR

The Atomic Energy Act stipulates that the installer of a nuclear power reactor, before commencing the operation of the nuclear installations, receives the relevant inspection to demonstrate that nuclear installations comply with the comprehensive and systematic safety assessments and safety analysis reports (SARs).

The pre-operational inspection (POI) for the set-up of nuclear installations is conducted to verify whether the nuclear installation is properly constructed in conformity with the conditions of the construction permit and whether the constructed nuclear installation may be operated safely throughout its lifetime. It is conducted for the installations of the SSCs and the performance tests of the facilities by means of a document review and a field inspection. The POI could be, therefore, conducted from the issuance of the construction permit until the demonstration tests for core performance have been completed. In general, it takes about 60 months. The inspection is conducted in steps according to the construction progress. The quality assurance (QA) inspection is also carried out to confirm whether the QA programme submitted by the applicant is implemented in a relevant way.

IV.1.1. Scope of the pre-operational inspection

The purpose of the POI is to confirm whether the SSCs of plants are designed, manufactured, installed and tested in compliance with the SAR and QA programme, and whether the performance of related facilities meets relevant technical requirements. The scope of the POI covers not only the facilities of the safety related functions but also those important to safety. According to the Ministry of Education, Science and Technology (MEST), ‘safety functions’ are defined as:

(a) Ensuring the integrity of the reactor coolant pressure boundary;
(b) Safe shutdown of reactor and maintaining shutdown conditions;
(c) Functions that prevent or mitigate situations that can exceed off-site radiation exposure dose limits.

IV.1.2. Inspection category

The POI is composed of five stages based on the field activities:

(1) Structure inspection;
(2) Installation inspection;
(3) Cold functional test (CFT) inspection;
(4) Hydrostatic test and hot functional test (HFT) inspection;
(5) Initial fuel loading and startup test inspection.

IV.1.3. Structure inspection

The structure inspection begins at the early stage of the site construction, at the time when the foundation excavation has started, and continues along the progress of civil works such as the reinforcing steel installation, the liner plate installation and the concrete placement for major structures. When the construction of the reactor containment has been completed, the inspection on a containment structural integrity test (SIT) and a containment integrated leakage rate test (ILRT) as part of the comprehensive construction tests are performed.

(a) Structures:
   (i) Foundation excavation and treatment works;
   (ii) Permanent dewatering system works;
   (iii) Structure backfill works;
   (iv) Facility waterproof treatment works;
   (v) Rebar installation works;
   (vi) Mechanical rebar splice works;
   (vii) Concrete works;
   (viii) Equipment foundation grout works;
   (ix) Containment post-tension system works;
   (x) Containment liner plate installation works;
   (xi) Steel structure installation works;
   (xii) Stainless liner plate installation works;
   (xiii) Concrete anchor bolt installation works;
   (xiv) Concrete masonry works;

(xv) Seismic qualification inspection;
(xvi) Radiation resistant coating works;
(xvii) Sealing works of safety related openings and penetrations.

(b) Integrated construction test:
   (i) SIT;
   (ii) ILRT.

IV.1.4. Installation inspection

Installation inspection of each facility is conducted when installation, welding, non-destructive tests and pressure tests of components and systems are possible.

(a) Reactor pressure vessel:
   (i) Reactor vessel:
      — Reactor vessel shell;
      — Upper head and its apparatus;
      — Fasteners;
      — Vessel support structure.
   (ii) Reactor vessel internal structure:
      — Upper structure;
      — Lower structure;
      — Core supporting structure.
   (iii) Control element driving mechanism (CEDM).
   (iv) In-core neutron flux instrumentation and its support:
      — In-core neutron flux detector;
      — Lower instrumentation tubing and support.

(b) Reactor coolant system facility:
   (i) Pressurizer:
      — Pressurizer;
      — Pressurizer relief tank;
      — Related piping and valves.
   (ii) Reactor coolant pumps.
   (iii) Steam generator.
   (iv) Coolant piping:
      — Reactor coolant piping.

(c) I&C facility:
   (i) I&C facility:
      — Signal detector, processor and signal line;
      — Signal processing logic and operating facility;

— Indication and monitoring facility;
— I&C cable and cable pat.

(ii) Control board and cabinet:
— Main control board facility;
— Emergency shutdown control panel facility;
— Cabinet facility.

(iii) Man–machine interface facility (human engineering):
— Main control room facility;
— Emergency shutdown facility;
— Safety performance display system.

(d) Fuel material handling and storage facility:

(i) Fuel transfer system:
— Fuel transfer car;
— Fuel transfer tube installation inspection of each facility is conducted when installation, welding, non-destructive test and pressure test of the following items are possible.

(ii) Fuel handling system:
— Crane, hoist and winches;
— Refuelling machine;
— Spent fuel handling machine.

(iii) Fuel storage system:
— New fuel storage rack;
— Spent fuel storage rack and leaktight gate.

(iv) Spent fuel pool cooling and cleanup system:
— Pool cooling and cleanup pump;
— Pool heat exchanger;
— Pool demineralizer, filter, and related piping and valves.

(e) Radioactive waste disposal facility:

(i) Liquid radioactive waste processing system:
— Tank;
— Pump;
— Liquid radioactive waste processing equipment and facility;
— Piping and valves;
— Instruments;
— Radioactive drain facility.

(ii) Gaseous radioactive waste processing system:
— Tank;
— Pump;
— Gaseous radioactive waste processing equipment and facility;
— Piping and valves;
— Instruments.

(iii) Solid radioactive waste processing system:
   — Tank;
   — Pump;
   — Solid radioactive waste processing equipment and facility;
   — Piping and valves;
   — Instruments;
   — Waste storage facility.

(f) Radiation control facility:
   (i) Site radiation monitoring system:
      — Area radiation monitoring device;
      — Process radiation monitoring device;
      — Effluent radiation monitoring device.
   (ii) Radiation control facility:
      — Access control facility;
      — Radioactive sample measuring and analysis laboratory;
      — Radioactive contamination protection facility and decontamination equipment;
      — Radiation measuring device and health physics equipment;
      — Shielding facility.
   (iii) Meteorology monitoring facility:
      — Meteorology monitoring sensor;
      — Meteorology monitoring recorder;
      — Data communication system;
      — Meteorological measurement control system;
      — Emergency backup power.
   (iv) Environment monitoring facility:
      — Environmental radiation survey instrument;
      — Environmental radioactivity counting device;
      — Data communication system;
      — Environment monitoring control system;
      — Emergency backup power;
      — Laboratory.

(g) Reactor containment facility:
   (i) Containment combustible gas control system:
      — Hydrogen recombiner;
      — Hydrogen monitoring system (analyser);
      — Combustible gas mixing facility;
      — Containment ventilation system;
      — Multiple penetration.

(ii) Containment isolation system:
- — Containment isolation valves;
- — Equipment hatch, and personnel and emergency airlocks;
- — Electrical penetrations;
- — Other penetrations.

(iii) Containment spray system:
- — Containment spray pumps;
- — Containment spray chemical additive tanks;
- — Spray educator;
- — Spray nozzle and header;
- — Related piping and valves.

(iv) Containment resident heat removal system:
- — Containment cooling fan;
- — Containment heat exchanger.

