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Regulatory Enforcement Policy Development and Implementation

IAEA SAFETY STANDARDS AND RELATED PUBLICATIONS

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REGULATORY ENFORCEMENT POLICY DEVELOPMENT AND IMPLEMENTATION

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REGULATORY ENFORCEMENT POLICY DEVELOPMENT AND IMPLEMENTATION

INTERNATIONAL ATOMIC ENERGY AGENCY
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FOREWORD

Enforcement is a core regulatory function and an important aspect of regulatory oversight of authorized facilities and activities for ensuring compliance with regulatory requirements. Enforcement provides a high level of assurance that the authorized party complies with all safety requirements at all steps of the authorization process and all stages of the lifetime of the facility or duration of the activity; meets the safety objectives, requirements and authorization conditions; and promptly identifies and corrects any non-compliance with safety requirements. In most States, the term 'enforcement' refers to the actions taken by the regulatory body in response to non-compliance with regulatory requirements and violations of authorization conditions; however, operation of a facility or conduct of an activity without valid authorization is prohibited and legal sanctions and enforcement can be used.

The regulatory body needs to be independent, competent, impartial and efficient in its ability to encourage compliance with the conditions of an authorization and all other regulatory requirements and to make enforcement decisions when necessary. Whenever an authorized party does not comply with regulatory requirements, enforcement actions may be warranted to restore compliance and prevent recurrence. The implementation of enforcement actions has to be commensurate with the significance for safety of the non-compliance, in accordance with a graded approach.

An effective enforcement policy and process is in place to deter non-compliance, encourage prompt identification of non-compliance and restore compliance. It also ensures that the scope, extent and timeliness of the corrective actions taken by the authorized party in response to enforcement actions are appropriate, including to prevent recurrence and hold the authorized party accountable for its prime responsibility for safety.

The enforcement policy is a tool aimed at establishing the organizational approach to achieve these objectives effectively. It is based on legal obligations and regulatory requirements for safety and is consistent with the national legal framework for enforcement.

Enforcement actions are not intended to be punitive against the authorized party, but rather to foster the culture for safety and ensure compliance with regulatory requirements and the conditions associated with an authorization. To make the design and implementation of such actions more consistent and transparent, there is a need to establish an enforcement policy in accordance with the concept of a graded approach. Additionally, there are certain factors that might increase the severity of the enforcement actions. Such factors may include wilful wrongdoing by the authorized party, inaction to correct known non-compliance, undetected persistence of a violation and recurrence of similar non-compliance.

This publication is the result of the collaboration of experts from different regulatory bodies; it gives a broad overview of enforcement policy and processes, techniques and methods. Its purpose is to assist regulatory bodies in developing or enhancing their enforcement policy and process for implementing enforcement to be effective, consistent and transparent. It includes information on methods for evaluating the significance of non-compliance using a graded approach and applying the appropriate enforcement actions. Through established laws, the regulatory body has the independence and authority to implement enforcement measures and corresponding actions in a timely manner that will ensure protection of the people and the environment.

The IAEA wishes to acknowledge the efforts of the experts who contributed to the development of this publication. The IAEA officers responsible for this publication were Z.H. Shah, T. Hussain, and T. Kobetz of the Division of Nuclear Installation Safety, and R. Pacheco and J. Bosnjak of the Division of Radiation, Transport and Waste Safety.

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CONTENTS

1. INTRODUCTION

1.1. BACKGROUND

Requirement 30 of IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety [1], requires the regulatory bodies to establish and implement an enforcement policy within the legal framework for responding to non-compliance by authorized parties with regulatory requirements and to ensure that such parties consequently take corrective actions.

IAEA Safety Standards Series No. GSG-13, Functions and Processes of the Regulatory Body for Safety [2], provides recommendations on the implementation of an enforcement policy by the regulatory body. Recommendations on the processes for ensuring the regulatory control of facilities and activities are provided in IAEA Safety Standards Series No. GSG-12, Organization, Management and Staffing of the Regulatory Body for Safety [3].

The IAEA has developed and implemented some workshops and training activities on the development and implementation of a regulatory enforcement policy and process. Feedback from the Member States through IAEA peer reviews and advisory missions such as Integrated Regulatory Review Service missions, Advisory Mission on Regulatory Infrastructure for Radiation Safety and Nuclear Security, conferences, and other IAEA activities have identified the need to develop guidance to assist Member States in the development and implementation of a regulatory enforcement policy and process that comply with IAEA safety standards.

1.2. OBJECTIVE

The objective of this publication is to provide regulatory bodies with practical guidance on developing and implementing an enforcement policy for safety in accordance with Requirement 30 of GSR Part 1 [1], including practical examples from regulatory bodies with relevant experience in the development and implementation of regulatory enforcement policies. The information provided in this publication also proposes attributes of regulatory enforcement that can enhance the effectiveness, efficiency and consistency of enforcement actions.

The publication provides further information about the factors to be considered when developing and implementing an enforcement process used to assess and address non-compliances.

1.3. SCOPE

This publication addresses the regulatory enforcement policy and process for facilities and activities for ensuring compliance with regulatory requirements for safety. Enforcement for nuclear security is not included in the scope. However, this publication may be useful in developing an enforcement policy for nuclear security for facilities and activities.

1.4. STRUCTURE

This TECDOC describes the fundamental concepts of regulatory enforcement, the development of an enforcement policy and processes for applying enforcement on authorized parties and other entities responsible for nuclear and radiation facilities and activities using a graded approach.

Section 2 describes the applicable IAEA safety standards and other publications related to regulatory enforcement. Section 3 presents the general concepts of an enforcement policy by describing the attributes of effective regulatory enforcement. Section 4 describes the overall structure of an enforcement policy in accordance with the legal provisions, associated regulatory requirements, roles, and responsibilities of regulatory staff at various levels in the organizational structure of the regulatory body, and aspects of coordination of the regulatory body with other organizations and/or agencies for legal actions and prosecutions, if required. Section 5 describes the enforcement process. Section 6 describes enforcement for special circumstances, assessment of effectiveness of the enforcement policy, revision and updating of the policy, and training aspects of the regulatory staff for taking enforcement actions.

Appendix I includes additional practical guidance for determining the significance of non-compliances. Appendix II includes examples of enforcement actions. The Annex provides examples of Member States' enforcement policies and processes.

2. RELEVANT CITATIONS AND IAEA PUBLICATIONS

The term 'enforcement' refers to "The application by a regulatory body of sanctions against an operator, intended to correct and, as appropriate, penalize non-compliance with conditions of an authorization".

In this TECDOC the term enforcement is used to refer to the actions that could be taken to deal with non-compliances with obligations stemming from IAEA safety requirement This publication includes information from relevant IAEA publications.

Requirement 2 of GSR Part 1 (Rev. 1) [1], states that "**The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated.**"

Further, para 2.5(18) of GSR Part 1 (Rev. 1) [1] states that "The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety." This framework for safety needs to set out the specification of offences and the corresponding penalties.

Requirement 30 of GSR Part 1 (Rev. 1) [1] states that "**The regulatory body shall establish and implement an enforcement policy within the legal framework for responding to non-compliances by authorized parties with regulatory requirements or with any conditions specified in the authorization.**"

Further, Requirement 31 of GSR Part 1 (Rev. 1) [1] states that: "**In the event that risks are identified, including risks unforeseen in the authorization process, the regulatory body shall require corrective actions to be taken by authorized parties.**"

IAEA Safety Standards Series No. GSR Part 2, Leadership and Management for Safety [4], establishes requirements for establishing, sustaining and continuously improving leadership and management for safety, and for an effective management system of the regulatory body. This is essential to foster and sustain a strong safety culture in an organization.

Paragraph 2.30 of IAEA Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [5] states that "The regulatory

body shall establish a regulatory system for protection and safety that includes … Enforcement of regulatory requirements".

GSG-12 [3] stipulates that the organization structure of the regulatory body could be established in a way that ensures that inspection and enforcement activities are coordinated. Additionally, guidance includes a graded approach to influence corrective actions supported by a range of enforcement sanctions ranging from verbal notification to prosecution.

GSG-13 [2] provides recommendations on inspection of facilities and activities and enforcement by the regulatory body. It discusses many areas, in addition to compliance with authorised conditions, that the regulatory body may need to inspect in order to gain a high level of confidence that safety objectives are being met. It also provides detailed recommendations on how to manage, organize, perform and report on inspections over the entire lifetime of the facility or duration of the activity. It also recommends that the regulatory body periodically assess the inspection and enforcement programmes for their continued effectiveness. On enforcement, it details the objectives of enforcement and highlights the importance of effective management of the enforcement process and the need to document enforcement decisions.

IAEA Safety Standards Series No. SSG-16 (Rev. 1) Establishing the Safety Infrastructure for a Nuclear Power Programme [6], provides recommendations on the phased implementation of a regulatory enforcement programme for an embarking country.

Reference [7] states that "The ability of a regulatory body to fulfil its responsibilities depends largely on the competence of its staff." It also provides generic guidance on managing the competence of regulatory bodies within their management system.

Reference [8] provides information on how authorized parties can identify and correct non-compliances.

Reference [9] provides guidance to facilitate regulatory compliance through the use of inspection of radiation sources and regulatory enforcement.

Reference [10] provides guidance for determining the safety significance of inspection findings for an operating nuclear power plant.

Reference [11] establishes the main elements to be considered in the training of personnel with enforcement responsibilities.

Reference [12] provides practical guidance for the application of a graded approach for the regulation of radiation sources, including inspection and enforcement actions and measures.

Reference [13] provides practical guidance for the application of a graded approach for the regulation of nuclear facilities, including inspection and enforcement actions and measures.

Reference [14] provides practical guidance to Member States on establishing and maintaining regulatory control through notification, authorization, inspection, and enforcement, in relation to facilities and activities with radiation sources, in order to achieve the fundamental safety objective and the objective of a State's nuclear security regime.

3. GENERAL CONCEPTS OF ENFORCEMENT POLICY

3.1. ATTRIBUTES OF AN EFFECTIVE REGULATORY ENFORCEMENT POLICY

Paragraph 3.8 of IAEA Safety Standards Series No. SF-1, Fundamental Safety Principles [15] states:

> "A properly established legal and governmental framework provides for the regulation of facilities and activities that give rise to radiation risks and for the clear assignment of responsibilities. The government is responsible for the adoption within its national legal system of such legislation, regulations, and other standards and measures as may be necessary to fulfil all its national responsibilities and international obligations effectively, and for the establishment of an independent regulatory body."

The application of this principle to enforcement involves the government adopting national legislation, putting in place an effective enforcement system aimed at deterring non-compliance with legal and regulatory requirements and providing the regulatory body with effective mechanisms to take enforcement action against authorized parties that do not comply with legal and regulatory requirements.

Authorized parties retain the prime responsibility for safety throughout the lifetime of facilities and duration of activities. This responsibility cannot be delegated. Therefore, the authorized party will be held accountable to comply with regulatory requirements and authorization conditions and for the timely correction of all non-compliances. The regulatory body may take enforcement actions to compel the authorized party into compliance and, where deemed necessary, to punish the authorized party for the non-compliance.

Based on the aforementioned principle and Requirement 2 of GSR Part.1 (Rev. 1) [1] the government has to promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety, including "the specification of offences and the corresponding penalties".

Requirement 2 and Requirement 30 of GSR Part 1 (Rev. 1) [1] set the framework for establishing an effective enforcement system, in which the government has the responsibility for organizing the enforcement system and the regulatory body has the responsibility for responding to non-compliances by effectively deploying the instruments and mechanisms provided by the legal and regulatory framework. The enforcement system has to be integrated with the common enforcement system of the State for responding to non-compliances with regulatory requirements of any nature and be consistent, as applicable, with the legal procedures and traditions of the State.

GSG-13 [2] provides recommendations for establishing an effective enforcement system. Paragraph 3.300 of GSG-13 [2] states:

> "The principal objectives of enforcement should be to provide a high level of assurance that the authorized party complies with all safety requirements at all steps of the authorization process and all stages of the lifetime of the facility or duration of the activity meet the safety objectives and authorization conditions, and that the authorized party promptly identifies and corrects non-compliances with safety requirements."

Paragraph 3.301 of GSG-13 [2] states:

> "Regulatory enforcement actions are taken by the regulatory body to address non-compliance by the authorized party with specified conditions and requirements. Such actions be taken to ensure that the authorized party modifies or corrects aspects of its procedures and practices, or of a facility or activity's structures, systems and components important to safety."

Considering these principles, requirements and guidance, effective regulatory enforcement includes the following attributes:

3.1.1. Legality

The regulatory body is subject to adherence with legal obligations. Therefore, all enforcement actions taken by the regulatory body have to be framed in accordance with legal requirements and implemented with strict adherence to applicable legal procedures.

In practice, this means that the regulatory body has to follow applicable legal procedures, enforce existing legal and regulatory requirements and conditions and issue sanctions for non-compliances using systematic methods and penalties in accordance with a graded approach.

3.1.2. Proportionality

Non-compliances that bring or could result in a higher risk to people or the environment may be expected to produce a more severe response from the regulatory body.

In practice, this means that a graded approach has to be applied to the enforcement process. When applying a graded approach, safety considerations have to be a determinant factor, but other factors, either 'aggravating or mitigating', may also be considered to ensure a fair response to non-compliances.

3.1.3. Fairness

Authorized parties are all to be treated equally such that similar non-compliances committed by different authorized parties are expected to produce similar enforcement actions against the authorized parties involved in the non-compliances.

Equality is one of the pillars of any legal system and, when applied to the framework for safety, means that non-compliances have to be assessed the same for all authorized parties. For instance, non-compliances at State-owned facilities or activities have to be assessed the same as non-compliances at privately owned facilities or activities.

3.1.4. Consistency

Authorized and other interested parties and the public may expect the regulatory body to take a similar approach when similar circumstances are found and that the response to similar non-compliances, including similar aggravating and mitigating factors, give rise to similar enforcement actions.

In practice, consistency is not a simple matter since the regulatory body may need to consider many variables including the degree of risk, the attitude and competence of the authorized party, any aggravating history of incidents or breaches involving the authorized party including previous enforcement action, and the seriousness of any breach. However, the regulatory body

has to make all efforts to ensure closeness of the agreement between the enforcement actions taken in response to similar conditions.

3.1.5. Accountability

The regulatory body is accountable to the government and to the public for its actions. This means that the regulatory body has developed policies and procedures against which the performance of the regulatory process can be judged, as well as effective and easily accessible mechanisms for handling concerns of interested parties and the public.

The enforcement policy and procedures of the regulatory body are also expected to ensure that enforcement actions are timely, thoroughly motivated and explained, produce a positive outcome in correcting non-compliances and preventing re-occurrence, and are fair, avoiding biases and conflicts of interest. Likewise, the enforcement policy and procedures need to have effective and easily accessible mechanisms to receive and address concerns of the public and other interested parties regarding enforcement actions taken or waived.