(h) Reactor safety system facility:

(i) Residual heat removal system:
- — Residual heat removal pump;
- — Residual heat removal heat exchanger;
- — Related piping and valves.

(ii) Safety injection system (SIS):
- — Safety injection tanks;
- — High pressure and low pressure safety injection pumps;
- — Related piping and valves.

(i) Electric power system facility:

(i) Off-site power system:
- — Switchyard switch gear facility;
- — Switchyard protection facility;
- — Switchyard power supply facility.

(ii) Site alternating current (AC) power system:
- — Emergency (standby, alternative) power supply facility;
- — Generator facility;
- — Transformer facility;
- — Switchgear facility;
- — Uninterrupted power supply facility;
- — Cable and cable path facility.

(iii) Site direct current (DC) power system:
- — Battery and charger facility;
- — Distribution panel facility;
- — Cable and cable path facility.

(j) Power conversion system facility:

(i) Main steam system:
- — Main steam line;
- — Main steam isolation and bypass valve;
- — Flow restrictors;
- — Main steam safety valve;
- — Main steam atmospheric dump valve;
- — Turbine bypass valve;
- — Related piping and valves.

(ii) Steam generator blowdown system:
- — Regenerative heat exchanger;
- — Non-regenerative heat exchangers;
- — Flash tanks;
- — High capacity blowdown transfer pumps;
- — Filters;
- — Ion exchanger;
- — Related piping and valves.

(iii) Feedwater and condensate system:
- — Condensate storage tank;
- — Condensate water pump;
- — Main feedwater pump;
- — Main condenser;
- — Circulating water pump;
- — Steam jet air ejector;
- — Condensate water demineralizer;
- — Main feedwater heater;
- — Main feedwater control and isolation valve;
- — Related piping and valves.

(iv) Auxiliary feedwater system:
- — Motor driven pumps;
- — Turbine driven pumps;
- — Related piping and valves.

(v) Turbine and turbine auxiliary system:
- — Turbine;
- — Turbine stop and control valves;
- — Turbine control oil pump and tank;
- — Moisture separator reheater;
- — Turbine control and safety facility;
- — Turbine integrity;

- Turbine lubrication oil pumps and tanks;
- Moisture separator and exhaust line;
- Related piping and valves.

(vi) Generator and related system:
- Generators (mechanical parts);
- Generator cooling system;
- Related piping and valves.

(vii) Auxiliary steam system:
- Boiler;
- Related piping and valves.

(k) Other facilities related to safety of a nuclear reactor:

(i) Service water system facility:
- Essential service water system: essential service water pump, travelling screen, related piping and valves;
- Component cooling water system: component cooling water pump, heat exchanger, surge tank, chemical addition tank, related piping and valves;
- Essential chilled water system: pump, chiller, air separator, compression tank, related piping and valves.

(ii) Heating, ventilation and air conditioning (HVAC) system facility:
- Main control room;
- Auxiliary building;
- Fuel building;
- Engineered safety facility;
- Containment;
- Radioactive waste building, blower, chiller, filter, duct and damper.

(iii) Auxiliary system facility:
- Compressed air system: air compressor, dryer, service and instrument air piping, storage tank, related piping and valves;
- Chemical and volume control system: regenerative heat exchanger, letdown heat exchanger, seal water injection heat exchanger, ion exchanger, volume control tank, chemical additive package, boric acid tank, charging pumps and boric acid make-up pump, reactor make-up water pump and storage tank, refuelling water storage tank, related piping and valves;
- Fire protection system: fire barrier, fire suppression facility, fire detection and alarm facility, related piping and valves;
- Diesel generator fuel storage and transfer system: diesel engine and auxiliary system, diesel generators, fuel oil storage tanks, fuel oil transfer pumps, related piping and valves;

— Seismic monitoring system: seismic monitoring sensor, seismic monitoring recorder, seismic monitoring control system.

IV.1.5. Cold functional test inspection

The objective is to confirm whether components and systems important to safety are properly installed and ready to operate in a cold condition. At the component level, the functionality that can be measured by physical instrumentation or observation can be checked:

(a) Reactor pressure vessel:
  (i) Core operating limit supervisory system test;
  (ii) Core protection calculator test;
  (iii) Comprehensive vibration assessment programme.
(b) Reactor coolant system facility:
  (i) Reactor coolant gas vent system test;
  (ii) Reactor coolant pump vibration monitoring system test;
  (iii) Loose part monitoring system test;
  (iv) Acoustic leak monitoring system test;
  (v) Reactor internal vibration monitoring system test.
(c) I&C system facility:
  (i) Engineered safety features actuation system test;
  (ii) Reactor regulating and reactor power cutback system test;
  (iii) Instrument correlation test;
  (iv) Reactor regulating system test;
  (v) Diverse protection system test;
  (vi) Plant protection system response time measuring test;
  (vii) Plant protection system test;
  (viii) Inadequate core cooling monitoring system test;
  (ix) Pressurizer pressure and level control test;
  (x) Ex-core nuclear instrumentation system test;
  (xi) Turbine control and protection system test;
  (xii) Feedwater control system test;
  (xiii) Steam bypass control system test.
(d) Fuel material handling and storage facility:
  (i) Spent fuel pool cooling and cleanup system test;
  (ii) Fuel transfer system and transfer tube test;
  (iii) Control rod exchange system test;
  (iv) Spent fuel handling crane test;
  (v) Refuelling machine test;
  (vi) Spent fuel pool leaktight gate.

(e) Radioactive waste disposal system facility:
  (i) Liquid radioactive waste system test;
  (ii) Gaseous radioactive waste system test;
  (iii) Solid radioactive waste system test.

(f) Radiation control facility:
  (i) Radiation monitoring system test (process, criticality, effluent and area radiation monitoring system);
  (ii) Personal monitoring and radiation survey instrument test;
  (iii) Radiation/radioactivity counting device test;
  (iv) Meteorological monitoring system test;
  (v) Environment monitoring system test.

(g) Reactor containment facility:
  (i) Containment local leakage rate test;
  (ii) Containment ventilation system test;
  (iii) Containment spray system test;
  (iv) Containment fan cooler test;
  (v) Combustible gas control system test.

(h) Reactor safety system facility:
  (i) Safety injection tank test;
  (ii) High pressure SIS test;
  (iii) Low pressure SIS test;
  (iv) Shutdown cooling system test.

(i) Electric power system facility:
  (i) Mechanical and electrical system test of the emergency (standby and alternative) diesel generator;
  (ii) AC power system test;
  (iii) DC power system test;
  (iv) Uninterrupted power supply system test;
  (v) Generator facility system test;
  (vi) Transformer facility system test;
  (vii) Switchyard facility system test;
  (viii) Reactor trip switch gear test.

(j) Power conversion system facility:
  (i) Main steam system test;
  (ii) Steam generator blowdown system test;
  (iii) Main feedwater and condensate water system test;
  (iv) Auxiliary feedwater system test;
  (v) Turbine and turbine auxiliary system test;
  (vi) Turbine control fluid system test;
  (vii) Generator auxiliary system test;
  (viii) Auxiliary steam system test.