3.1.6. Transparency

The regulatory body needs to ensure that legal and regulatory obligations are clear and unambiguous to all authorized parties and that the rationale for enforcement actions is openly communicated to authorized parties with a right to appeal. Authorized parties need to know what is expected of them and what they can expect from the regulatory body.

The regulatory body needs to have processes for keeping employees, their representatives, interested parties and the public clearly informed about enforcement processes, having regard to legal constraints and requirements.

3.2. COMPLEXITY OF THE ENFORCEMENT POLICY

The framework for safety in a Member State with multiple types of radiation source and nuclear installation may lead to the establishment of a more complex enforcement system and, consequently, to a more complex enforcement policy of the regulatory body, and associated process in order to deal with the range of activities and facilities to ensure consistent and fair decision making. In contrast, a Member State with just a small range of facilities and activities using radiation sources, may have a simpler policy and process. Additionally, in accordance with a graded approach, the enforcement process may be simpler for those non-compliances that are less significant and be more complex for those violations that are more significant.

The complexity of the enforcement policy and process may depend on the following:

— Legal structure of the State and governmental and legislative framework;

— Number, type and complexity of nuclear and radiation facilities and activities;

— Legal authority of the regulatory body and associated powers of the regulatory staff;

— Organizational structure of the regulatory body (e.g. whether there are regional offices or a single organizational structure);

— Interface arrangements within the regulatory body responsible for enforcement actions;

— Availability of information on the risks and hazards associated with the facilities and activities;

— Interaction of the regulatory body with other enforcement authorities;

— Existence of more than one regulatory authority;

— Other factors that may be specific to the regulatory environment of a specific Member State including leadership, management, and culture.

3.3. GRADED APPROACH

In accordance with Principles 3 and 5 of SF-1 [15], a graded approach is to be utilized when assessing safety and taking any action accordingly. Paragraph 2.5 of GSR Part 1 (Rev. 1) [1], requires that the government promulgate laws and statutes to make provision for an effective governmental, legal, and regulatory framework for safety, including provision for the enforcement of regulations, in accordance with a graded approach.

It is important that the enforcement policy in a Member State recognizes that non-compliances will occur, and they are not all of equal significance. A graded approach to enforcement is achieved by having a structured method where the enforcement actions are commensurate with the risk or severity of the non-compliances. Considerations include the type of the facility and its inherent risk, the actual or potential safety consequences of the non-compliance, who identified the violation, timeliness of corrective actions, repetitiveness, frequency, and potential wilfulness. The way that a non-compliance is then considered in choosing the appropriate enforcement action is intended to reflect the seriousness of the non-compliance and the circumstances involved. Implementation of an enforcement policy establishes the graduated methods or actions that will be used for non-compliances of differing significance. However, authorized parties remain obligated to correct all non-compliances regardless of their significance.

As not all non-compliances are of equal significance, a graded approach may be applied to enforcement in the following ways:

3.3.1. Significance of non-compliance

The evaluation of the significance of a non-compliance needs to be commensurate, to the extent practicable, with the likelihood and possible consequences of non-compliance. It is recognized that not all non-compliances lend themselves to risk analysis and then have to be evaluated by a graded set of factors. Determining the significance of non-compliance and selecting the appropriate enforcement actions will vary based on the type of facility or activity being regulated.

3.3.2. Enforcement action

Non-compliances are not all equivalent; therefore, more significant non-compliances deserve more significant enforcement actions. For example, non-compliances resulting in high radiological risk or actual effects to workers and the public warrant more severe actions than administrative errors. Additionally, any non-compliances that are committed wilfully,

deliberately or through gross negligence becomes more significant, especially if senior executives are involved.

3.3.3. Use of resources

To optimize resources, it is important to focus on those non-conformances that carry higher risk. In practice, this means allocating more resources to establishing and delivering enforcement actions for more significant non-compliances. Additionally, it is preferred to follow-up on non-compliances involving significant corrective actions, rather than those related to less significant non-compliances.

3.3.4. Monetary level of the penalty

The concept of graduated monetary penalties generally considers the safety significance of the non-compliance as the primary consideration and the ability to pay as a secondary consideration. Thus, non-compliances involving operations with greater inventories of nuclear or other radioactive material may have higher potential consequences (i.e. in terms of the exposure of people and the environment) associated with a release of radioactive material and may receive higher monetary penalties. It is not intended for the economic impact of a penalty to be so severe that it adversely affects an authorized party's ability to safely conduct authorized activities or puts an authorized party out of business. Orders or other authorization methods, rather than monetary penalties, are used when the intent is to suspend or terminate authorized activities.

4. STRUCTURE AND DEVELOPMENT OF A REGULATORY ENFORCEMENT POLICY

An enforcement policy is used by the regulatory body to execute enforcement actions in a transparent manner considering the concept of a graded approach with respect to associated risk or consequences. The structure of an enforcement policy may vary among Member States based on the legal framework, responsibilities, functions and obligations of the regulatory body but, in general, may contain the following elements to meet the intent of GSR Part 1 (Rev. 1) [1]:

(a) Introduction of the policy (see Section 4.1);

(b) Purpose of the policy (see Section 4.2);

(c) Legal and regulatory framework (see Section 4.3);

(d) Scope of the policy (see Section 4.4);

(e) Attributes and bases for enforcement (see Section 3.1)

(f) Roles, responsibilities and authorities of the regulatory body staff and management (see Section 4.5);

(g) Coordination with other agencies (see Section 4.6);

(h) Enforcement process (see Section 5);

(i) Appeal process (see Section 5.7).

4.1. INTRODUCTION OF THE POLICY

The introduction would normally consist of a brief overview of the mandate of the regulatory body and how enforcement fits into that mandate and the legal framework applicable.

4.2. PURPOSE OF THE POLICY

This section of the enforcement policy discusses the overall goals of enforcement, roles and responsibilities of the regulatory body for enforcement and what considerations are part of the policy for taking enforcement actions against non-compliances. The primary goal of the enforcement policy is to promote compliance with the regulatory body's mission and thus protect people and the environment from harmful effects of ionizing radiation. The policy may also clearly state that the purpose is not to take punitive actions against authorized parties and their associated entities but to foster compliance with regulatory requirements. Paragraph 3.302 of GSG-13 [2], provides information in this regard, for example:

— Deterring non-compliance by encouraging authorized parties to identify problematic areas and correct them before they become safety significant issues;

— Identifying the extent of the condition and restoring compliance in a timely and effective manner;

— Ensuring that appropriate corrective actions are taken to prevent recurrence.

4.3. LEGAL AND REGULATORY FRAMEWORK

This section describes the legal authority, role and responsibilities of the regulatory body for enforcement in accordance with the legislation governing facilities and activities. In particular, this section of the policy may list and describe laws which authorize or empowers the regulatory body to enter the premises of relevant facilities, require the authorized party to provide relevant information, collect evidence of non-compliances, perform regulatory inspections to investigate non-compliances, issue directives or orders, and take enforcement actions.

Any associated laws and regulations applicable or issued by other authorities in the State which are necessary for complete implementation of an enforcement policy may also be listed in this section.

4.4. SCOPE OF THE POLICY

This section of the enforcement policy needs to address all facilities, activities, and parties for which the regulatory body has oversight responsibility. The type and complexity of the facilities and activities may be taken into account when considering non-compliances and the type and the severity of the enforcement actions may vary greatly on a case-by-case basis. Considerations need to be given to the extent which entities may affect the safety of nuclear and radiation facilities and activities. For example, the type of regulated facilities and activities may include:

— Nuclear installations (nuclear power plants, research reactors, fuel cycle facilities);

— Radiation sources facilities and activities (medical, industrial, research and education);

— Radioactive waste and spent fuel management facilities;

— Uranium ore mining, milling and processing;

— Transport of radioactive material.

The person or organization responsible for the non-compliances may include:

— Authorized party;

— Other non-authorized staff;

— Licenced control room staff;

— Radiation protection officer;

— Senior manager;

— Applicant for a licence or authorization;

— Vendor, manufacturer or supplier;

— Contractor or sub-contractor;

— Any entity or individual performing an activity subject to the regulatory control of the regulatory body and under the legal framework.

4.5. ROLES, RESPONSIBILITIES OF REGULATORY BODY STAFF AND MANAGEMENT

The enforcement policy needs to clearly define the roles and responsibilities of the management and staff (e.g. inspectors) of the regulatory body for implementing the enforcement function of the regulatory body.

The organizational structure of the regulatory body varies greatly between Member States. Depending upon the significance of the non-compliance, the roles and responsibilities may vary within the organization's hierarchy. For instance, roles and responsibilities can be distributed as follows:

4.5.1. Decision makers and senior management

— Establish the expectations on how to develop the enforcement policy and process and assign roles and responsibilities for their implementation;

— Approve written processes with all inputs, procedures and steps to implement the policy;

— Approve procedures which define appropriate steps to apply the policy fairly and consistently by all staff involved;

— Delegate authority to the appropriate decision maker based on level of responsibility;

— Approve the final enforcement action;

— Meet with senior authorized party management, when necessary, to emphasise the significance of a particular enforcement action and to discuss any required short, interim and long term corrective actions when the necessary corrective action is complex in nature or requires special circumstances for implementation (e.g. routine or special shutdown of a nuclear power plant, halting the construction process or special activity, stopping a medical practice).

4.5.2. Supervisors

— Determine whether the recommended enforcement action is correct, valid and consistent with enforcement policy and process;

— Ensure applicability of the regulatory requirements;

— Ensure appropriateness and timeliness of corrective actions;

— Ensure adequate documentation of the facts associated with the non-compliance.

4.5.3. Inspectors

— Identify potential non-compliances within the law, regulations, authorization conditions or other regulatory requirements;

— Document the facts of the non-compliance and the corresponding requirements which have been breached. This may be in an inspection report or other document;

— Review the immediate and planned corrective actions, including for timeliness;

— Evaluate the non-compliance to determine if the immediate risk is significant enough to warrant immediate enforcement action when allowed by the legislative framework, as appropriate;

— Communicate to the authorized party and to others in the regulatory body;

— Evaluate the significance of the non-compliance;

— Collect relevant documentation and evidence to be consulted and preserved related to the non-compliance.

4.5.4. Technical staff (other than inspectors)

— Identify findings which may trigger enforcement actions (in some cases, such as authorization reviews, identify and document the facts of the non-compliance);

— Evaluate the significance of the non-compliance;

— Identify the relevant legal and regulatory basis;

— Ensure appropriateness and timeliness of corrective actions;

— Carry out investigation procedures to develop evidence.

4.5.5. Regulatory legal staff

— Provide legal advice for consistency of the policy for enforcement with the national legal framework;

— Support the evaluation and identification, if necessary, of the legislative or regulatory requirements that have been breached;

— Confirm or seek sufficient evidence to support the enforcement actions;

— Provide legal guidance, in accordance with the law and applicable regulatory framework, on the proposed enforcement action;

— Communicate legal information to the parties concerned, if necessary;

— Support the investigation process to implement action and in the appeal stage to ensure due process;

— Assess the case for legal sufficiency, if needed, to be presented in the court of law.

4.5.6. Management system owner

— Manage the record of the enforcement actions and all supporting records and documentation;

— Disseminate information and actions to the appropriate organizational units responsible for other core regulatory processes;

— Ensure that enforcement decisions are documented in order to provide basis for review and revision of enforcement policy within the regular review interval or more frequently, if required;

— Periodically conduct an evaluation of the enforcement policy and process implementation and make improvements.

4.5.7. Enforcement coordinator

In some Member States there may be an enforcement coordinator to ensure that the enforcement policy and implementing process and procedures are consistently applied. This position might not be necessary for all regulatory bodies or may be combined with management system owner.

4.6. COORDINATION WITH OTHER AGENCIES

Other parties and authorities may be involved in enforcement and may be counted as part of the enforcement process and procedures. In some cases, there will need to be formal agreements between the parties on how to coordinate and who has authority over which jurisdiction (e.g. Memoranda of Understanding).

4.6.1. Criminal investigation outside the regulatory body

Some Member States may have dedicated investigators to investigate wilful non-compliances. In such cases, a dedicated procedure needs to be established to interact with the other regulatory staff, as described in the regulatory body processes.

4.6.2. Judicial authorities

Regulatory bodies may refer cases for prosecution to judicial authorities, in accordance with Member State's legal structures.

4.6.3. Other governmental agencies

Under the legal system in some Member States, other national, regional and/or local agencies may be involved in the enforcement process such as local law enforcement officials or other agencies.

5. ENFORCEMENT PROCESS

The enforcement process has the following basic steps:

(1) Identifying non-compliances;
(2) Determining significance of the non-compliances;
(3) Determining the appropriate method for enforcement;
(4) Communicating and issuing the final enforcement action to the authorized party;
(5) Communicating with interested parties (as appropriate);
(6) Oversight of corrective actions;
(7) Appealing against the enforcement action (if the authorized party does not agree with the identified non-compliance or the enforcement action);
(8) Referring to judicial process (as appropriate);
(9) Recording the enforcement.

The steps in the enforcement process vary for different types of non-compliances and the enforcement process may end after issuing the final enforcement action. The enforcement process in general is summarized in Fig. 1.

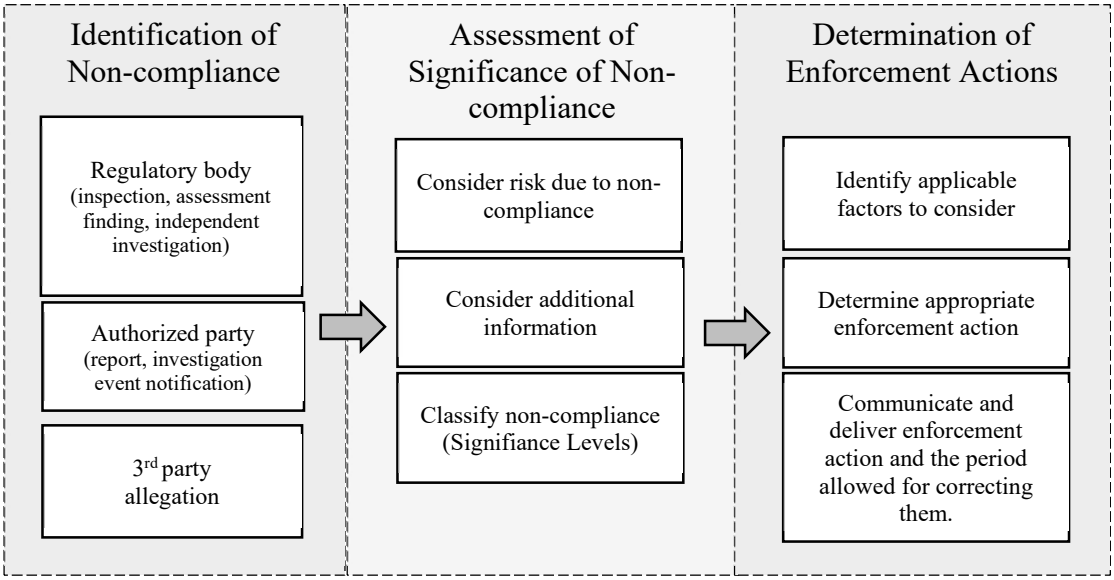

FIG. 1. The enforcement process.