(k) Other facilities related to the safety of a nuclear reactor:
   (i) Service water system:
      — Essential service water system test;
      — Component cooling water system test;
      — Essential chilled water system.
   (ii) HVAC system facility:
      — Control room;
      — Auxiliary building;
      — Fuel building;
      — Engineered safety features;
      — Containment;
      — Radioactive waste building.
   (iii) Auxiliary system facility:
      — Compressed air system;
      — Sampling system;
      — Chemical and volume control system;
      — Fire protection system;
      — Fire detection and alarm system;
      — Diesel generator fuel system test.
   (iv) Containment polar crane.
   (v) Seismic monitoring system.

IV.1.6. Hydro test and hot functional test inspection

As soon as the CFT has been completed, the system integrity tests, such as hydropressure tests for primary and secondary systems, should be conducted. The secondary hydro test is conducted for confirming the structural integrity of the secondary systems, covering the area from steam generator tube to main steam isolation valves. It is followed by the primary hydro test. When the integrity of the primary and secondary systems are confirmed, they should undergo HFTs to determine whether the system integrity and functionality comply with appropriate specifications at a temperature of normal operating conditions.

(a) Hydrostatic test:
   (i) Reactor coolant system hydrostatic test;
   (ii) Steam generator secondary side hydrostatic test.
(b) Hot functional test:
   (i) Reactor pressure vessel:
      — Reactor internal vibration assessment test.
   (ii) Reactor coolant system facility:
      — Normal and transient condition vibration test of piping systems;

— Expansion and restriction of piping and systems;
— Reactor coolant pump sealing and cooling function test;
— Primary pressure relief system test.

(iii) I&C system facility:
— Instrument correlation test;
— Control element driving mechanism (CEDM) function test;
— Integrated test of engineered safety feature system;
— Inadequate core cooling monitoring system test;
— Remote shutdown control panel test.

(iv) Fuel material handling and storage facility (not applicable).

(v) Radioactive waste disposal system facility (not applicable).

(vi) Radiation control facility (not applicable).

(vii) Reactor containment facility (not applicable).

(viii) Reactor safety system facility:
— SIS test;
— Shutdown cooling system test.

(ix) Electric power system facility (not applicable).

(x) Power conversion system facility:
— Main steam system test;
— Steam generator blowdown system test;
— Main feedwater and condensate water system test;
— Auxiliary feedwater system test;
— Turbine and turbine auxiliary system test.

(xi) Other facilities related to the safety of a nuclear reactor:
— Service water system facility;
— HVAC system facility (not applicable);
— Auxiliary system facility (sampling system test, and chemical and volume control system test).

IV.1.7. Initial fuel loading and startup test inspection

Once the functionality and integrity are verified through the previous two system tests, the regulatory authority — Korea Institute of Nuclear Safety (KINS) — can make decision on issuing the operation licence based on both the safety review results of final safety analysis report and the inspection results conducted all throughout the construction phases including CFT and HFT. When the operation licence is granted, the operator can proceed to load fuel into the reactor and continue for core physics and power ascension tests. There are 33 inspection items:

— Initial fuel loading;
— Initial criticality test;
— Core performance assessment test;
— Axial xenon oscillation test;
— Moderator temperature reactivity coefficient;
— Rod worth;
— Boron reactivity worth measurement;
— Initial critical boron concentration;
— Power reactivity coefficient assessment and power defect measurement;
— Reactor coolant system flow measurement test;
— Unit load transient test;
— Reactor internal vibration monitoring test;
— Loose part monitoring system test;
— Acoustic leak monitoring system test;
— Reactor coolant pump vibration monitoring system test;
— Reactor coolant system hydrostatic test;
— Pressurizer function test;
— Natural circulation test;
— Post-core loading CEDM function test;
— Power ascension test and instrument correlation test;
— Core function test in case of control rod drop and ejection;
— Core protection system test;
— Chemical and radiochemistry tests;
— Neutron and gamma radiation level measuring and shielding capability test;
— Turbine trip test;
— Reactor power cutback system test;
— Plant shutdown from outside the control room;
— Loss of off-site power test;
— Load rejection test for each power level;
— Control system checkout test;
— Atmospheric dump valve and steam bypass valve capacity test;
— Main feedwater control valve transfer test;
— Main turbine protective function test.

IV.1.8. Inspection criteria

Regulations on the technical standards for reactor facilities, MEST notices, Korea Electric Power Industry Code (KEPIC) and the technical standards of other Member States, Canada, France and the United States of America, which furnished their reactor types to the Republic of Korea, are employed as the inspection criteria. KEPIC was developed in 1995 by the Korea Electric

Association (KEA) based on industrial codes and standards in the United States of America.

IV.1.9. Inspection methods

Generally, inspection activities consist of the pre-inspection preparation and the on-site inspection stage. The on-site inspection includes the review of quality related records generated during construction, the witness of construction works or tests, and interviews with plant staff.

At the inspection preparation stage, a preliminary review of regulatory requirements and collected data is conducted. The following documents are usually reviewed:

- Regulatory requirements (regulations on technical standards, and regulatory guidelines);
- Safety analysis report and related safety evaluation reports;
- Construction specifications and procedures;
- Applicable technical standards and standard requirements;
- Reports describing major problems found during previous POIs.

More attention is paid to new equipment and construction methods that are firstly introduced. The major issues raised during the construction permit review should be carefully examined to confirm whether the commitments are implemented in an appropriate way. The inspectors should also keep aware of the important issues identified during the inspection of previous plants, the revised requirements of regulatory guidelines and technical standards, and licensee's corrective actions for non-conformance items.

IV.2. APPLICATION OF A GRADED APPROACH

KINS applies a graded approach to inspections (see also Table 1):

(a) Safety classification 1 and 2 (100%):
  (i) Procedures;
  (ii) Test results;
  (iii) Witness hold points;
  (iv) Documentation;
  (v) Technical qualifications;
  (vi) Methodology.

TABLE 1. KINS APPLICATION OF A GRADED APPROACH TO INSPECTIONS

Safety classification verified by the regulatory body	Comprehensive control	Technical control by sampling	Management system audit	Focused audit	Reactive intervention	Regulatory body	Third party/inspection organization	Lincensee
1	X		X		X	X		X
2	X	X	X		X	X	X	X
3		X		X			X	X
Non-safety				X				X

(b) Safety classification 3 (sampling informed by past construction experience and reliance on licensee implementation of QA):
    (i) Example of polar crane: KINS will verify certain aspects of documentation, such as leveling of crane and technical qualifications.

Suggested practice to have the transition from construction to commissioning be controlled and documented by the licensee should involve the construction and the commissioning organizations of the licensee. This process may be subject to regulatory inspection and verification.

Pre-operational testing consists of tests conducted following completion of construction and construction related inspections and tests, but prior to fuel loading, to demonstrate — to the extent practical — the capability of SSCs to meet the performance requirements to satisfy the design criteria. 'Initial startup testing' consists of test activities that are scheduled to be performed during and following fuel loading. These activities include fuel loading, practical tests, initial criticality, low power tests and power ascension tests.

(a) Inspection of the structures of a nuclear reactor facility is conducted at commencement of inspection items and when verification of main processes is possible. Inspection of integrated leakage rate tests of containment is conducted when the review of test procedure such as leakage rate calculation methodology and test are possible.
(b) Installation inspection of each facility is conducted when installation, welding, non-destructive test and pressure tests are possible.
(c) Inspection of CFT of each facility is conducted when tests are possible.
(d) Inspection of hydrostatic test and HFT is conducted when tests are possible.
(e) Inspection of initial fuel loading and commissioning test is conducted when tests are possible.
(f) KINS requires the licensee to submit test procedures six months prior to commencing the tests.

Appendix V

EXAMPLES FROM MEMBER STATE INSPECTION PROGRAMMES: PAKISTAN

The legal framework (PNRA Ordinance) provides legal power to the Pakistan Nuclear Regulatory Authority (PNRA) to conduct inspections and take enforcement actions as required. The licensing regulations provide a more detailed framework for regulatory inspections during all licensing stages, including provisions for obtaining services of consultants for inspections. The PNRA performs regulatory inspections according to its inspection programme, which is also made available for the licensees. The programme is supplemented by detailed inspection plans, management and technical procedures, checklists and inspection guidelines. Detailed criteria have been established for inspectors' qualifications, and all inspections are conducted by PNRA inspectors.

The PNRA performs management system inspections as well as inspections of technical areas. In addition, the PNRA performs general surveillances during all stages of the licensing process. The licensees are required to provide the necessary documentation and information about the schedule of their activities in advance to facilitate regulatory inspections. The main features of PNRA inspection activities during various licensing stages are described in the following subsections.

V.1. SITING INSPECTIONS

During the siting stage, the PNRA performs management system inspections of the applicant to verify effectiveness of the system for conducting site evaluation.

V.2. CONSTRUCTION INSPECTIONS

The construction inspections include inspections of the management system once every two years and technical inspections at the construction site (civil construction, installation of electrical, I&C, and mechanical equipment and systems) and at equipment manufacturing sites. The on-site inspections are conducted by PNRA regional offices, which are located at nuclear power plant sites, whereas the inspections of equipment manufacturing are controlled by the headquarters. Generally, PNRA inspection activities mainly focus on seismic category I structures, safety class (SC) 1 and 2 mechanical equipment/systems, and SC 1E electrical and I&C equipment and systems by applying a graded approach based on safety significance and complexity.

The inspections at a construction site include daily general surveillance and control point inspections (hold, witness and record points). The licensees are required to provide quality plans of construction and installation activities for selection of inspection control points by the PNRA. Accordingly, the licensee informs the PNRA of the schedule of selected activities in advance. The items for technical inspections during equipment manufacturing are identified during the review of the construction licence application. The licensee is required to arrange PNRA inspections for this identified equipment and provide quality plans for the selection of specific items for inspection. The licensee is further required to provide the necessary documentation for inspections a few months in advance (generally three months), serve a tentative notice about one month in advance and a final notice one week prior to the inspection date.

V.3. COMMISSIONING INSPECTIONS

The PNRA performs management system inspections before the start of commissioning and mid-way during commissioning tests, control point inspections (hold, witness and record points), inspections of test results to allow the advancement from one substage to the next, and general surveillance. In addition, the PNRA performs inspection of the transfer of responsibility from construction to commissioning and to operating organizations to verify systematic and smooth transfer and effectiveness of the licensee's management system.

During the review of the commissioning programme, the PNRA selects commissioning tests for control point inspections. Hydrostatic test of reactor coolant system, containment leakage rate and integrity test, fuel loading, initial criticality and some other important activities are selected as PNRA hold points. As a condition to the authorization issued for commissioning, the licensees are required to obtain PNRA written approval to advance from one commissioning substage to the next. The approval is given after reviewing the test reports for the preceding stage and ensuring that the results are acceptable and no outstanding items are left. General surveillances are conducted on a daily basis.

V.4. PNRA INSPECTION PROGRAMME

The main content of the PNRA inspection programme includes:

— Objective;
— Scope;
— Inspection organization (responsibilities, authorities, interfaces and line of communication);
— Inspection policy;
— Types of inspection (planned and reactive inspections, both announced and unannounced);
— Selection of inspection areas;
— Relationship with licensee;
— Guidance on the preparation of the inspection plan for various licensing stages;
— Guidance for inspectors;
— Inspectors' qualification requirements;
— Description of inspection methods;
— Inspection reports (including contents of report), follow-up and closure;
— Assessment of the inspection programme.

V.5. PAKISTAN ENFORCEMENT PROCESS

The legal framework — the PNRA Ordinance — provides power to the PNRA to conduct inspections and take enforcement actions, as required. The Pakistan Nuclear Regulatory Authority Enforcement Regulations — (PAK/950) provide a more detailed framework of enforcement actions. Enforcement actions include: suspension or cancellation of authorization or licence, penalties and imprisonment, depending on the severity of the offences.

In case of information regarding non-compliance of safety requirements by a licensee, the director or any other official designated by the PNRA sends a notice to the licensee to obtain information to ascertain whether the provisions of the PNRA Ordinance or the rules and regulations or terms and conditions of the licence have been, or are being, adequately complied with. The concerned person is bound to facilitate and to provide the PNRA inspector all relevant data, records, information and full access to the necessary areas to perform the duties and functions without any obstruction, hindrance or delay. The reply has to be given within the time frame stipulated in the notice. However, if the PNRA does not receive any reply to the notice within 30 days of its serving, it may issue a show cause notice.

Every person related to a facility or activity, whether licensed or unlicensed, is bound to assist the inspector. The inspector may seek assistance of the local police in case of any resistance during entry and inspection. In case of locked premises, efforts will be made to inform the owner before entering the premises with the help of local police. An inspector who determines that the provisions of the PNRA Ordinance or the rules and regulations or terms and conditions of the licence and directives have not been, or are not being, complied with, may submit a report to the director concerned for an assessment of violation.

The director considers the report of violation and the documents submitted by the inspector. The director considers the following factors, among others: safety significance of the violation; effectiveness of physical protection; repeatability of violation; whether the cause is due to negligence, deliberate or wilful; and the past performance and record of the violator.

After considering the report of violation and the documents, the director will assess the violation or constitute a committee for the assessment of violation. After the assessment, the director may issue a show cause notice on behalf of the PNRA or issue a final directive to the licensee, or the authorization holder, to rectify the violation or to submit a compliance report with terms and conditions of the licence or the authorization, within a specified period. The director may even reject the violation report. The show cause notice is preferably to be drafted by a legally qualified person. The director, on receipt of reply to show cause notice, assesses whether to accept or to reject the reply.

A licence or an authorization may be suspended or cancelled if the licensee or authorization holder has violated, breached, defaulted in payment of fee or not complied with any provision of the PNRA Ordinance or the rules and regulations or terms and conditions of the licence, authorization or any other directive issued by the PNRA.

In case of rejection of the reply or no reply by the violator, the director may refer the matter to the PNRA Director General (Inspection and Enforcement) — DG (I&E) — who may:

- Seek assistance of a legal consultant or technical expert for evaluation of the reply to the show cause notice;
- Accept or deny the violator’s reply;
- Call for comments before the conduct of hearing;
- Cause a notice of hearing to the violator.

The same is communicated to the persons concerned a minimum seven days prior to the date of the hearing.

The DG (I&E) conducts the hearing on the date and time as communicated to the parties. It may conclude the hearing in a single day or, if required, adjourn it to such subsequent dates as it may deem necessary. Where the violator is a licensee or authorization holder and the DG (I&E) has determined and decided that contravention of the PNRA Ordinance has taken place or the violator has consistently failed to comply with the rules and regulations or terms and conditions of the licence or authorization or the directives, the DG (I&E) may, on behalf of the PNRA, suspend or cancel the licence or authorization.