5.1. IDENTIFICATION OF NON-COMPLIANCE

Findings indicating potential non-compliances may be identified by authorized parties or by the regulatory body including:

— Events reported to the regulatory body by the authorized party in accordance with regulatory requirements or licence conditions;

— Findings identified by the authorized party through the integrated management system;

— Findings identified by the authorized party or the regulatory body from the assessment of unanticipated events or accidents;

— Findings resulting from the review and assessment of design changes;

— The results of regulatory inspection or independent investigations;

— Findings from safety equipment failures during testing or during operation;

— Assessment of information routinely reported to the regulatory body;

— Investigation of information reported from vendors or suppliers;

— Analysis of national and international operating and regulatory experience;

— Allegations and whistleblowing.

The process that follows from the moment that a finding has been identified until a non-compliance has been confirmed and categorized can be complicated and long. For the most complex situations, this process can take months or even years. The regulatory body may need to implement one or several reactive inspections or investigations to collect information, request additional information from the authorized party, request corrective or compensatory actions to ensure that an acceptable level is maintained until the examination has been completed, interview individuals within the organization of the authorized party or from third parties (e.g. vendors, suppliers or providers of services) or engage other competent authorities where applicable. All these actions are necessary to answer questions such as:

— Which regulatory requirement or authorization condition was violated?

— How was the requirement or authorization condition violated?

— Who caused the violation?

— When and in which specific context was the requirement or authorization condition violated?

— How long has the non-compliance existed?

— How, when, and by whom (licensee or regulatory body or other) was the non-compliance discovered?

— What is the apparent significance of the non-compliance (e.g. actual or potential consequences, potential for impacting the regulatory process)?

— Was wilfulness involved?

— What was the apparent cause?

— What corrective actions have been taken or are planned to be taken by the authorized party (if known)?

— Did the regulatory body need to request corrective or compensatory action in response to inaction or delayed response by the authorized party?

— Did the authorized party include the non-conformance in its corrective action programme (if applicable)?

— Was the authorized party required to report the violation and, if so, what was the applicable reporting requirement?

— If a report was required, when was the report made available to the regulatory body?

A comprehensive, exhaustive and well-documented analysis of the responses to these questions is indispensable to ensure that, first, there are enough grounds to formally initiate the enforcement process and, second, there is enough factual information in order to decide on the significance of the non-compliance.

The enforcement policy and procedures may provide appropriate guidance for the relevant organizations and the specific staff of these organization to exercise leadership for safety and be prepared to overcome the pressures of a process that can be demanding and stressful.

The regulatory body needs to ensure that safety prevails over all other influencing factors and interests, even if this can delay the initiation of a formal enforcement process. The regulatory body has to keep in mind that its actions and resolutions may be judged at a later stage in an appeal process, internally or in front of another administrative body or court, and a lack of evidence or mistakes committed during the process can have negative repercussions on the credibility of the regulatory body and result in civil and penal responsibility for financial losses and other damages.

At the end of this process 'incumbent staff' of the regulatory body will need to provide enough factual information and compelling reasons to justify the non-compliance in order to proceed with the assessment of its significance and for the corresponding authority to make a well-informed decision in this regard.

5.2. SIGNIFICANCE DETERMINATION OF NON-COMPLIANCES

After a non-compliance has been identified, the regulatory body assesses its severity or significance (both actual and potential). More severe enforcement actions may be warranted for non-compliances that have greater risk, safety significance, or security significance, while less severe enforcement actions may be appropriate for non-compliances that have lower risk, safety significance, or security significance. The regulation of nuclear and radiological activities in many cases does not lend itself to systematic treatment, and judgment has to be exercised in determining the appropriate enforcement actions. In determining the appropriate enforcement action for the non-compliance, the regulatory body considers the factors discussed below:

— Is there an immediate risk to the health and safety of people, or of significant damage to the environment?

— Is there a need for immediate regulatory action, including enforcement?

— What (if any) was the actual safety significance and safety consequences?

— What were the potential safety significance and resulting consequences?

— How adequate is the authorized party's determination of the extent of the non-compliance?

— How adequate is the authorized party's determination of the cause(s) of the non-compliance?

— How long has the non-compliance existed?

— How is the facility being operated with regard to the regulatory requirements and authorization conditions while this non-compliance exists?

The outcome of this evaluation is the basis to determine what, if any, enforcement action is warranted. Refer to Appendix I for further guidance.

5.3. DETERMINING THE APPROPRIATE ENFORCEMENT METHOD

The enforcement policy and process need to clearly define the methods of enforcement available to the regulatory body and provide comprehensive guidance, using a graded approach. Additionally, guidance may be provided on how to oversee the authorized party's corrective actions. The policy needs to be established in a manner that ensures enforcement actions are consistent, predictable and repeatable, and the process has to be developed in accordance with the enforcement policy and approved by the appropriate management level.

5.3.1. Methods for enforcement

Once a non-compliance has been confirmed, Member States may choose any of the following enforcement actions based on the significance of the non-compliance:

— Verbal notification of non-compliance: Verbally informing the authorized party of the non-compliance of minor significance.

— Written notification of non-compliance: Informing the authorized party of the non-compliance in writing, typically in an inspection report or letter. This notification may require a response from the authorized party.

— Written warning, show-cause notice or hearings: Requesting the authorized party to take further action and, if action is not taken, more serious regulatory consequences follow. A hearing notice may also be served to the authorized party to appear in front of a panel of senior regulators as defined in the national regulatory framework.

— Directives or orders: Requiring specific actions to be taken by the authorized party such as the instances where the regulatory body is not confident that the authorized party will take the necessary actions unless legally compelled, where the recipient is not an authorized party and legal record of the enforcement action is needed, or to restrict, suspend, or revoke an authorization.

— Penalties: Imposing or recommending monetary penalties depending on the Member State regulatory framework. Penalties are usually reserved for serious non-compliances with regulatory requirements or for repeated non-compliances of a more serious nature.

— Restriction or suspension of activities: The regulatory body may require the authorized party to restrict or suspend the operation of specified facilities or activities and to take

additional actions to restore an adequate level of safety when there is evidence of a deterioration in the level of safety, or in the event of a serious non-compliance that, in the judgement of the regulatory body, poses an imminent radiological hazard to people or the environment.

— Modification, suspension, or revocation of the authorization: The regulatory body may direct the authorized party to cease the operation of a facility or the conduct of an activity and may suspend or revoke the authorization in the event of a persistent or extremely serious or wilful non-compliance with regulatory requirements, or a significant release of radioactive material to the environment due to serious malfunction of equipment, damage to structures, systems and components or incorrect operation of a facility or conduct of an activity. In some cases, the regulatory body may lock and seal the facility with the help of law enforcement agencies. In such cases, the regulatory body may impose additional regulatory requirements and conditions on the authorized party.

— Referral to judicial process: Criminal prosecutions are typically not conducted directly by the regulatory body; however, the regulatory body needs to have the authority to institute prosecution through the legal process, in accordance with the legal system of the State. In some Member States final appeals are handled by the judiciary**.**

— Individual actions: Normally enforcement actions are issued to the authorized party as they are responsible for the acts of their employees. In circumstances of a serious nature and when the non-compliance is committed intentionally or wilfully, enforcement actions may be taken against an individual. Any of the above methods may be used.

5.3.2. Factors to consider in selecting the appropriate method of enforcement

The enforcement policy and associated implementing procedures need to contain sufficient information on the use of a graded approach to ensure that enforcement is applied in a consistent, repeatable and fair manner in accordance with the facts of the non-compliance. The regulatory body procedures, as appropriate, need to contain comprehensive information and elaborate each enforcement step with the use of flow charts, tables, software etc. to ensure consistent application of the enforcement policy.

The following has to be considered when determining potential enforcement options:

— Whether there were actual safety consequences;

— The safety significance;

— Who identified the non-conformance (e.g. the regulatory body or the authorized party);

— Was the non-compliance reported, as required;

— Timeliness and appropriateness of the corrective actions;

— Repetitiveness;

— Past performance of the authorized party;

— Impacts on the regulatory body to fulfil its statutory obligations and responsibilities;

— Wilfulness or intentionality; this is especially important when senior managers are involved;

— Prevailing safety culture in the organization;

— Licensee's ability to take corrective action;

— Consistency with previous enforcement actions in similar circumstances.

The safety culture of the authorized party plays an important role in reducing the number and severity of non-compliances. Requirement 12 of GSR Part 2 [4], requires that individuals in the organization, from senior managers downwards, foster a strong safety culture. The management system and leadership for safety also have to foster and sustain a strong safety culture. Paragraph 5.2 of GSR Part 2 [4] requires that senior managers and all other managers advocate for and support the acceptance by individuals of personal accountability for their attitudes and conduct with regard to safety; the reporting of problems relating to technical, human and organizational factors and reporting of any deficiencies in structures, systems and components to avoid degradation of safety, including the timely acknowledgement of, and reporting on, actions taken and safety oriented decision making in all activities.

When using a graded approach in applying enforcement actions the lack, or breakdown, of safety culture may warrant escalating the significance and focus of the actions – especially when senior managers are involved. When a lack of safety culture is identified as one of the primary causes of the non-compliance, the regulatory body may consider whether escalation of the enforcement is warranted.

5.4. COMMUNICATIONS WITH THE AUTHORIZED PARTY

When implementing enforcement actions, the regulatory body needs to ensure professionalism, transparency and credibility in communication with the authorized party at all levels. All non-compliances need to be communicated to the authorized parties. This may include documentation such as inspection reports or correspondence.

For more significant enforcement actions (e.g. penalties, suspension of licence, etc.) the regulatory body is expected to communicate formally with the authorized party at various managerial levels, giving opportunities to receive detailed arguments that question or explain the facts or assumptions used in the enforcement process, and allowing the authorized party to appeal the decisions at various organizational levels of the regulatory body (if necessary). The purpose of the communications (meetings or correspondence) is to ensure there is a common understanding of the following:

— Applicable regulatory requirements;

— Facts of the non-compliance;

— Root cause of the non-compliance, if known;

— Extent of the non-compliance;

— Extent of the cause;

— Risk or significance of the non-compliance;

— The extent and timeliness of the corrective actions;

— Any extenuating circumstances.

If there is a meeting, the minutes of such meeting(s) may be documented, and the regulatory body may consider allowing interested parties to observe the proceedings. This will promote the openness and transparency of the regulatory body and gain public confidence. The guidelines for organizing such a meeting may be contained in the enforcement policy implementing procedures.

Following final decisions, the regulatory body issues the enforcement actions to the authorized party.

5.5. COMMUNICATIONS WITH INTERESTED PARTIES

The regulatory body needs effective communication mechanisms in order to inform interested parties, government agencies, and the public about regulatory decisions and criteria used in an enforcement process. Requirement 36 of GSR Part 1 (Rev. 1) [1], requires that the regulatory body communicate and consult with interested parties. Furthermore, para. 4.66 of GSR Part 1 (Rev. 1) [1] requires that the regulatory body communicates to the public on regulatory judgements and decisions and the bases for them.

To meet the requirements of GSR Part 1 (Rev. 1) [1], the enforcement policy needs to establish the expectations of the regulatory body to make enforcement actions accessible to interested parties and have a process in place to ensure this occurs.

Interested parties may include:

— The general public;

— National government;

— State, provincial or regional government;

— Local government;

— Authorized party;

— The nuclear industry;

— Regulatory bodies in other States;

— International organizations;

— The media;

— Radiation workers;

— Activist groups;

— Civic groups.

There are many communication tools available, and the regulatory body needs to consider a graded approach when determining the appropriate set of tools for communicating enforcement related information to interested parties. Examples of methods may include:

— Regulatory body website;

— Social media;

— Newspaper;

— TV and radio;

— Media/press releases;

— Public meetings;

— Inspection reports;

— Annual reports;

— Government journals;

— Sharing with the international community when applicable;

— Responding to requests for information from interested parties.

5.6. CORRECTIVE ACTIONS AND REGULATORY FOLLOW-UP

Requirement 31 of GSR Part 1 (Rev. 1) [1], states that "In the event that risks are identified, including risks unforeseen in the authorization process, the regulatory body shall require corrective actions to be taken by authorized parties."

The regulatory body may consider including in the enforcement process its expectations of regulatory oversight of the authorized party corrective actions in response to enforcement actions. In some Member States, inspectors along with necessary staff conduct compliance verification inspections to physically verify the implementation of corrective actions within the period specified. The detailed follow-up guidance would likely be included in inspection or oversight procedures.

5.7. APPEAL PROCESS

National legislation needs to include provisions for the appeal of decisions by the regulatory body. Such provisions could be in the nuclear or radiation safety relevant legislation or reference could be given in the general legislative framework. Although it is expected that the regulatory body will exercise its functions in a responsible manner, it is always possible that regulatory decisions will be made that do not reflect an accurate understanding of the facts of a situation or that are based on an incorrect interpretation of the law or applicable regulations.

There may be instances where, despite several meetings or other exchanges of information between the regulatory body and the authorized party, the authorized party still disagrees with the enforcement action. The arguments for disagreement can range from claims that no non-compliance occurred, to assertions that the regulatory body misevaluated the safety significance, or that the regulatory body did not understand all the facts, and therefore, the enforcement action is inappropriate.

Therefore, the regulatory body needs an appeal process for the authorized party or other interested parties. The appeal process usually includes two elements: the appeal mechanism, in which the appeal is assessed by the regulatory body itself, based on an established process, and as a second step, the entity/individual subject to the enforcement action may also seek judicial review in front of a tribunal, as per the existing right of recourse available at the national level. In such cases, the national legislative framework typically provides an opportunity for the authorized party or regulatory body to seek further review through the State's normal appeal procedure. In all cases the regulatory body needs to be prepared to justify its enforcement actions.

A State's system of enforcement strongly depends on its national legal system. For appeals processed within the regulatory body, the final appeal decision for significant cases is normally made at a level higher in the organization than made the original decision (e.g. the head of the regulatory body, the higher administration). It is important that the regulatory body act independently in its regulatory decision making process.

In some Member States, the national legal systems require all appeals to be processed through the judicial system. If this is the case, it is documented as such in the enforcement policy or process. If possible, the appeal has to be reviewed by persons independent of the original decision.

5.8. REFERRAL TO JUDICIAL PROCESS

In cases requiring criminal prosecution, the regulatory body may refer cases to judicial authorities or to another government department responsible for such actions.