The DG (I&E) may, after the pronouncement or issuance of a decision, cancel the decision, provided that the violator has rectified the violation to comply with the terms and conditions of the licence or authorization and such action has been verified by the DG (I&E) through its own means.

If the licence is cancelled or suspended, the DG (I&E) may take all or any of the actions specified in the PNRA Ordinance. In the case of non-compliance of PNRA orders, the DG (I&E) or the director of the concerned directorate may forward the report to the registrar for filing the complaint for prosecution pursuant to the PNRA Ordinance.

Appendix VI

EXAMPLES FROM MEMBER STATE INSPECTION PROGRAMMES: UNITED STATES OF AMERICA

Sections of Appendix VI have been adapted from NRC Inspection Manual Chapter 2506, Construction Reactor Oversight Process: General Guidance and Basis Document [31].

The Nuclear Regulatory Commission (NRC) inspection programme is its principal process for collecting information about licensee performance. NRC inspectors perform a fundamental role in collecting this information and in determining whether or not licensees operate their plants safely and in accordance with their regulatory requirements and commitments. The NRC has resident inspectors assigned to each plant and construction site and augments the inspections, as appropriate, by sending additional inspectors from NRC regional offices and headquarters.

VI.1. NEW NUCLEAR POWER PLANT CONSTRUCTION INSPECTION PROGRAMME

The construction inspection programme (CIP) for new reactors provides reasonable assurance that the facility has been constructed and will be operated in conformity with the licence and NRC rules and regulations — recognizing that the NRC has finite inspection resources. The CIP for new reactors is based on inspections of the Inspections, Tests, Analyses and Acceptance Criteria (ITAAC) and construction and operational programmes which are identified in the licensee's combined licence (COL). The inspection programme is discussed in greater detail in the NRC Inspection Manual Chapter (IMC) 2503 [32], and IMC 2504 [33]. IMC 2503 and 2504 inspections continue until the 10 CFR 52.103(g) finding has been made by the NRC.

The ITAAC inspection philosophy contained in IMC 2503 [32] recognizes that several ITAAC are expected to be closely related, thereby providing the NRC with the opportunity to evaluate a group of ITAAC based upon an examination of some representative ITAAC within the group. Such an inspection approach would allow for the efficient use of NRC inspection resources, not only for ITAAC examinations but also for the routine evaluation of the construction processes that result in ITAAC products and completion.

To direct and to govern this ITAAC focus, a methodology was developed using a sampling inspection approach. Based upon an analysis and estimate of the NRC inspection resources required to review and to conduct direct inspection of ITAAC related work for two certified designs — the Advanced Passive 1000 (AP1000) and the Advanced Boiling Water Reactor (ABWR) — it was determined that the CIP would rely on an ITAAC sampling inspection process. This decision was based on the view that complete coverage and direct inspection of the activities associated with the entire population of the AP1000 and ABWR ITAAC is an inefficient and unnecessary use of dedicated NRC inspection resources. In order to facilitate the use of sampling inspections to confirm adequate licensee control and completion of ITAAC, an inspection planning tool called the ITAAC Matrix was developed. The sampling methodology and the ITAAC Matrix are described in detail in appendix B of IMC 2506 [31] and in IMC 2503 [32].

IMC 2504 [33], which was conducted in parallel with IMC 2503 [32], defines the inspection programme for the evaluation of the licensee's construction programmes, including: quality assurance (QA); ITAAC closure and security (including Fitness For Duty); operational programmes prior to fuel load; and pre-operational testing. The purpose of construction programme inspections is to verify that the licensee has programmes established and implemented to:

(a) Control construction activities at the site;
(b) Identify problems and resolve them;
(c) Report deficiencies and identify failures to do so;
(d) Ensure design requirements are translated to construction documentation;
(e) Ensure the adequacy of ITAAC determination packages for submittal to the NRC;
(f) Ensure the adequacy of the pre-operational testing programme.

The purpose of operational programme inspections is to verify that operational programmes required for low power testing have been established and are being implemented, to the degree required, in accordance with the COL conditions related to operational programmes, and to determine the operational readiness of a plant licensed in accordance with 10 CFR 52.103(g). Completion of this phase of the CIP is intended to provide the NRC with reasonable assurance that the facility is constructed and will operate in conformity with the licence. Inspections related to IMC 2503 [32] and 2504 [33] will end when the NRC has made its finding that all acceptance criteria in the COL are met.

VI.2. BASELINE INSPECTION PROGRAMME FOR CONSTRUCTION INSPECTIONS

The overall objectives of the baseline inspection programme are (a) to provide a sufficient basis to support the NRC determination, in accordance with 10 CFR 52.103(g), that the acceptance criteria in a COL have been met; and (b) to develop confidence in the licensee's programmatic controls. To meet the first objective, the baseline programme is designed to give confidence that licensee ITAAC completion and verification processes are effective and provide reasonable assurance that licensee ITAAC completion notifications are sufficient and accurate. To meet the second objective, the baseline programme confirms an adequate level of quality in construction products and verifies that operational programmes are consistent with the final safety analysis report.

In implementing these objectives, the programme allows for flexible scheduling to permit the adjustment, including expansion or reduction of inspection scope, and includes ITAAC across a full range of significance, with effort being weighted toward those with higher significance. The baseline inspection programme also informs the NRC of the status of operational programmes before the anticipated date for loading fuel.

The baseline inspection programme delineates specific inspection activities to evaluate aspects of the licensee's programmes and processes and their implementation by identifying findings that are indicative of licensee performance problems. Inspection findings from the baseline programme are evaluated for significance and used to assess licensee performance. The baseline inspections are not diagnostic assessments of licensee performance, leading to a root cause determination. Those assessments and root cause determinations are intended to be reviewed or independently made during supplemental inspections that are outside the scope of the baseline inspection programme. The baseline inspection programme is risk informed. The risk informed approach means that inspectable areas were selected based partly on their significance from a risk perspective. Risk has been factored into the baseline inspection programme primarily by ranking ITAAC.

VI.3. PLANT SPECIFIC SUPPLEMENTAL AND REACTIVE INSPECTIONS

Plant performance is assessed using IMC 2505 [34]. Plants whose performance is outside the licensee response band in the construction action matrix will receive plant specific supplemental inspections based on their assessed performance. The depth and breadth of specific supplemental inspections chosen for implementation will depend upon the significance of the identified issues and will be conducted pursuant to the inspection procedure specified in the construction action matrix. In addition, staff may conduct reactive inspections in response to non-performance events and issues that occur at the facility. Reactive inspections include inspections required for allegation response and event follow-up. Guidance for reactive inspections is in IMC 2504 [33].

The OECD Nuclear Energy Agency reports that the NRC assigns at least two resident inspectors to each operating reactor and construction site [35]. Their primary job is to observe, evaluate and to report on the adequacy of licensee nuclear safety activities, concentrating on day-to-day licensee operations, event follow-up activities, and licensee activities and processes important to safety and reliability. In addition, they coordinate on-site activities of the various agency offices and participate in emergency exercises. Resident inspectors carry out the major part of the baseline inspection programme and participate in other inspections at their assigned site.