Regulatory enforcement may include cases that involve the authorized party not complying with enforcement decisions by the regulatory body, even after completion of the appeal process. In such cases, measures will be taken by the regulatory body to present the matter in a court of law to compel the authorized party to take action.

Proper provisions in the regulatory framework to pursue enforcement cases in a court of law and the sufficient expertise of the relevant regulatory staff for legal prosecution of enforcement actions need to be in place.

5.9. RECORDS OF ENFORCEMENT ACTIONS

Within its management system, the regulatory body is expected to describe its process for documenting and recording enforcement decisions, including the steps that led to the final decision. Internal records of decisions relating to enforcement actions and any supporting documentation has to be kept by the regulatory body in such a way that they are easily accessible and retrievable when needed. Paragraphs 3.316–3.319 of GSG-13 [2], provide further guidance on the types of enforcement record that have to be retained. An example of enforcement records includes:

— Records of non-compliance;

— Records of correspondence regarding corrective actions for non-compliance;

— Records of decision making;

— Records of authorized party response;

— Records of meetings, exchange of information and other communications to or from the authorized party;

— Records of appeals and final decisions;

— Records of execution of lock and seal process (e.g. lock and seal report);

— Records of receiving of important letters (e.g. final directives, non-compliance notices, show-cause notices).

6. OTHER CONSIDERATIONS

6.1. APPROACH TO ENFORCEMENT UNDER SPECIAL CIRCUMSTANCES

The regulatory body may consider, within the boundaries of the applicable legal and administrative procedures, establishing approaches in its enforcement policy to deal with special circumstances where application of the general policy may lead to unintended outcomes. These approaches ought to be utilized as a last resort and for unique circumstances.

The enforcement policy includes the assessment of the potential negative impacts that a certain enforcement action may have on the safety of people and the environment. In exceptional circumstances, an inadequately conceived or executed enforcement action could lead to an increase in risk elsewhere or to a significant degradation of essential services.

The assessment of potential negative impacts of an enforcement action may include the consideration of factors such as:

— The negative consequences on the safety of vulnerable groups that warrant protection;

— The long term consequences of the enforcement action;

— The impact on safety of the enforcement action.

The regulatory body may consider including information in its enforcement policy to deal with such special circumstances.

For example, if a facility is operating without an operating licence or with an invalid operating licence (e.g. as the result of an unauthorized change in the facility) in many cases this will lead to requesting an immediate halt in the operation of the facility (in addition to other concurrent penalties). However, halting the operation of the facility may lead to stopping services vital for vulnerable population, such as critical medical services under way or planned in the short term. In such cases, the regulatory body, when duly justified and after assessing the safety consequences of permitting the continued operation of the facility, may choose to request compensatory actions (i.e. increasing the testing frequency of vital equipment, imposing extended operability of back-up equipment, increasing the number of operating personnel) until a valid licence is obtained, and then subsequently apply monetary penalties to avoid an economic benefit resulting from a non-compliance.

In other cases, the very same enforcement action may have an impact on safety. For example, requesting the immediate shutdown of a nuclear power plant to respond to a non-compliance may lead to unsafe configurations of the plant or to unwarranted stress in items important to safety. Therefore, the consequences of the enforcement action have be thoroughly considered by the regulatory body prior to initiating them. Alternative enforcement actions to allow a planned shutdown of the plant could be warranted in such cases.

In all cases, alternative enforcement actions will only be considered if the regulatory body is clearly satisfied that the course of action resulting from the alternative enforcement action is consistent with ensuring safety and/or security. This decision has to be documented, justified and made available to interested parties.

The regulatory body may also consider alternative enforcement approaches to respond to non-compliances in cases involving severe weather or other natural phenomena, based upon

balancing the safety and security of not operating against the potential radiological or other hazards associated with continued operation, and a determination that safety will not be unacceptably impacted by exercising this alternative enforcement.

Special circumstances may also arise when the regulatory body does not have sufficient factual evidence of a non-compliance or when the evidence has been obtained under circumstances that might not be acceptable during legal proceedings (e.g. evidence provided by whistle-blowers obtained in a way that disqualified the evidence). In such cases, the application of the enforcement action may lead to appeal and to request compensation for loss of profit. In such cases, the regulatory body may opt for not taking the enforcement action as a precautionary measure, as long as the non-compliance does not compromise safety.

The use of alternative enforcement actions does not change the fact that a non-compliance occurred, and the regulatory body still needs to evaluate the non-compliance to determine whether the alternative enforcement actions are consistent with the objectives of the enforcement policy.

6.2. ASSESSMENT OF THE ADEQUACY AND EFFECTIVENESS OF THE ENFORCEMENT POLICY AND PROCESS

There are various reasons which may necessitate that the enforcement policy and process are reviewed, revised and updated, such as a revision of the legal framework, revision of regulations or applicable guidelines and procedures of the regulatory body. The enforcement policy needs to be revised to keep it up-to-date and compatible with the applicable laws. Additionally, within its management system, the regulatory body needs to periodically evaluate the effectiveness of its enforcement policy and programme and adjust these as necessary.

The regulatory body may also review and evaluate previous records of enforcement actions in the course of carrying out its regulatory programmes. Such evaluation may help the regulatory body to consistently apply enforcement actions, identify regulatory documents in need of improvement, identify the types of facility or practice for which additional resources may be needed, or identify other changes needed for its regulatory approach in certain areas.

Evaluation may include the following:

— Number of enforcement actions imposed by type of facility and activity;

— Types of actions;

— Examination of possible common root causes of non-compliances;

— Efficiency of resource utilization;

— Implementation of corrective actions.

6.3. TRAINING OF STAFF

6.3.1. Staff competence training

Staff of the regulatory body that have responsibility for taking enforcement actions need to have relevant qualifications, experience and knowledge in the relevant technical areas and appropriate knowledge and competence in the application of the relevant legal frameworks in the State, including the enforcement policy and processes. A team composed of individuals with technical and legal backgrounds is needed to work together in a complementary manner. Further information is provided in Ref. [7].

The additional elements to be considered in the training of staff with enforcement responsibilities include:

— Understanding of the legal framework and the regulatory body's enforcement policy and processes;

— The ability to clearly identify the non-compliance, including the breached requirements;

— The ability to collect evidence, record facts, and draft the non-compliance and enforcement action adequately in the documentation;

— Understanding of the regulatory framework and processes and how enforcement fits into these;

— The ability to judge the significance of non-compliances and to identify commensurate enforcement actions;

— The availability of technical expertise on the facility or activity against which enforcement action is being taken;

— The ability to decide upon and initiate enforcement actions in response to non-compliances using a graded approach;

— The ability to determine whether other regulatory processes (such as inspection or authorization) are needed to support an enforcement action;

— The ability to determine where liaison with other agencies is needed to support an enforcement action (such as evidence gathering by law enforcement agencies, referral to criminal prosecution, legal advice or actions by other regulatory body);

— The ability to evaluate and confirm the effective implementation of appropriate corrective actions;

— An appreciation of the adequacy of the enforcement policy and processes and the ability to identify and implement necessary improvements;

— The adequacy of behavioural competence and attitudes in interacting with interested parties regarding enforcement-related actions.

The level and depth of training of regulatory staff will depend on the scope of the enforcement programme and potential risks associated with the regulated facilities and activities in the State.

The development of regulatory staff competence also depends on the regulatory processes they are to conduct. Separate staff may be responsible for review and assessment, authorization, inspection, and enforcement. However, in most cases, particularly in small regulatory bodies, the same staff may be responsible for performing multiple regulatory functions. Therefore, training needs to be tailored to ensure those executing the various roles are fully trained on their responsibilities.

The regulatory body needs to establish a training policy, not only regarding initial qualification, but also refresher training to maintain competence.

6.3.2. Personal and behavioural competencies

Regulatory body staff have to exemplify the principles of enforcement detailed in Section 3. The staff are expected to act in a fair, impartial manner in their treatment of the authorized party whilst ensuring the safety of facilities and activities and thus ensuring the protection of the public and the environment.

Regulatory body staff are to be independent from the authorized party and consider that they are always accountable to the public. They have to be mindful to ensure that there are no direct or indirect conflicts of interest.

Regulatory body staff need to be transparent with the authorized party regarding regulatory expectations, clearly describing regulatory requirements and processes. Their behaviour needs to be in accordance with legal and regulatory requirements for dealing with authorized parties consistently.

Regulatory body staff need to actively listen to authorized parties along with other interested parties to ensure that they are fair and that the facts are representative of the non-compliance. They need to be impartial to ensure that enforcement actions are fair and just.

Regulatory body staff need to ensure that they act within their responsibilities and authority and seek support and advice from specialists, as appropriate.

Appendix I

DETERMINATION OF SIGNIFICANCE OF NON-COMPLIANCES AND ENFORCEMENT METHOD EXAMPLES

To determine the appropriate enforcement action in response to a non-compliance, the regulatory body has to conduct an assessment of the actual and potential impact of the non-compliance on nuclear safety, radiation safety and the overall risk to workers, public, and the environment from harmful effects of ionizing radiation. Determining the significance of non-compliances and selecting the appropriate method of enforcement will vary based on the type of facility or activity being regulated.

This Appendix provides generic levels of non-compliances and examples of enforcement methods. However, Member States may have additional levels based on number, type and complexity of nuclear and radiation facilities and activities that are regulated.

I.1. CLASSIFICATION OF NON-COMPLIANCE

Non-compliances can be classified according to the severity of their consequences (actual or potential) on facility operation, human health and the environment. Within this context, levels of non-compliance can be classified as follows:

I.1.1. Level 1 non-compliance

Non-compliances that may pose a serious risk to the safety of people or the environment. Operations are considered unsafe if they resulted in or could have resulted in serious consequences.

To classify a non-compliance as level 1, it has to be established that there has been a serious risk to people or the environment. Additionally, it has to be established that there has been a reduction in the safe operation of the facility or activity in such a way that the remaining safety devices, mechanisms or barriers, or the available administrative measures, do not guarantee the avoidance of exposure to ionizing radiation at levels that might result in deterministic effects. Furthermore, it has to be shown that the current or future uses of property or the environment could be affected.

I.1.1.1. Examples of level 1 non-compliance

— Operation of a facility or conduct of an activity without having obtained the required authorization (or after the authorization has expired, been suspended or revoked) and in which there is a serious risk to people or the environment;

— Failure to comply with the terms, limits or conditions of the authorization, as well as the failure to implement technical, administrative, or other measures that are imposed on the operation of a facility or the conduct of an activity or the failure to comply with the deadlines for implementation and there is a serious risk to people or the environment;

— Release of radioactive material to the atmosphere, water, soil or subsoil, where their magnitude and characteristics can pose a serious risk to the health and safety of people or the environment;

— The supply or transfer of radioactive material to individuals or entities that do not have the required authorization for their possession and use, or without meeting the established requirements for identification and marking when there is a serious risk to people or the environment;

— Failure of safety system(s) when called upon to prevent or mitigate a serious event.

I.1.2. Level 2 non-compliance

Level 2 non-compliance applies in cases where there has been no serious risk to people or the environment, and the safe operation of the facility or conduct of the activity has not been significantly affected, and there are no situations where undue exposure to ionizing radiation could arise, or in such situations, the doses are below the limits established by regulation.

I.1.2.1. Examples of level 2 non-compliance

— Operation of a facility or conduct of an activity without having obtained the necessary authorization (or after it has expired, been suspended or revoked) and where there is not a significant risk to people or the environment;

— Failure to comply with the conditions of authorization, as well as the failure to implement technical, administrative or other measures that are imposed on the operation of a facility or conduct of an activity, or the failure to comply with the deadlines for implementation and where there is not a risk to people or the environment;

— Failure to comply with the obligations related to the generation, filing and custody of the records required for the operation of a facility or the conduct of an activity or for the control of radioactive material and non-compliance leads to a loss of information;

— Failure or unavailability of a safety system(s), for a relatively short period of time, which are necessary to prevent or mitigate a serious event.

I.1.3. Level 3 non-compliance

Level 3 non-compliance applies in cases where there has been no risk to people or the environment, and overall there are low potential safety consequences.

I.1.3.1. Examples of level 3 non-compliance

— Operation of a facility or conduct of an activity regulated by the nuclear law or its related regulations without having obtained the required authorization, or after it has expired, been suspended or revoked, provided that the violation has no significant safety consequences;

— Failure to comply with the obligations related to generation, filing and custody of the records required for the operation of a facility or the conduct of an activity or for the control of radioactive material, if the information is eventually recovered;

— Not having the required systems for storage, treatment and, where appropriate, discharge of effluents or radioactive waste, if this violation does not lead to a risk to people or the environment;

— Failure or unavailability of a safety system, for a relatively short period of time under specific circumstances, such as unique environmental conditions, necessary to prevent or mitigate a serious event or accident.

Additionally, there may be non-compliances that are less significant than level 3. These normally do not warrant enforcement actions and are not documented in inspection reports. However, these non-compliances still need to be corrected.

I.2. PRACTICAL EXAMPLES

An NPP operator forgets to confirm (signoff) on completion of a maintenance procedure that a valve was returned to the correct position (this could be a level 3 non-compliance). In another example, an operator signs off that the valve was returned to the proper position without actually observing the position of the valve (could be level 2). Or more significantly, the operator signs off on the procedure knowing that a safety significant valve is in the wrong position (could be level 1).

A radiation worker receives a dose in excess of the authorized party's dose constraint, but less than the regulatory dose limit of 20 mSv per year (could be level 3). A radiation worker receives a dose in excess of the dose limit but less than 100 mSv, which is the dose limit over five years (could be level 2). More significantly, a radiation worker receives a dose more than 100 mSv (could be level 1).

A worker in a radiotherapy facility does not change his personal dosimeter in the prescribed interval (could be level 3). The dosimetry equipment is used without the proper calibration by a secondary standard dosimetry laboratory (could be level 2).

During an inspection of a nuclear medicine facility, it was discovered that records for the quality assurance program for medical exposures were not maintained. (could be level 3). In another case, the patient who has undergone radionuclide therapy has not been provided with the written instructions at the time the patient is discharged from the facility and a Radiation Protection Officer (RPO) or medical physicist neglected to conduct surveys of the patient's treatment room to check for residual radioactivity or contamination. (could be level 2). A radiopharmaceutical was administered to a wrong patient due to an error in patient identification and failure to adhere to patient verification protocols. In addition, the patient is discharged from hospital without complying with approved procedures (could be level 1).

I.3. AGGREGATING NON-COMPLIANCES

Less significant non-compliances may be 'aggregated'. A group of non-compliances can be assessed together and assigned a single increased level, which can result in a more significant non-compliance. For example, aggregation may be warranted if the non-compliances have the same cause or programmatic deficiencies, or where the consequences were indicative of a similar underlying problem.

The purpose of aggregating non-compliances is to focus the authorized party's attention on the underlying causes subject to enforcement action and reflect the fact that multiple non-compliances with a common cause may be more significant collectively than individually, and, therefore, can lead to more substantial enforcement action.

I.4. ESCALATION OF ENFORCEMENT ACTIONS

The standard enforcement process provides opportunities to resolve non-compliances in a consistent manner; however, in some cases the initial enforcement action does not reflect the significance of non-compliance. Therefore, the enforcement action may be escalated or mitigated based on the following specific factors or circumstances:

— Implementation of corrective actions;

— Repetitiveness of a non-compliance (e.g. within last 2 years or last 2 inspections);

— Wilfulness, intentionality or deliberate violation;

— Organizational safety culture;

— Compliance history;

— Response to near misses.

For example, a non-compliance may be considered more significant if it includes indications of wilfulness, or if the authorized party has a history of poor compliance or organizational safety culture or if the non-compliance is repeated.

I.5. ENFORCEMENT METHOD EXAMPLES

I.5.1. Verbal notifications of non-compliance

A facility expects that workers will follow operating procedures: each procedure step needs to be completed and initialled. During satisfactory conduct of the procedure, one step out of 25 was not initialled, which is a non-compliance. It is clear from the outcome of the procedure that the step was satisfactorily completed. The consequences of this failure to initial were minimal. This non-compliance would not rise to a level 3. Verbal notification to the authorized party is appropriate. The authorized party subsequently corrected the documentation with an appropriate notation.

I.5.2. Written notification of non-compliance

A facility expects that workers will follow operating procedures: each procedure step needs to be completed and initialled. During conduct of the procedure, one step of 25 was not completed. The step required the operator to start a fire pump. Failure to start the pump is a level 3 non-compliance. The non-compliance was documented in the inspection report and a response from the authorized party was requested to inform the regulatory body of the planned corrective actions.

I.5.3. Written warning, show-cause notice or hearings

A facility expects that workers will follow operating procedures: the procedure requires that the control rods be withdrawn from the reactor core in a specific order as the reactor is restarted following a refuelling outage. The control room operator responsible for withdrawing the control rods withdraws the control rods in the wrong order, and there is no control room supervision of this activity. The incorrect withdrawal leads to the reactor going critical before what is expected by procedure. No core operating parameters were challenged. The failure to

follow the procedure correctly is a level 2 non-compliance. The regulatory body issues a written warning to the authorized party to demonstrate how they will oversee control room operations, in particular during core manipulations, without the need for additional regulatory requirements.

I.5.4. Directives or orders

Several non-compliances occur with a common root cause of insufficient safety culture of an authorized party that prioritizes production over safety. The regulatory body issues a directive/order to have the authorized party contract with a safety culture expert to assess the adequacy of the authorized party's root cause analysis and planned corrective actions. Additionally, the authorized party is required to have the third party assessment sent directly to the regulatory body.

I.5.5. Penalties

For level 1 and 2 non-compliances, the regulatory body may consider issuing monetary penalties in conjunction with the written notification or warning. An example of a possible decision making flowchart is shown in Fig. 2.

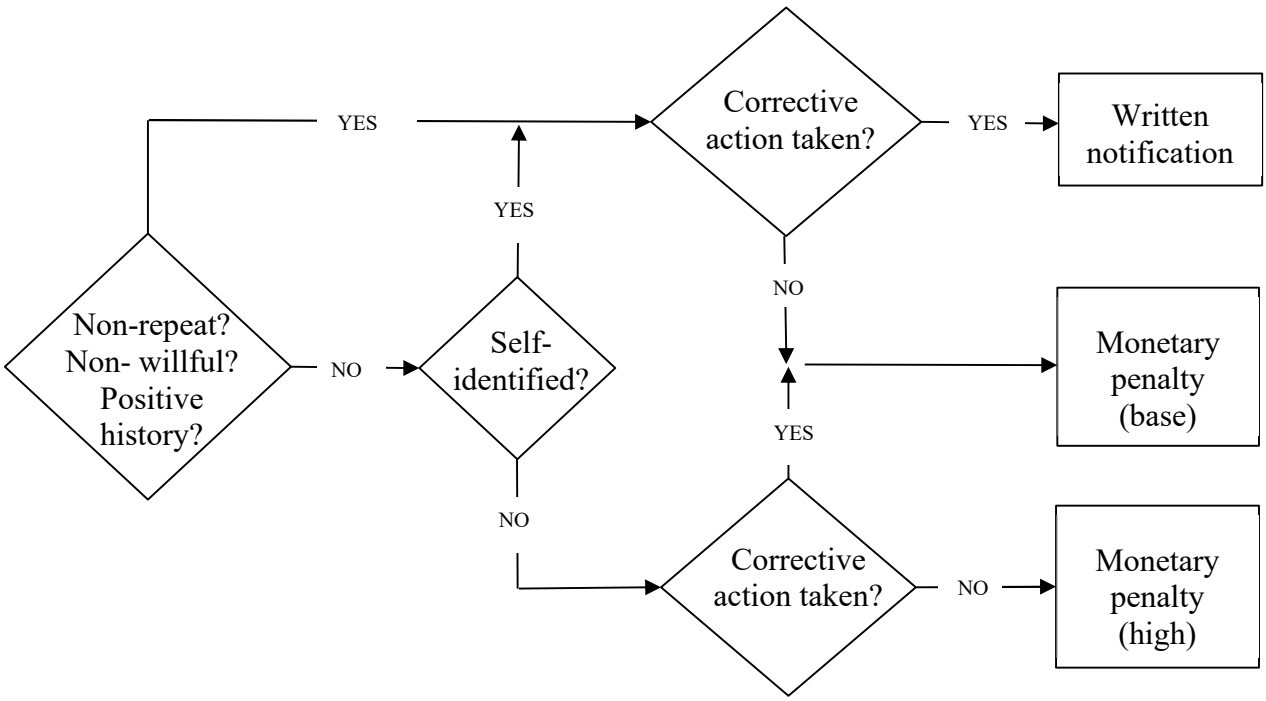

FIG. 2. A decision making flowchart (an example).

For example, in the instance of the written notification level 2 non-compliance proposed in Section I.5.3, the non-compliance could result in a high range monetary penalty if there had been previous non-compliances involving adherence to procedures, that were identified by the regulatory body, and inadequate corrective actions had been taken.

I.5.6. Restriction or suspension of activities

An unqualified person conducts industrial radiography operations. There were no safety consequences from these operations. This non-compliance is level 2. The regulatory body issues an amendment to the authorization suspending further radiographic operations until third party training is conducted and all staff who are to perform radiography operations are adequately trained and qualified.

I.5.7. Modification, suspension, or revocation of the authorization

At an irradiation facility, multiple workers received exposures exceeding the regulatory dose limits, resulting in some persons suffering serious injury. These non-compliances are level 1. The regulatory body issues a suspension of the authorization for all operations, except for the storage and safe removal of the radioactive material. Following removal of material and satisfactory decommissioning, the authorization will be revoked.

I.5.8. Referral to judicial process

In some Member States, it may be necessary to refer a potential case to another governmental organization to pursue possible criminal actions. A regulatory body may have some amount of evidence developed through inspection that would document that a non-compliance was potentially wilful and, which, in accordance with their regulatory framework is potentially criminal. For example, in Section 1.5.6, the regulatory body identifies that the owner of the radiography company knew that the person was not appropriately trained and qualified, and in fact was recently hired out of school, with no technical training. However, the owner sent the person to perform radiography alone. The regulatory body may need the assistance of another governmental organization to conduct the criminal investigation and develop the evidence for the criminal prosecution.

I.5.9. Individual actions

In the case of an individual knowingly violating requirements, an action may be taken directly against that person. If, in the radiography example in Section 1.5.6, if the person knew they were not qualified to undertake radiography, the non-compliance could be considered wilful. The regulatory body could issue a directive or order to the person prohibiting them from working as a radiographer within the jurisdiction of the regulatory body because they lack confidence that the person would comply with regulatory requirements in the future.

Appendix II

EXAMPLES OF ENFORCEMENT ACTIONS

II.1. EXAMPLE OF NON-COMPLIANCE THAT WOULD WARRANT VERBAL NOTIFICATION ONLY

During an inspection of silicon foam penetration seals, an inspector noted that the foam extrusion from repaired seals was 10 mm, which is less than the 13 mm specified in the seal repair procedure. However, the silicon foam vendor's instructions permit extrusions as little as 7 mm. The authorized party failed to perform the seal repair in accordance with the procedure which is a non-compliance with regulatory requirements. However, the functionality was not affected since the silicon foam vendor's instructions permit extrusions as little as 7 mm.

During an inspection at a hot cell laboratory, an inspector noted that a procedure for safe evacuation of an area, the authorized party stated that staff could complete an evacuation within 90 seconds. It is later determined that completing the evacuation could take as long as 110 seconds. The authorized party failed to ensure the procedure met design requirements. However, accident analysis assumed the evacuation was completed in 150 seconds. Therefore, this was a non-significant non-compliance.

During an inspection at a medical facility, an inspector noted that notices were not posted for providing information to employees on who they can contact within their management and at the regulatory body in case of any question about radiation safety in the facility. Prior to departing the facility, the inspector provides a copy of, or link to, the required notices to the authorized party to facilitate proper posting.

II.2. EXAMPLE WRITTEN NOTIFICATION AS PART OF AN INSPECTION REPORT

DATE
AUTHORIZATION NUMBER
Authorized Party
Address

SUBJECT: SPECIFIC NUCLEAR INSTALLATION INSPECTION REPORT No.1234

Dear Mr/Ms. Authorized Party Senior Manager:

On DATE, the regulatory body completed an inspection at the specified nuclear installation. The results of this inspection are documented in the enclosed report. The inspectors identified a Level 3 non-compliance when the authorized party failed to establish a programme to ensure that motor-operated valves continue to be capable of performing their design basis safety functions. Specifically, the authorized party failed to shorten the diagnostic test frequency for motor-operated valve MOV987 from 10 years to 6 years, following the identification of low safety margin for the closed thrust.

If you contest the non-compliance or the significance or severity documented in this inspection report, you have to provide a response within 30 days of the date of this inspection report, with the basis for your denial, to the regulatory body at ADDRESS.

This letter, its enclosure, and your response (if any) will be made available for public inspection on the regulatory body website at WEB ADDRESS …

If you have any questions, please contact REGULATORY BODY MANAGER.

Sincerely,

Regulatory Body Manager

Enclosure: As stated

ENCLOSURE: INSPECTION REPORT

Failure to Perform Diagnostic Testing of Low Margin Valve Within the Required Test Interval.

The inspectors identified a non-compliance of Regulation B.1 when the authorized party failed to establish a programme to ensure that motor operated valves continue to be capable of performing their design basis safety functions. Specifically, the authorized party failed to shorten the diagnostic test frequency for motor-operated valve MOV987 from 10 years to 6 years, following the identification of low safety margin for the closed thrust.

The inspectors reviewed work order 465768, which recorded the results from the 2016 test. The work order documented a margin of 2.5 percent for the closed thrust. Per the MOV programme and the MOV-EN-753 test interval matrix, Class B valves having a margin less than 5 percent are required to be tested every 6 years. The inspectors questioned why no periodic verification tests had occurred since 2016 for valve MOV987. In response, the authorized party concluded that, when initially reviewing the test data in 2016, engineers had failed to recognize the low

margin and had failed to initiate an action to change the periodic verification frequency from 10 years to 6 years.

The authorized party initiated condition report CR-2022-234567 to document the failure to adjust the periodic verification test frequency. The inspectors reviewed recent quarterly stroke time tests and preventative maintenance records for valve MOV987 and did not identify any adverse trends or indications of degradation since the 2016 test.

The failure of the authorized party to adhere to the appropriate diagnostic test interval in accordance with the test interval matrix in procedure MOV-EN-753, 'MOV Periodic Verification', for valve MOV987 was a non-compliance.

The inspectors determined the non-compliance was Level 3. Specifically, the failure to conduct more frequent periodic verification testing of a low margin valve can allow for degradation in the available thrust to go unrecognized and could lead to the failure of the valve to perform its safety related functions. This is consistent with regulatory body Enforcement Policy example 2.9.

NOTICE OF NON-COMPLIANCE

Regulation B.1 states, in part, that the authorized party has to establish a programme to ensure that motor-operated valves continue to be capable of performing their design basis safety functions. Procedure MOV-EN-753, MOV Periodic Verification, Revision 7, is the authorized party's procedure for establishing a programme to ensure motor-operated valves continue to be capable of performing their design basis safety functions.

Contrary to the above, since DATE, the authorized party failed to establish a programme to ensure that motor-operated valves continue to be capable of performing their design basis safety functions. Specifically, the authorized party failed to conduct periodic verification testing of valve MOV987 within 6 years in accordance with MOV-EN-753 Table 1, 'Test Interval Matrix', to demonstrate that MOV987 continued to be capable of performing its safety function.

This non-compliance is being treated as a Level 3, consistent with Section 2.9 of the Enforcement Policy.

II.3. EXAMPLE WRITTEN NOTIFICATION LEVEL 2 ENFORCEMENT ACTION

Tracking Number 123
Name of Authorized Party Senior Manager
Address

SUBJECT: RESEARCH REACTOR – NOTICE OF NON-COMPLIANCE

Dear Senior Manager:

This letter refers to the regulatory body special inspection conducted on DATES at your research reactor facility. The special inspection was conducted pursuant to your notification on DATE describing the causes of, and corrective actions for, operation of the research reactor at power levels in excess of the licenced maximum power level. The inspection report identified two apparent non-compliances that were considered for significant enforcement.

Based on the information gathered during the inspection and the information that you provided in your response, the regulatory body staff has determined that two non-compliances of requirements occurred. These non-compliances are cited in the enclosed Notice, and the circumstances surrounding the non-compliances are described in detail in the inspection report. The first non-compliance involves the research reactor operating at steady state power levels in excess of Licence Condition 1.A.

The second non-compliance involves your failure to perform appropriate surveillance testing before considering the nuclear instrument (NI) system operable following replacement of the NI system and detectors, contrary to Technical Specification (TS) 1.2.a. The regulatory body considers the non-compliances described above to be significant because the two non-compliances are related to operation of the research reactor at steady state levels above the licensed maximum power level on several occasions over an approximately one-year period. Therefore, these non-compliances are categorized Level 2. The Enforcement Policy can be found on the regulatory body website at WEB ADDRESS….

In accordance with Enforcement Policy, a monetary penalty in the amount of ####€ is considered for Level 2 non-compliances. Because your facility has not been the subject of significant enforcement action within the last 2 years, corrective actions taken to date have included preparing and implementing a new written Standard Operating Procedure (SOP) for properly calibrating the NI, reviewing and verifying other facility procedures; and submitting an authorization amendment request for proposed TS changes to allow for reactor operation for the purpose of performing calibration of the NI by foil activation. The amendment request and TS change was approved by the regulatory body on DATE.