Vendor and contractor inspections may be planned or reactive in nature and determine whether suppliers of materials, components, and services used in nuclear power plants are complying with NRC requirements. As stated in Working Group on Inspection Practices: Nuclear Regulatory Inspection of Contracted Work Survey Results [36], the NRC has the authority under the Energy Reorganization Act of 1974 to perform inspections of records, components, systems, and of the premises of organizations (i.e. vendors and contractors) providing components or activities important to safety to oversee the commercial nuclear industry to determine whether its requirements are being met by licensees and their contractors. However, the NRC does not perform routine periodic audits or inspections of vendors or contractors. Rather, the majority of the effort to ensure compliance with the regulations is performed by the licensees. The licensee is responsible for developing and maintaining a detailed QA plan in accordance with 10 CFR Part 50 Appendix B requirements. Through a system of planned and periodic audits and inspections, licensees are responsible for ensuring that suppliers, contractors and vendors have suitable and appropriate QA programmes that meet NRC requirements, guides, codes and standards. Although the NRC does not routinely inspect suppliers, contractors or vendors, it does perform inspections if there is an allegation implicating these entities and the allegation has some merit for further investigation.

Reactor operator licensing requalification inspections were implemented as part of the Fiscal Year 1994 amendment to the NRC's operator licensing regulations. The NRC uses this performance based inspection programme to evaluate licensee examination and training programmes and to improve operational safety through early identification and correction of programmatic weaknesses [35].

VI.4. TRANSITION FROM CONSTRUCTION TO OPERATION

Towards the end of the construction, the licensee will complete all ITAAC and notify the NRC that this has been done. At this time, the NRC will verify that all ITAAC have been completed and issue a notification to the licensee that they may load fuel in accordance with their licence requirements and federal regulations. At this point, the new reactor site becomes an operational reactor and will proceed to load fuel and perform all the necessary startup related programmes.

The NRC resident staff will make the transition from construction residents to operational residents upon the NRC finding. Inspector overlap will occur for a sufficient amount of time to ensure a seamless transition. It is expected that operational residents will be on-site for some time before the authorization to load fuel occurs, and the construction resident inspectors will remain on-site to assist the operational residents as they take over the primary inspection responsibility.

Appendix VII

EXAMPLES FROM MEMBER STATE INSPECTION PROGRAMMES: CANADA

Sections of Appendix VII have been adapted from the Canadian National Report for the Convention on Nuclear Safety: Sixth Report [37].

Section 26 of the Nuclear Safety and Control Act (NSCA) prohibits any person from preparing a site, constructing, operating, decommissioning or abandoning a nuclear facility without a licence granted by the Canadian Nuclear Safety Commission (CNSC) Tribunal. Subsection 24(4) of the NSCA states the following:

> "No licence shall be issued, renewed, amended or replaced…unless, in the opinion of the Commission, the applicant…:
> (a) is qualified to carry on the activity that the licence will authorize the licensee to carry on; and
> (b) will, in carrying on that activity, make adequate provision for the protection of the environment, the health and safety of persons and the maintenance of national security and measures required to implement international obligations to which Canada has agreed."

Subsection 24(5) of the NSCA gives the CNSC Tribunal the authority to include in licences any term or condition that it considers necessary for the purposes of the NSCA.

Section 30 of the NSCA authorizes CNSC staff to carry out inspections to verify licensee compliance with regulatory requirements, including any licence conditions. Licensees are expected to have a set of programmes and processes in place to adequately protect the environment, and the health and safety of workers and the public.

The CNSC licensing system is administered in cooperation with federal, provincial and territorial government departments and agencies in such areas as health, environment, aboriginal consultation, transport and labour. Before the CNSC issues a licence, the concerns and responsibilities of these departments and agencies are taken into account in the licensing basis. Where necessary, agreements may be set up between the CNSC and those departments and agencies to determine roles and responsibilities for inspection activities where the licensee is concerned.

If the CNSC Tribunal decides to issue a licence, any of the information submitted with a licence application that is referenced in the licence becomes a legal requirement for the licensee. This ties the regulatory review to regulatory inspection work. Licences may also contain other terms and conditions, such as references to standards, which licensees must meet. For reactor facilities, this information is organized into logical groups called Safety and Control Areas (SCAs) within the licence. CNSC compliance verification activities (including inspections) are derived from these SCAs and are specific to each licensee and licensing phase.

Each facility licence is accompanied by a licence condition handbook (LCH), which contains the acceptance criteria used to confirm compliance with the licensing basis for that specific facility.

In the CNSC lexicon, the IAEA term 'inspection' is known as 'verification of compliance' and includes all the activities related to determining and documenting whether a licensee's programmes and performance comply with legal requirements and conform to acceptance criteria. Compliance verification activities are primarily focused on the licensee, including the licensee's management system and oversight over all activities performed by contractors. Compliance with the licensing basis for the facility is measured against the criteria contained in the LCH. Verification activities include the following:

(a) **Type I inspections** are highly planned and detailed inspections which consist of audits of licensee programmes or processes and their implementation.
(b) **Type II inspections** focus on the performance or output of the programmes or processes, including rounds, routine system inspections and surveillance.
(c) **Desktop reviews** include reviewing licensee documents such as the station safety analysis reports and event reports.

Inspections typically include interviews with responsible licensee staff, reviews of documentation, data, logs, event reports and field component line-up checks. Some inspections monitor licensee activities as they unfold (e.g. exercises or outages).

In consultation with the licensee, CNSC staff establish performance objectives and criteria for all of the SCAs covered by the licence to clearly communicate the outcomes expected of the licensee at the programme level and how these outcomes will be evaluated. Criteria represent a set of specific licensee programme outputs or 'measurables' which can be used to determine whether an objective is being met.

In general, acceptance criteria that can be used to assess compliance may be derived from one or more of the following:

(a) Legal requirements;
(b) CNSC documents that clarify how the CNSC Tribunal intends to apply the legal requirements;
(c) Information supplied by licensees to the CNSC Tribunal defining how they intend to meet legal requirements in performing the licensed activity;
(d) CNSC staff's expert judgements, including knowledge of industry best practices.

While most inspections are planned and scheduled with licensees, inspectors have and do use the power to conduct unscheduled inspections, in reaction to events or other findings.

To help achieve regulatory effectiveness, efficiency, consistency and clarity, the CNSC compliance programme uses a planned set of baseline activities. The baseline set is established by identifying a group of Type I and Type II inspections as well as promotion activities and desktop reviews for a typical facility and operations. The baseline set is subsequently refined to represent a reasonable set of inspections for a licensee having acceptable ratings in the safety areas during the preceding period.

For nuclear power plants, the baseline regulatory activities take place over a schedule of five years, the typical licence duration for this type of facility. For safety areas where the licensee does not meet acceptable compliance and safety standards, risk management principles are used to identify focused activities that CNSC staff will undertake in the next period to supplement the baseline inspections. Monitoring includes the quarterly review of results of all verification activities. This represents a risk informed approach to inspection that has worked well for the CNSC and was seen by the 2009 IRRS Mission to Canada as a "good example of optimization of regulatory resources to encourage licensees to improve their regulatory performance" [38].