The regulatory body has concluded that information regarding: (1) the reasons for the non-compliances; (2) the corrective actions that were taken and the results achieved; and (3) the date when full compliance was achieved as already adequately addressed in the public record in Special Inspection Report 1234, and your letter dated DATE. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position.

If you have any questions concerning this matter, please contact REGULATORY BODY MANAGER at phone number 123-456-789.

Sincerely,

Regulatory body Senior Manager

Enclosure:
As stated
Distribution List

NOTICE OF NON-COMPLIANCE

Research Reactor Licence No. 123

During a regulatory body special inspection conducted during DATES, two non-compliances of requirements were identified. In accordance with the regulatory body Enforcement Policy, the non-compliances are listed below:

(a) Research Reactor Licence Condition 1.A, 'Maximum Power Level', states: "The licensee is authorized to operate the facility at stead-state power levels not in excess of XX kilowatts (thermal)." Contrary to the above, the research reactor was operated at steady-state power levels in excess of XX kilowatts (thermal) (kW(t)) on several occasions between DATE 1 and DATE 2. Specifically, the reactor was inadvertently operated at steady-state power levels greater than XX kW(t) during this time due to NI calibration calculation errors. These errors caused the NIs to indicate reactor power levels that were approximately three times lower than actual reactor power. Therefore, when the licensee operated the reactor above 1/3 XX kW(t) (indicated power) several times between DATE 1 and DATE 2, the actual reactor power exceeded the maximum authorized power level of XX kW(t).

(b) Research Reactor TS, Section 1.2.a states, in part, "Appropriate surveillance testing on any TS required system has to be conducted after replacement, repair, or modification before the system is considered operable and returned to service." Contrary to the above, on DATE, the licensee considered the NI system to be operable and returned the research reactor to service, after replacement of the system during an extended shutdown in the previous year, before completing the appropriate surveillance testing. The licensee operated the reactor without completing the required TS surveillance testing between DATE 1 and DATE 2.

The regulatory body has concluded that information regarding the reason for the non-compliances, the corrective actions taken and planned to correct the non-compliance and prevent recurrence and the date when full compliance will be achieved is already adequately addressed in Special Inspection Report 1234, and your letter dated DATE. However, you are required to submit a written statement or explanation if the description therein does not accurately reflect your corrective actions or your position. Non-compliance A and B are each Level 2

II.4. EXAMPLE WRITTEN WARNING

Our Ref 1234/02
Dr. Director Hospital
CAPITAL CITY

Dear Director of the Hospital

I have enclosed a copy of the report of the unannounced inspection conducted by our inspectors of your interventional radiology unit on 23 October 2003.

A number of non-compliances with the regulations and/or the guidelines for the Safe Use of X ray imaging in medical diagnosis have been identified. In accordance with the Authority's policy, this warning letter is issued to inform you that remedial action to correct these non-compliances needs to be completed by 15 November 2003. After these dates if the non-compliances identified are not corrected, the Authority will close the interventional radiology unit of your hospital.

The completed remedial action to address the non-compliances stated in the attached inspection report have to be reviewed by your RPO and a copy of the report submitted to me as evidence that the work has been satisfactorily completed before the specified date above.

If you require further information, please let me know. The Authority's staff will be pleased to discuss the report with your RPO (or your Qualified Expert).

Yours sincerely
Dr. Director of Authority
26 October 2003
E-mail: rra@isp.gov.country

NOTICE OF NON-COMPLIANCE

During an unannounced inspection to St. John's Hospital, the Regulatory Authority inspectors found that the dosimetry records of the workers at the interventional radiology unit presented anomalous data. In the case of four physicians, there were no readings higher than 0 for the last six years. This was an indication that the physicians were not using their dosimeters while performing their work.

Non-compliances identified by the inspectors:

In the inspection report the inspectors identified three non-compliances of Regulatory Authority requirements:

— Failure to monitor occupational exposure of workers from licenced sources of radiation, in accordance with Article 26 and Article 44 from the Regulations. The licensee failed to monitor individuals' occupational exposure to radiation sources under the control of the licensee and require the use of individual monitoring devices. Specifically, interventional radiology physicians whose occupational exposure could exceed 10 percent of the occupational exposure limits were not monitored over the course of 6 years;

— Failure to implement certain elements of the hospital radiation protection programme sufficiently to ensure compliance with the provisions of the regulations, Article 5 and Article 33. The licensee failed to implement a radiation protection programme commensurate with the scope and extent of licenced activities and sufficient to ensure compliance with the occupational exposure limits. Specifically, the licensee's procedures failed to include provisions regarding actions to be taken when individuals' doses were less than the licensee's Investigational Level, such as when dosimeters were returned unused or had unexpectedly low exposures;

— Failure to provide instructions to occupational workers regarding radiation safety, specifically involving the proper use of dosimeters, in accordance with Article 22, and Article 37 from the Regulations.

The licensee failed to provide instruction to individuals, who in the course of employment were likely to receive in a year an occupational dose that exceeds investigation levels, on the applicable provisions of the regulatory body regulations and licences for the protection of personnel from exposure to radiation and/or radioactive material. Specifically, the licensee failed to provide instructions regarding radiation safety involving the proper use and storage of dosimeters to four interventional radiology physicians, which resulted in their failure to wear dosimetry to monitor their exposure to occupational radiation.

II.5. EXAMPLE LEVEL 2 NON-COMPLIANCE WITH MONETARY PENALTY

Tracking No. 123
Authorization No. NPP-321
Authorized Party Senior Manager
Address

SUBJECT: NOTICE OF NON-COMPLIANCE AND MONETARY PENALTY - XX, XX €

Dear Mr./Ms. Senior Manager:

This letter is in reference to a special inspection conducted from DATE 1 to DATE 2 at the Specific Nuclear Power Plant (SNPP). A significant non-compliance was identified for the failure take effective corrective action following an earlier event to prevent recurrence. The report documenting the inspection and the apparent non-compliance (Report No. 12345) was sent to you on DATE. An enforcement meeting was held at the regulatory body office on DATE, at which time the non-compliance, root causes and corrective actions were discussed.

The non-compliance in the enclosed Notice pertains to a DATE event. This non-compliance is considered significant because it involves a failure to take lasting corrective actions following a similar event in the previous year. The DATE event occurred as operators were returning a hydraulic power unit (HPU) for the reactor recirculation system 'B' Flow Control Valve to service. The operators were required to confirm that output power was available from the HPU programmable logic controller prior to restarting the HPU. A technician reported that a fuse was blown, indicating an operate/isolate solenoid valve had no power.

The non-compliance represents a breakdown in the implementation of corrective actions following an incident the previous year, as corrective actions from that event were insufficient to prevent recurrence of a similar event on DATE. This non-compliance also represents a potentially significant lack of attention toward reactivity control. Therefore, the non-compliance is categorized in accordance with the regulatory body enforcement policy as a Level 2 non-compliance. In addition to the non-compliance, we are concerned that the shift supervisor became overly focused on restarting the flow control valve HPU instead of maintaining a broad perspective of operational conditions.

In accordance with the enforcement policy, a base monetary penalty in the amount of XXX, XXX€ is considered for a Level 2 non-compliance. Since the SNPP has been the subject of a significant enforcement action within the last two years, the regulatory body considered whether credit was warranted for identification and corrective action in accordance with the monetary penalty assessment process in Section 1.2.3 of the enforcement policy. Credit was not warranted for identification because the event was self-identified and a similar event in the previous year provided prior opportunity to identify that starting the HPU with a blown fuse could result in reactivity excursions. Also, several workers from differing disciplines were involved in developing the plan to return the flow control valve to service. This provided plant personnel with additional opportunities to identify anticipated problems prior to restarting the HPU.

You are required to respond to the non-compliance as stated in the enclosed Notice of Non-compliance. In accordance with regulatory body guidance, a copy of this letter, its enclosure, and your response will be placed on the regulatory body website.

NOTICE OF NON-COMPLIANCE AND IMPOSITION OF MONETARY PENALTY

Authorization No. NPP-321

During the regulatory body inspection conducted from DATE 1 to DATE 2 a non-compliance of regulatory body requirements was identified. In accordance with the regulatory body enforcement policy, the regulatory body is imposing a monetary penalty pursuant to the Nuclear Law Section ###. The non-compliance and associated monetary penalty are set forth below:

Regulation X.5, "Corrective Actions," requires, in part, that measures have to be established to assure conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective materials and equipment, and non-conformances are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures assure that the cause of the non-compliance is determined, and corrective action taken to preclude repetition.

This is a Level 2 Non-compliance.

Monetary Penalty – XXX, XXX€

In requesting mitigation of the penalty, the factors addressed in Section X.Y.1 of the enforcement policy will be addressed. The attention of the licensee is directed to the other provisions of Enforcement Policy Section X.Y.2, regarding the procedure for imposing a monetary penalty.

Upon failure to pay any monetary penalty due which subsequently has been determined in accordance with the applicable provisions of the regulations, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section ### of the Nuclear Law.

The responses noted above has to be addressed to the regulatory body Senior Manager at address…

Issuance date…

II.6. EXAMPLE SUSPENSION OF LICENCE INCLUDING REPETITION AND HISTORY

Our Ref: 1234/02
Director of XX Industrial Company
Box Post Office
CAPITAL CITY

Dear Director of the Company,

I have enclosed a copy of the report of the inspection conducted by our inspectors on site LLLLL where your company is conducting industrial radiography work, dated 3rd March 2022.

A number of non-compliances with regulations, especially Articles 6(2), 12(6) and 26(5) and with your licence conditions have been identified:

(a) Survey meter was not calibrated in the prescribed interval;

(b) Two out of three radiographers were not certified;

(c) No radiation protection officer (RPO) was available in the working area, and it would be impossible for the RPO to come within few hours.

In addition, and from the enforcement records of your company in the last five years, the company had serious non-compliances, including administrative warnings for:

(a) Not providing sufficient radiation protection equipment in the field;

(b) Not having an RPO available for about 6 months;

(c) Being late in submitting an application for licence renewal.

In accordance with the Authority's policy, and taking in consideration the enforcement records of your company, the following enforcement action is being taken:

— To suspend your company licence No: IR0015L issued by the Authority on 6 October 2015.

Accordingly, your company has to stop all industrial radiography work immediately at all sites inside the country.

If you require further information, please let me know. The Authority's staff will be pleased to discuss this decision with your company's staff at your convenience.

If your company would like to appeal against this enforcement action, please see Document Number Appeal 5/22/A at the Authority's website.

Yours sincerely,
Director of Authority
6 March 2022
E-mail:

NOTICE OF NON-COMPLIANCE IN THE INSPECTION REPORTS

During an inspection of your industrial radiography company holding a licence No: IR0015L authorizing the use of industrial radiography exposure devices for the purpose of material testing, conducted on 3rd March 2022, the Regulatory Authority inspectors identified the following non-compliances:

(a) The calibration certificate of the survey meter was expired;

(b) Two out of three radiographers were not certified.

(c) No RPO was available in the working area, and it would be impossible for the RPO to come within few hours

II.7. EXAMPLE OF INDIVIDUAL ACTION

DATE
Tracking number
Individual by name
HOME ADDRESS DELETED DUE TO PRIVACY

SUBJECT: ORDER PROHIBITING INVOLVEMENT IN REGULATORY BODY AUTHORIZED ACTIVITIES

Dear Individual:

This letter refers to an investigation conducted by the regulatory body on DATES to determine, in part, whether you, as owner of Radiography Company A, engaged in deliberate misconduct that caused Radiography Company A to be in non-compliance with regulatory body requirements. Based on the results of the investigation, the regulatory body determined that you deliberately conducted industrial radiography work, or instructed others to do so, at LOCATION X, on DATES 1 and 2 without holding a specific authorization authorizing such activities as required by Regulation 1.2. The regulatory body determined that your actions described above violated Regulation 3.4 which states, in part, that any authorized party or employee of an authorized party may not engage in deliberate misconduct that causes or would have caused, if not detected, an authorized party, to be in non-compliance of any rule, regulation, order, or any term, condition, or limitation of any authorization issued by the regulatory body.

Your deliberate actions caused Radiography Company A to be in non-compliance of Regulation 1.2. A copy of the enforcement action issued to Radiography Company A was issued on DATE. In a letter dated DATE, addressed to you as an individual, the regulatory body provided you with a factual summary of the regulatory body report and informed you that the regulatory body was considering enforcement action against you for the apparent non-compliance to Regulation 1.2. In that letter, the regulatory body offered you the opportunity to discuss the apparent non-compliance at an enforcement meeting. On DATE the regulatory body held an enforcement meeting with you by telephone to discuss the apparent deliberate misconduct non-compliance. During the meeting, you did not dispute the non-compliance, and you stated that after Radiography Company A authorization was modified to possession and storage only, you continued to conduct work for financial gain. You also acknowledged that your actions were contrary to the regulations.

Because of your deliberate actions, the regulatory body lacks the requisite reasonable assurance that you are willing to comply with the regulatory body requirements. Consequently, the regulatory body is issuing an Order (Enclosure 1) prohibiting your involvement in authorized activities for a period of five years from the date of this Order. During the five-year period, you will be prohibited from conducting, supervising, directing or otherwise engaging in any regulatory body-authorized activities as defined in Section IV of the Order. In addition, for a period of one year after the five-year prohibition period expires, the Order requires you to provide to the regulatory body in writing the name, address, and telephone number of the first employer or other entity for whom you will be engaging in authorized activities.

Pursuant to Nuclear Law 123, any person who wilfully violates, attempts to violate, or conspires to violate, any provision of this Order will be subject to criminal prosecution as set forth in that section. Violation of this Order may also subject the person to a monetary penalty. In

accordance with Regulation 5.6, you are required to respond to the enclosed Order within 30 days of issuance and need to follow the instructions specified in the enclosed Order when preparing your response. If you have additional information that you believe the regulatory body needs to consider, you may provide it in your response to the Order. The regulatory body will use your response, in part, to evaluate the appropriateness of the enforcement action, as well as whether further enforcement action is necessary to ensure compliance with regulatory requirements. To the extent possible, your response does not include any personal, privacy, proprietary or security sensitive information so that it can be made available to the public without redaction.

The regulatory body also includes significant enforcement actions on its website. In accordance with the regulatory body policy, a copy of this letter and its enclosure will be made available electronically for public inspection on the regulatory body website. If you have any questions concerning this matter, please contact Regulatory Body Manager.

Sincerely,

Regulatory Body Senior Manager

ENCLOSURE 1

REGULATORY BODY

In the Matter of Individual A

ORDER PROHIBITING INVOLVEMENT IN REGULATORY BODY AUTHORIZED ACTIVITIES

At the time of the events discussed below, Individual A was the owner of Radiography Company A, an industrial radiography company located in LOCATION. On DATE, Radiography Company A was issued a radioactive source authorization No. 1234, which authorized Radiography Company A to possess and utilize by-product material in up to three (3) devices for the purposes of industrial radiography. During the relevant time periods discussed below, Radiography Company A authorization had been amended to possession and storage of radioactive material only.

On DATE, a regulatory body investigation was conducted to determine whether Radiography Company A deliberately conducted unauthorized and/or unlicenced radiography activities. Based on the evidence gathered during the investigation, the regulatory body concluded that an apparent non-compliance of requirements occurred. On DATES Radiography Company A performed radiographic operations at LOCATION without a valid authorization. The regulatory body also concluded that Individual's actions appeared to constitute deliberate misconduct in non-compliance of Regulation 3.4. Individual was aware of the requirements for authorization based on their work experience. Individual went to the LOCATION and conducted radiography that day, and they continued to conduct radiography at the LOCATION on numerous other occasions between DATES 1 and 2.

The regulatory body concluded that Individual apparently engaged in deliberate misconduct that caused Radiography Company A to be in non-compliance of 1.2 when they engaged in, or directed others to engage in, industrial radiography at the LOCATION knowing that

Radiography Company A did not possess a regulatory body authorization authorizing such activities.

In the letter dated DATE, the regulatory body offered Individual the opportunity to attend an enforcement meeting to present their perspective on the apparent non-compliance. A meeting was conducted on DATE. During the meeting, Individual stated that they did not dispute the non-compliance. Individual also stated that they kept working to earn money because the financial benefits were more than the penalty fee, and they acknowledged knowing at the time that performing radiography under these conditions was not in accordance with the regulations.

Based on the results of the regulatory body investigation, and information provided during the meeting, the regulatory body concluded that Individual engaged in deliberate misconduct in non-compliance with Regulation 3.4.

Accordingly, pursuant to sections specified in the Nuclear Law, and the regulatory body's regulations IT IS HEREBY ORDERED THAT:

(a) Individual is prohibited for five years from the date of this Order from conducting, supervising, directing, or in any other way engaging in regulatory body authorized activities;

(b) If Individual is currently involved in authorized activities, they ought to immediately cease those activities; inform the regulatory body of the name, address, and telephone number of the employer or other entity for whom he is conducting authorized activities; and provide a copy of this Order to the employer or other entity;

(c) For a period of one year after the five-year prohibition on engaging in regulatory body authorized activities has expired, Individual has to, within 20 days of accepting their first employment offer involving regulatory body authorized activities or otherwise first becoming involved in authorized activities, as defined above, provide notice to the regulatory body Senior Manager at address..., of the name, address, and telephone number of the employer or other entity for whom they will be participating in or conducting the authorized activities. In the notification, Individual has to include a statement of their commitment to compliance with regulatory requirements and the basis for why the regulatory body can have confidence that they will now comply with applicable requirements. The regulatory body Senior Manager, may, in writing, relax or rescind any of the above conditions upon demonstration by Individual of good cause. In accordance with Regulation 5.6, Individual will submit a written answer to this Order under oath or affirmation within 30 days of its issuance. Individual's failure to respond to this Order could result in additional enforcement action in accordance with the regulatory body's enforcement policy. In addition, Individual and any other person adversely affected by this Order may request a hearing on this Order within 30 days of its issuance. Where good cause is shown, consideration will be given to extending the time to answer or request a hearing.

All documents filed in regulatory body adjudicatory proceedings including documents filed by an interested State, local governmental body, or designated agency thereof that requests to participate under Regulation … INCLUDE MEMBER STATE APPROPRIATE LEGAL PROCESSES.

REFERENCES

[1] INTERNATIONAL ATOMIC ENERGY AGENCY, Governmental, Legal and Regulatory Framework for Safety, IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), IAEA, Vienna (2016).

[2] INTERNATIONAL ATOMIC ENERGY AGENCY, Functions and Processes of the Regulatory Body for Safety, IAEA Safety Standards Series No. GSG-13, IAEA, Vienna (2018).

[3] INTERNATIONAL ATOMIC ENERGY AGENCY, Organization, Management and Staffing of the Regulatory Body for Safety, IAEA Safety Standards Series No. GSG-12, IAEA, Vienna (2018).

[4] INTERNATIONAL ATOMIC ENERGY AGENCY, Leadership and Management for Safety, IAEA Safety Standards Series No. GSR Part 2, IAEA, Vienna (2016).

[5] EUROPEAN COMMISSION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).

[6] INTERNATIONAL ATOMIC ENERGY AGENCY, Establishing the Safety Infrastructure for a Nuclear Power Programme, IAEA Safety Standards Series No. SSG-16 (Rev. 1), IAEA, Vienna (2020).

[7] INTERNATIONAL ATOMIC ENERGY AGENCY, Managing Regulatory Body Competence, IAEA Safety Report Series No. SRS-79, IAEA, Vienna (2014).

[8] INTERNATIONAL ATOMIC ENERGY AGENCY, Effective Corrective Actions to Enhance Operational Safety of Nuclear Installations, IAEA-TECDOC-1458, IAEA, Vienna (2005).

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[11] INTERNATIONAL ATOMIC ENERGY AGENCY, Status of Research and Technology Development for Supercritical Water Cooled Reactors, IAEA-TECDOC-1869, IAEA, Vienna (2019).

[12] INTERNATIONAL ATOMIC ENERGY AGENCY, Application of a Graded Approach in Regulating the Safety of Radiation Sources, IAEA-TECDOC-1974, IAEA, Vienna (2021).

[13] INTERNATIONAL ATOMIC ENERGY AGENCY, Application of a Graded Approach in Regulating the Safety of Radiation Sources, IAEA-TECDOC-1980, IAEA, Vienna (2021).

[14] INTERNATIONAL ATOMIC ENERGY AGENCY, Notification, Authorization, Inspection and Enforcement for the Safety and Security of Radiation Sources, IAEA-TRS-1002, IAEA, Vienna (2022).

[15] EUROPEAN ATOMIC ENERGY COMMUNITY, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, INTERNATIONAL MARITIME ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Fundamental Safety Principles, IAEA Safety Standards Series No. SF-1, IAEA, Vienna (2006).

Annex

COUNTRY SPECIFIC EXAMPLES

A–1. PAKISTAN

A–1.1. Overview of the enforcement mechanism of the regulatory body in Pakistan

A–1.1.1. Introduction

Regulatory bodies use enforcement actions against non-compliances to ensure implementation of regulatory requirements for safety of nuclear installations and radiation facilities. The Pakistan Nuclear Regulatory Authority (PNRA), a corporate body operating as the regulatory body for safety in the country is mandated to independently regulate nuclear safety, radiation protection and physical security related aspects associated with nuclear and radioactive materials and other sources of ionizing radiations. PNRA has been mandated with a number of functions including development of regulatory requirements, review and assessment, authorization and licensing, inspection and enforcement, and enforcement.

A–1.1.2. Enforcement framework

The regulatory framework for enforcement in PNRA has been imbedded in the Ordinance (Law). The hierarchy follows the regulations made thereunder and then the downstream enforcement procedures as shown in Fig. A–1. The Ordinance empowers PNRA to take various enforcement actions (e.g. cancellation or suspension of an authorization, lock and seal of the facility etc). In order to execute the enforcement powers delineated in the Ordinance, 'Pakistan Nuclear Regulatory Authority Enforcement Regulations–(PAK/950)' was promulgated. 'PAK/950' defines the requirements and procedural steps to be followed for various enforcement actions such as final directives, show cause notices, offense reports, lock and seal, hearing etc. Standard operating procedures (SoPs) are third (3rd) tier documents in which stepwise enforcement procedure has been described in detail, such as:

— PNRA Enforcement Procedure;

— Procedure for Conduct of Hearing;

— Procedure for Filing of Complaint.

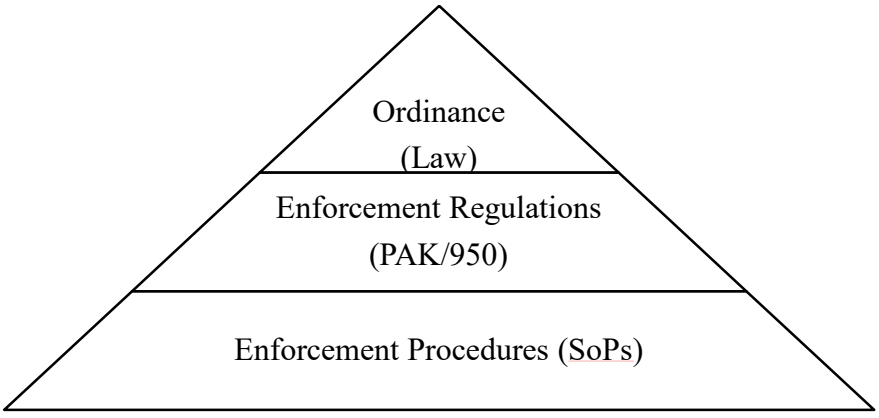

Fig. A–1. The PNRA enforcement framework/documents.

A–1.1.3. ORGANIZATIONAL INFRASTRUCTURE

In order to perform its functions, PNRA has established Directorates, Inspectorates and an Office of Legal Affairs. The organizational structure has been extended in a specific scheme with focus on the core regulatory functions.

A–1.1.3.1 Directorates and inspectorates

Offices which are directly involved in licensing, authorization, inspection, and enforcement processes are termed as Directorates and Inspectorates. Licensing Directorates at Head Quarters (HQs) working under the Director General (Licensing and Authorization) whereas Regional Nuclear Safety Directorates (RNSDs) and Regional Nuclear Safety Inspectorates (RNSIs) working under the Director General (Inspection & Enforcement) are responsible for execution of enforcement activities in their respective domains.

Three (03) Regional Nuclear Safety Directorates (RNSDs) and five (05) Regional Nuclear Safety Inspectorates (RNSIs) (have been established at eight (08) locations in the country to ensure efficient and effective regulatory oversight by the Authority. These offices, predominantly staffed with inspectors, have direct interface with licensees and relevant stakeholders. They perform inspections and initiate due enforcement actions, if so required. Such enforcement actions include issuance of violation notices, final directives, show cause notices, work stoppage notices, etc.

A–1.1.3.2 Office of legal affairs

Office of Legal Affairs (OLA) has been established under the supervision of the Director General (Regulatory Affairs). This office is staffed with lawyers and a registrar (enforcement coordinator) of the Authority. Among others, the tasks and functions of OLA are to provide guidance and assistance for effective implementation of Enforcement Regulations-PAK/950 and execution, assistance, and follow-up of litigation cases at judicial forums.

A–1.1.4. Enforcement basis

There are various scenarios that may lead to an enforcement action by PNRA. A few examples are discussed below:

A–1.1.4.1 Violation of ordinance or regulations

If a licensee or an authorization holder is found to be engaged in activities which may endanger the safety of people or the environment or found guilty of unprofessional performance, wilful misconduct, or negligence pertaining to obligations arising out of Ordinance and Regulations, it is considered a violation, leading to enforcement action. Further, obtaining or attempting to obtain a licence or authorization or renewal thereof by fraudulent representation or through provision of incorrect information; providing the Authority with false or misleading information is also considered violation and will lead to enforcement action.

A–1.1.4.2 Non-provision of information

It may simply be a matter of seeking some information from a licensee or a non-licensee. In this case, the relevant Directorate may send a notice to obtain information for the purpose of

satisfying themselves as to whether the provisions of the Ordinance or the regulations or terms and conditions of the Licence or Directives, have been or are being adequately complied with. Refusal to share the requested information with Authority may lead to an enforcement action.

A–1.1.4.3 Denial for unhindered access to the premises

Similarly, if it seems necessary, an inspector may enter into premises and every person related to the facility or activity is by law is bound to assist and facilitate the inspector and to provide relevant data, records and full access to areas of interest in performance of their duties and functions without any obstruction, hindrance or delay. Denial of access to premises or relevant data or record may lead to enforcement action.

A–1.1.4.4 Holding authorization (time specific)

Conduct of operations of facility, after the Authority decided to withhold an authorization or impose a time specific condition as a pre-requisite for issuance of an authorization may also result in enforcement action.

A–1.1.5. Enforcement process

The PNRA enforcement process is reflected in Fig. A–2.

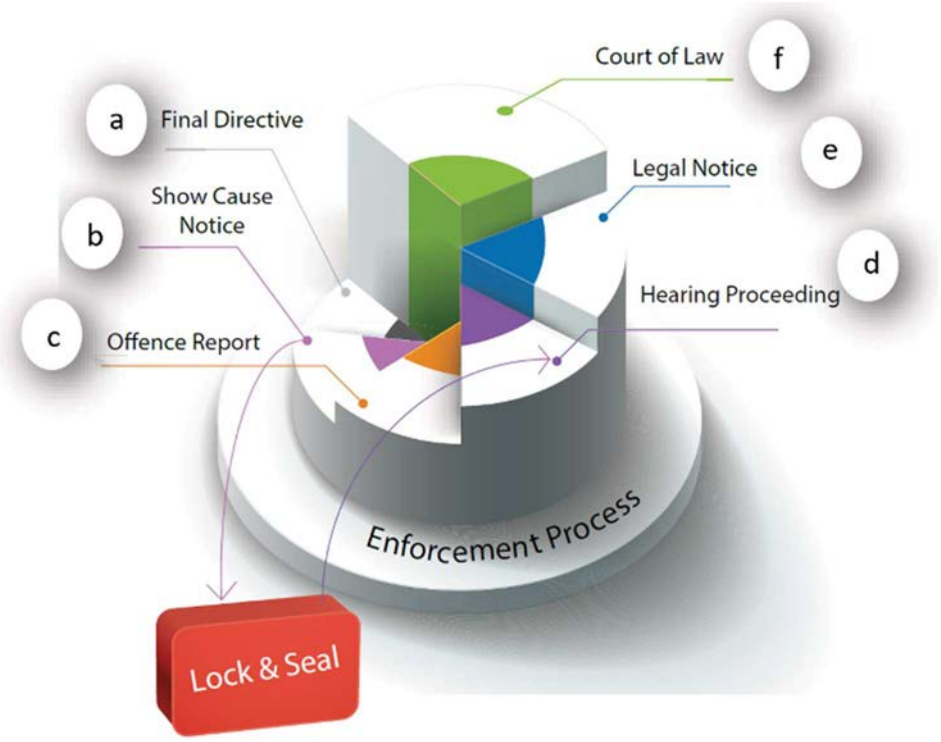

FIG. A–2. Enforcement Process of PNRA.

A–1.1.5.1 Issuance of final directive

Section 12 (2) (b) of PAK/950 empowers a director for the issuance of final directive. Upon report of a violation (e.g. through inspection), the director of the concerned directorate will consider the report for its assessment in light of factors such as safety significance, previous record, nature of cause (deliberate, wilful, negligence), frequency of occurrence, the violator's preparation and willingness towards rectification and any other factor considered essential by

the Authority. Upon assessment, the Director may decide for issuance of a final directive or rejection of the violation report. In the former case, the Director, on receipt of reply to the directive will assess whether to accept or reject the reply.