The CNSC management system contains a core process called 'assure compliance' which is further broken down into four subprocesses:

- Plan compliance activities;
- Conduct compliance verification;
- Execute graduated enforcement;
- Analyse and report on compliance.

Under conduct compliance verification, the CNSC employs a process document entitled Overview of: Conducting an Inspection [39] to describe the consistent, systematic approach to conducting inspections. This process describes the boundaries for conducting inspections at the CNSC and includes activities starting from planning an inspection and confirming the scope to issuing the final inspection report.

With regard to newly built small reactors and nuclear power plants, the CNSC is, as a matter of regulatory efficiency, in the process of establishing requirements, guidance and inspection activities to assess how the licensee is executing licensed activities to be ready for future licensing stages. For example, the licensee's performance under the licence to prepare a site will be used, in addition to licensing submissions, to predict the performance of the licensee under a future licence to construct. Performance under the licence to construct would inform prediction of the licensee's performance under a licence to operate. For example, during facility construction, the licensee will most likely establish their operator headcount through an operator training programme, the regulatory body may comment on any gaps that may exist as the licensee prepares to make the transition to facility operation under an operating licence.

The results from compliance verification activities are communicated as expeditiously as possible to the licensee for action, where necessary, but results also feed into the safety performance indicators for the licensee, which are regularly reported to the CNSC in a public forum.

Appendix VIII

EXAMPLES FROM MEMBER STATE INSPECTION PROGRAMMES: UNITED ARAB EMIRATES

VIII.1. PROGRAMME MANAGEMENT AND COORDINATION

The Federal Authority for Nuclear Regulation (FANR) Department of Nuclear Safety has the responsibility for managing and coordinating implementation of the construction inspection programme (CIP) for Barakah.

The other departments in the operations division will be responsible for supporting and conducting inspections for their assigned area. A senior project management specialist will be assigned to plan and schedule the needed inspections at Barakah. In addition, the aim is to assign a lead inspector for each of the major functional areas to coordinate inspection activities, perform as a team leader for the associated inspections, integrate findings to identify performance issues, verify that problem areas are addressed, and ensure the baseline inspections are completed on a project basis. The subject matter experts that have been associated with the review of the plant design and requirements will be included in the inspection teams to provide the required technical support.

The major functional areas needing a lead inspector include:

- Management system/QA;
- Vendor;
- Civil/structural;
- Electrical/I&C;
- Mechanical;
- Welding/non-destructive examination;
- Radiation protection;
- Environmental protection;
- Emergency response;
- Security;
- Operations.

VIII.2. PROGRAMME DESCRIPTION AND SCOPE

The details of the CIP implementation are discussed in the generic inspection guidance procedure. The general inspection scopes are defined by the individual inspection instructions and associated regulatory requirements and standards.

The FANR is developing an inspection programme for the construction and commissioning activities at Barakah, using information from the Republic of Korea's Ministry of Education, Science and Technology (MEST) and the Korea Institute of Nuclear Safety (KINS).

VIII.3. HIGH CONFIDENCE AND VERIFICATION OF CONSTRUCTED PLANT CONSISTENCY WITH THE SAFETY ANALYSIS REPORT

Assurance that the plant's construction is consistent with the SAR is based on two key activities: (1) a comprehensive FANR inspection programme conducted throughout the construction and commissioning process that would identify any deviation between the SAR and the plant, as constructed; and (2) successful conduct of sufficient licensee quality verification activities and statements made by the licensee that the plant was constructed consistent with the application as presented to the FANR.

The purpose of the FANR inspection programme is to provide a high level of confidence that:

(a) Facility is constructed in accordance with the licence (and in accordance with the PSAR);
(b) Facility will be operated safely and in accordance with UAE Nuclear Law and FANR regulations.

The FANR's approach to inspection includes the Nuclear Law and IAEA fundamental principle that the operator is responsible for safety and that the regulatory body should not hinder that responsibility. Therefore, the licensee bears the prime responsibility for a high level of confidence, providing assurance that it complies with the law and regulations and that the licensee's QA programme of audits and surveillance is adequate.

The licensee's prime contractor provides another layer of audits, surveillance and inspections to ensure that it has constructed the facility in accordance with the construction licence, and the associated codes and standards. Subcontractors, including the authorized nuclear inspector or equivalent, will also be required to demonstrate that the associated components and systems have been constructed and installed appropriately. The licensee and contractor QA manuals also require vendor certification and qualification for any safety related components.

The FANR is conducting a detailed review of the construction licence application and will impose appropriate licence conditions to ensure that the construction is accomplished in accordance with the PSAR and the FANR safety evaluation report.

The FANR has developed an inspection programme using experience and lessons learned from other mature nuclear regulatory programmes and has included a comprehensive set of inspection instructions covering design, siting, management systems/QA, vendor inspections, construction fieldwork, component installation, pre-operational and hot functional testing, commissioning testing and operational readiness.

Finally, the FANR also expects that there will be an additional set of final integrated reviews. The licensee will perform an independent review of construction completion and readiness for fuel load (possibly by the World Association of Nuclear Operators or another third party). In addition, the FANR will perform an independent construction verification team inspection before fuel loading. These reviews will provide additional confidence that the licensee has constructed the facility in conformance to the final SAR.

VIII.3.1. General programme structure

The general programme structure of the CIP is discussed in the generic inspection guidance procedure. The structure uses information from IAEA Safety Standards Series No. GS-G-1.3 [2] and focuses on the primary stages of the construction project: site selection, site preparation, limited construction, and construction and commissioning. These stages are further divided into the following areas of inspection:

(a) Management systems/QA;
(b) Structures;
(c) Installation;
(d) Cold functional and hot functional testing;
(e) Resident inspection;
(f) Special inspection;
(g) Other construction related inspection instructions.

The commissioning stage is broken down into the following areas:

— Initial fuel loading and startup testing;
— General plant readiness programmes.

The Barakah construction and commissioning inspection programme comprises direct examination of plant SSCs and commodities (e.g. cable, welds and coatings), and oversight of the construction activities of the licensee and prime contractor for Barakah design, engineering, procurement and construction, and various key vendors and subcontractors to those principal entities. The construction and commissioning inspection programme begins upon completion and licensing of the plant design and covers the same five phases of the KINS pre-operational inspection (POI) programme:

(1) Construction of structures (construction programme);
(2) Installation of systems and components (construction programme);
(3) Cold functional testing (construction programme);
(4) Hydrostatic and hot functional testing (construction programme);
(5) Initial fuel load and startup testing (commissioning programme).

The construction and commissioning inspection programmes end with plant commissioning.

VIII.4. INSPECTION AREA INSTRUCTIONS

For each of these inspection areas, detailed inspection instructions have been developed that provide inspection objectives, regulatory requirements and general inspection guidance for the technical area. The generic inspection guidance procedure also provides the recommended timing for each inspection activity, and a frequency for those inspections that may occur more than once.

The FANR Integrated Management System Core Process, CP-3, is implemented via an inspection procedure, an allegation procedure and an enforcement procedure. Additional guidance is provided in the FANR generic inspection guidance procedure. As a general rule, inspections should be conducted in accordance with the inspection instructions developed for the subject area. However, it is not possible to anticipate all the unique circumstances that might be encountered during the course of a particular inspection and, therefore, individual inspectors are expected to exercise some initiative in conducting inspections, as required, based on their training, expertise, experience, risk insights and contact with their supervisor, to ensure that all the inspection objectives listed in the instruction are achieved.

VIII.5. INSPECTION PLANNING PROCESS: INSPECTION PHASE PLAN, ANNUAL INSPECTION PLAN AND INDIVIDUAL INSPECTION PLAN

The inspection phase plans will be developed for each of the POI phases (i.e. construction of structures, installation, cold functional tests, hot functional tests, and fuel loading and startup testing). These inspection phase plans will follow the format used by KINS, and show the planned baseline inspection activities for the entire plant construction and commissioning life cycle.

An annual inspection plan (AIP) will be developed for each nuclear facility. The AIP will show a schedule of upcoming inspections at least 12 months in advance and be updated biannually. For verification of the overall performance of the licensee, inspections of adequate depth should be conducted in a wide range of subject areas and at appropriate intervals, which are defined in the appendices to the generic inspection guidance procedure. The AIP should include the baseline inspections planned for that period and any inspections that may be added from the assessment or enforcement process. The AIP will be developed using the POI phase plans. The AIP should be approved by the appropriate level of FANR management; and any significant changes should receive the same level of approval.

The AIP should, as a minimum, contain the following fields:

- Name of the licensee or site to be inspected;
- Planned start date;
- Planned stop date;
- Inspection instruction(s) that will be used;
- Title or general description of the inspection activity;
- Name of the lead inspector or team leader;
- Number of additional inspectors planned to be on-site.

The AIP should be flexible enough to permit inspectors to respond to particular needs and situations. For this reason, not all of the available inspection resources should be allocated for baseline inspections in the AIP. For example, in different States it is the practice to target about three quarters of the inspection programme resources of the overall inspection programme for routine inspections and to keep the remaining quarter available for reactive inspections (note that this does not mean that each inspector’s time is scheduled for 75% of his or her time.)

Planned baseline inspections (i.e. routine) at nuclear facilities should normally be announced to the licensee beforehand. The main advantage of announcing inspections is that the inspector is able to discuss plans and needs with the licensee’s personnel in advance to secure assurances that documentation will be available for inspection, personnel will be available for interviews and ongoing activities can be inspected as scheduled. Hence, the announcement of inspections may enhance their effectiveness. Inspections should generally be announced at least two weeks in advance. Advance notice of a month or more should be provided for team inspections. Each team inspection will have a team leader, who will be in charge of coordinating on-site activities of the team members and also have responsibility for lead communication with the licensee or applicant management.

An overall plan or charter for the inspection will be developed by the team leader that will contain the scope and intended purpose of the inspection. The inspection may be very structured and follow rigorously one or more of the FANR inspection instructions, or be less structured and allow more flexibility for the inspector to accomplish his or her task. Because of the need for licensee support, team inspections must be scheduled well in advance. In order to prepare team members, the team leader will usually visit the site several weeks before the inspection to survey the availability of information and bring certain documents back to the FANR offices to allow better preparation by team members.

VIII.5.1. Method for selection of inspection samples

The FANR inspection programme is structured to verify limited samples of licensee activities in particular areas. The proposed strategy is to use a risk informed selection and prioritization process to guide the allocation of FANR resources for construction inspection activities. FANR is preparing a framework for the CIP, based on the MEST/KINS model, which will develop the details of the sample selection and prioritization process.

The FANR is developing a list of all of the plant’s SSCs and the associated construction activities. Then, to determine the importance of the various inspections activities for selection and planning purposes, FANR will develop a risk informed approach that considers:

(a) Safety significance of the plant’s SSCs and associated construction activities, processes and practices, by both probabilistic and deterministic means;
(b) Other considerations that drive the need to inspect particular SSCs and activities, as well as helping to determine when they need to be inspected for maximum effectiveness and efficiency of the programme.

In the initial screening, using traditional deterministic considerations, the SSCs (and associated activities) to be selected for inspection will comprise safety related SSCs and certain categories of non-safety related SSCs, taken together, known as SSCs important to safety. Then, using risk insights from the Barakah probabilistic risk assessment (PRA), the relative risk significance of those SSCs will be determined. Depending on when the Barakah PRA becomes available, a preliminary risk ranking may be performed using insights from the PRAs of the System 80+ design or the reference AP-1400 plant, Shin Kori.

To further refine and prioritize the list of SSCs and activities to be inspected, the FANR will consider certain other factors that would also drive the need to inspect. A high, medium or low value will be assigned to each activity for each of the following risk-ranking factors:

(a) Propensity for error as shown by industry operating experience (including event/failure modes and effects analyses) and difficulty/complexity or novelty of construction activity;
(b) Relevant experience, training, qualification, supervision and QA of construction organizations and individual personnel (including vendors and subcontractors), and the availability and use of resources including materials, tools and equipment;
(c) Opportunities to verify key attributes by other means;
(d) Level and rigor of oversight by other parties (basis for the confidence the FANR has in that oversight).

In other words, inspection importance is a function of how critical the SSC or activity to be inspected is, how hard it is to get it right to ensure the design margin of safety and reliability, and how necessary is direct inspection by the FANR in real time in light of accessibility or inspectability, alternate means of verifying key attributes and how much has been, is being, or will be inspected by other reliable or trusted entities.

As a complement to the risk informed selection criteria described above, other factors would also need to be qualitatively considered based on available information and revisited periodically as new information becomes available. International experience has identified areas that are more likely to have implementation issues during construction, and these will be used to assist the inspectors in planning inspections and selecting specific samples.

VIII.5.1.1. New technology, processes or programmes

First of a kind applications or approaches are more likely to have implementation problems because methods are unproven and there is usually limited or no experience. The observation or review of new processes can be very important to provide assurance that subsequent or related activities will be performed properly.

VIII.5.1.2. Defence in depth

There are systems and programmes that are important to safety which may not be identified in the PRA. These items are often provided for in defence in depth or in those function provides facility wide protection (e.g. fire protection, security and radiation protection).

VIII.5.1.3. Feedback

As construction proceeds and experience is gained, problem areas or opportunities for improvements that are learned during the initial implementation of the programme can be used to revise the selection process. This would also include any new relevant international experience.

VIII.5.1.4. Expediency

It may not always be possible for the inspector to observe or to review the most safety significant or new process because of schedule conflicts or resource availability. In some cases, it may be preferable to inspect a process or activity that is an available opportunity rather than wait or take the time to inspect a more risk significant activity with the understanding that the process inspected or observed would be conducted in a similar manner to the more risk significant activity.

The construction inspection strategy for programmes is to perform an initial review of all major safety related implementing programmes and then to periodically sample these programmes to ensure their continued effectiveness. The AIP will include planned inspections to review relevant Emirates Nuclear Energy Corporation (ENEC) programmatic activities prior to the start of construction (or at least early in implementation of the new activity) to verify completeness, use and understanding throughout the organization. In addition, the plan will include reviews of the key ENEC vendors to verify that the contractor is in compliance with and implementing the ENEC programmatic requirements. It is also envisioned that specific elements of these programmes will be sampled during field verification of construction inspection activities. That is, during the observation of a given activity, the inspectors will also review elements such as personnel qualifications, test controls and procurement controls to provide added insurance as to the effectiveness of the programme controls implementation.

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ISSN 1020–6450