A–1.1.5.2 Issuance of show cause

Section 24 (2) of the ordinance states that before taking any action under subsection (1), the Authority issues a notice to the violator to show cause and give them an opportunity to be heard or an opportunity to rectify the omission, subject to such conditions as the Authority may specify. A time bound show cause notice is issued by relevant director as per Section 12 (2) (a) of PAK/950 if the reply to the final directive of the authorized party is disagreed or there is no reply.

A–1.1.5.3 Offence report

In case of unsatisfactory response or no response, the director will refer the matter to the 'Director General Inspection and Enforcement (I&E)', by submitting an offence report as per Section 20 of PAK/950. DG (I&E) may decide to call the violator in order to conduct the hearing with the consultation of OLA.

A–1.1.5.4 Hearing proceedings

An opportunity to be heard is provided to the violator in the form of hearing proceedings chaired by DG (I&E). The registrar of the Authority is responsible to make the arrangements for effective hearing proceedings as per Section 16 of PAK/950. If DG (I&E) concludes that a non-compliance has taken place, they may:

(a) Direct a violator to comply with regulatory requirements within a specified time;

(b) Suspend or cancel the licence or authorization;

(c) Direct the relevant Director/Inspector to proceed to lock and seal the facility.

Afterwards, a written decision of the hearing proceeding is issued to the violators for compliance.

A–1.1.5.5 Legal notice

If a violator does not comply with the hearing decision or he/she fails to appear for the hearing, then a legal notice is served by OLA as per Section 25 of PAK/950 before filing a complaint against the violator in the court of law.

A–1.1.5.6 Referrals to the court of law

In case of no or unsatisfactory response to the legal notice, a complaint is filed by OLA in the court of law for prosecuting the violator as per Section 26 of PAK/950.

A–1.1.5.7 Lock and seal

An inspector or a directorate, at any stage of the enforcement process, may proceed for work stoppage or lock and seal of the facility (Section 29 (f) of the Ordinance and Section 7 (g) of PAK/950). In general, the decision of lock and seal is applied to non-compliances committed by radiation facilities.

A–1.1.5.8 Lock and seal scenarios

The possible scenarios related to radiation facilities leading to lock and seal of a facility could be as follows:

(a) A licensee is committing repeated safety violations and does not rectify safety related issues despite various directives or not renewing their licence, even after lapse of the stipulated time period.

- Such a case is reported by the relevant inspector to the respective director, along with all documentary evidence (i.e. reminders, inspection reports, directives, final directive, show cause notices, etc.) to acquire necessary approval for lock and seal of the facility.

(b) A registrant/licensee committing a severe violation of radiation safety or radiation protection and does not rectify the violations despite the PNRA directive.

- The inspector will take the decision to lock and seal the whole facility or any part of the facility thereof (such as the X ray room only) on the spot, by informing the concerned director by telephone or through any other rapid means of communication.

(c) After suspension/cancelation of licence by the decision of DG (I&E) during hearing proceedings.

- The inspector on site may lock and seal such a facility without any further deliberation to implement the hearing decision issued by DG (I&E).

A–1.1.5.9 Involvement of law enforcement agencies

In order to facilitate the process, the inspector or any other authorized official of the Authority may contact the law enforcement agencies for provision of necessary personal security during the execution of lock and seal of the facility. A preliminary meeting may also be held with law enforcement agencies prior to the enforcement activity to share the violation in detail and address concerns of law enforcement agencies, if any. In the case of any hindrance, other appropriate measures may also be taken by the inspector in coordination with the concerned director, which may include filing of an FIR (First Information Report) in a local police station or filing a complaint in the court of law.

A–1.1.5.10 Post lock and seal activities

After lock and seal of the facility, the violator is directed to appear before DG (I&E) on a specified date/time/location for hearing proceedings to clarify his/her position. During hearing proceedings, the violator either submits a compliance report or requests the Authority for time relaxation in order to comply with regulatory requirements, which is assessed by a technical team, as well as by OLA. If the response of the violator is acceptable, onsite verification of compliance is done by PNRA inspectors. In case of compliance, the respective regional director with the approval of DG (I&E) may authorize the facility for de-sealing.

A–1.1.6. Dispute resolution

PNRA has issued ‘Regulations on Dispute Resolution-PAK/949’, which describes the process for licensee to appeal against any regulatory decision, including enforcement decisions. PAK/949 defines the process for establishment of a tribunal by Chairman PNRA from the professional staff of the Authority, except those belonging to a directorate against whom the dispute is referred. The tribunal may resolve disputes, or such other matters as assigned.

A–1.1.7. Examples of enforcement

Previously, a number of enforcement actions have been taken against nuclear installations, as well as radiation facilities. For reference, three examples have been summarized below:

A–1.1.7.1 Enforcement action against a nuclear power plant

As per PNRA regulations PAK/909 on licencing of nuclear installations, the licensee is required to submit a commissioning programme for review and approval by the regulatory body. Commissioning tests of structures, systems and components (SSCs) important to safety can only be started after approval of this programme. In this case, the commissioning programme of the plant was in the approval process; however, the regional directorate had come to know that plant authorities had started commissioning tests of certain safety related systems. A work stoppage notice after confirmation was issued to the plant to stop commissioning tests of SSCs important to safety until approval of the commissioning programme had been granted to meet the regulatory requirements of PAK/909. Commissioning tests of the plant were stopped immediately after issuance of the work stoppage notice. Commissioning tests were restarted after completing the approval process and issuance of authorization to proceed with the commissioning activities accordingly.

A–1.1.7.2 Enforcement action against a nuclear power plant

The construction of different layers of the Nuclear Island (NI, RX Foundation) base mat of an NPP were in progress and each layer had a curing time requirement of 28 days, in accordance with design specifications. PNRA received a control point inspection notice for construction of H layer; whereby, it was observed that the curing time of the already constructed G layer will not be met if H layer is poured on the date specified in the notice (with this the curing time for G layer would have been 26 days). A meeting between PNRA and the operating organization was held to discuss and resolve the issue; however, the presented justification of operating organization was not acceptable to PNRA. Therefore, PNRA issued a work stoppage notice and did not allow concrete pouring of H layer of NI base mat until the full curing time of G layer had been completed, in accordance with the design specifications.

A–1.1.7.3 Enforcement action against a radiation facility

The licence of the licensee for the use of three (03) Nuclear Gauges (Am-241) had expired and was not renewed. Various Licence Renewal Notices (LRNs) were issued to the violator, but the violator did not comply with the regulatory requirements. Later, a Show Cause Notice was issued to request compliance with regulatory requirements or stern legal action would be initiated pursuant to relevant provision of PNRA Ordinance and PNRA enforcement regulations PAK/950.

In accordance with the requirements of PAK/950 regulations, an offence report was filed to the registrar of the OLA by the licencing directorate. Subsequently, a hearing notice was issued to provide an opportunity for an internal hearing by DG (I&E). However, the violator did not attend the hearing proceedings. Afterward, a Legal Notice was issued to the violator, per the enforcement procedure, but no response was received. Finally, a complaint was filed with the Judicial Magistrate (1st Class) under section 19, 44 & 45 of PNRA Ordinance read with Section 200 of Code of Criminal Procedure Pakistan.

After the trial, the court decided the case in favour of PNRA by convicting the violator and issuing a fine amounting to Rs. 300,000/- under section 44(1), 44(3) and 44(4) or sixty (60) days imprisonment in case of non-payment of the fine. The violator paid the fine and fulfilled all applicable regulatory requirements.

Note: PNRA Ordinance and relevant regulations can be accessed through official website of PNRA (www.pnra.org).

A–1.2. Overview of application of a graded approach in enforcement actions in Pakistan

A–1.2.1. Application of a graded approach

PNRA Ordinance has defined different punishments with consideration of a graded approach depending upon contraventions made under section 44 of the ordinance implemented though the court of law. The most severe enforcement action, such as cancellation or suspension of an authorization or a licence is defined in section 24 (1) of the Ordinance.

The graded approach applied for enforcement actions as covered in section 44 of the Ordinance for contraventions or violations of different requirements, as mentioned in different sections of the PNRA Ordinance or provisions of any rules or regulations made under the PNRA Ordinance is described as:

— Any person who contravenes any of the provisions of sections 19, 20, 21, 22 or 23 of the PNRA Ordinance has to be punishable with imprisonment for a term which may extend to seven years, or with a fine which may extend to one million rupees, or both.

— Any person who fails to provide any return required under the PNRA Ordinance or the rules and regulations made thereunder, or wilfully provides any false return or information, or obstructs any officer or other person duly authorized under this Ordinance in the discharge of their duty thereunder, will be punishable with imprisonment for a term which may extend to one year, or with a fine which may extend to 0.25 million rupees, or both.

— Any operator licenced under section 19 or any person authorized under sections 20, 21, 22 or 23 of the PNRA Ordinance, who contravenes any of the provisions of any rules or regulations made under the PNRA Ordinance, or any term or condition imposed thereunder, will be punishable with imprisonment for a term which may extend to three years, or a fine which may extend to 0.5 million rupees, or both.

— Any person who fails to comply with, or contravenes any provisions, conditions or requirements contained under the PNRA Ordinance or the rules and regulations made thereunder, or commits an offence, where no penalty is elsewhere provided, will be punishable with imprisonment for a term which may extend to six months, or a fine which may extend to 0.1 million rupees, or both.

A–1.2.2. Consideration of a graded approach in enforcement actions

The enforcement actions taken by PNRA can be divided in to three levels as shown in Fig. A–3. The first, or elementary level actions, are those taken by the licensing/authorizing directorates and include directives, violation notices, show cause notices, work stoppage, lock and seal etc.

If a licensee does not comply following the directorate level enforcement actions, the level is elevated and now the case is heard by the DG (I&E). DG (I&E) will conduct hearing proceedings to listen the licensee's and PNRA's relevant directorate's point of view and a decision will be taken and issued accordingly.

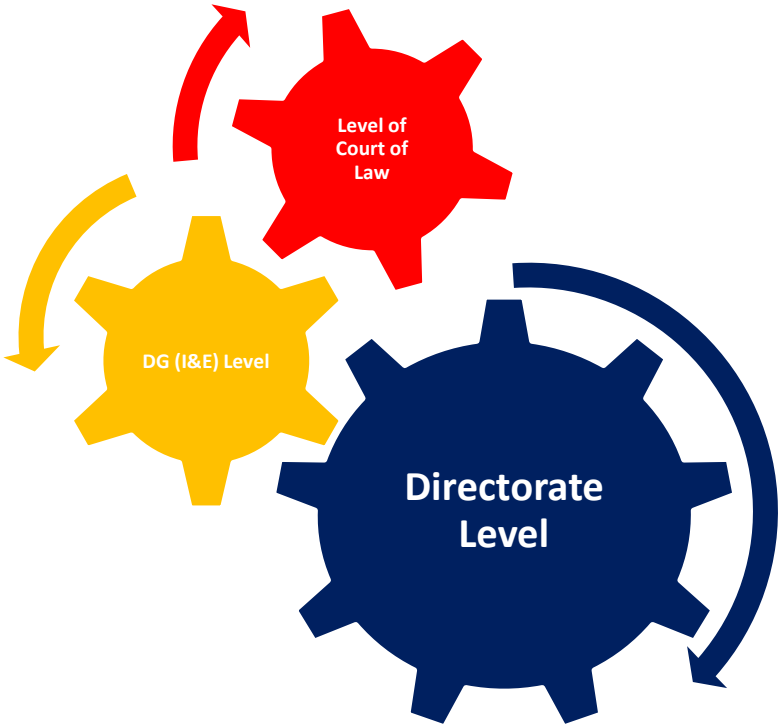

FIG. A–3. Levels of enforcement actions.

The third level is to take the case to a court of law. The court hears the case and an order is issued in the light of PNRA Ordinance. Thus, PNRA enforcement process is such that a licensee has multiple opportunities to comply with the regulatory requirements before stern enforcement action is taken. These opportunities in the enforcement process are shown in the below Fig. A–4. The severity of the non-compliance decides the level of enforcement action to be taken.

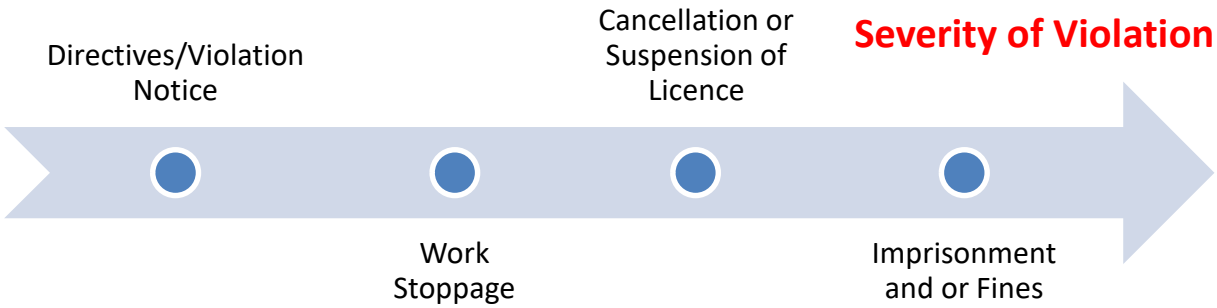

FIG. A–4. Severity of violation is met by an appropriate enforcement action.

A–1.2.3. Utilization of other Techniques to Enhance Compliance with Regulatory Requirements

PNRA also utilizes other techniques to enhance compliance with regulatory requirements, including resolution of inspection findings. PNRA conducts inspections during different licensing stages of nuclear installations according to its inspection programme. PNRA issues inspection reports along with corrective actions (if any). If any non-compliance is not addressed by the licensee, then directives may be issued from PNRA headquarters to resolve the non-compliance.

Some unresolved non-compliances are discussed in coordination meetings arranged at various management levels with different frequencies.

During the construction phase of NIs, PNRA conducts regulatory inspections to verify compliance with regulatory requirements. PNRA conducts a three-party meeting (owner, main contractor, and regional director of PNRA) to discuss different unresolved non-compliances on a quarterly basis. Furthermore, coordination meetings at the Director General level are arranged on a quarterly basis to address unresolved non-compliances from lower management level meetings and to share the progress of the infrastructure development of the project, including human resource development.

During the operation phase of NPPs, the frequency of coordination meeting is changed to biannually due to reduction in the number of issues and inspection findings.

Coordination meetings are also arranged at the corporate level at specified frequencies to discuss outstanding issues as well as policy matters to ensure compliance with regulatory requirements and agreed positions are issued in the form of minutes for further actions (Fig. A–5).

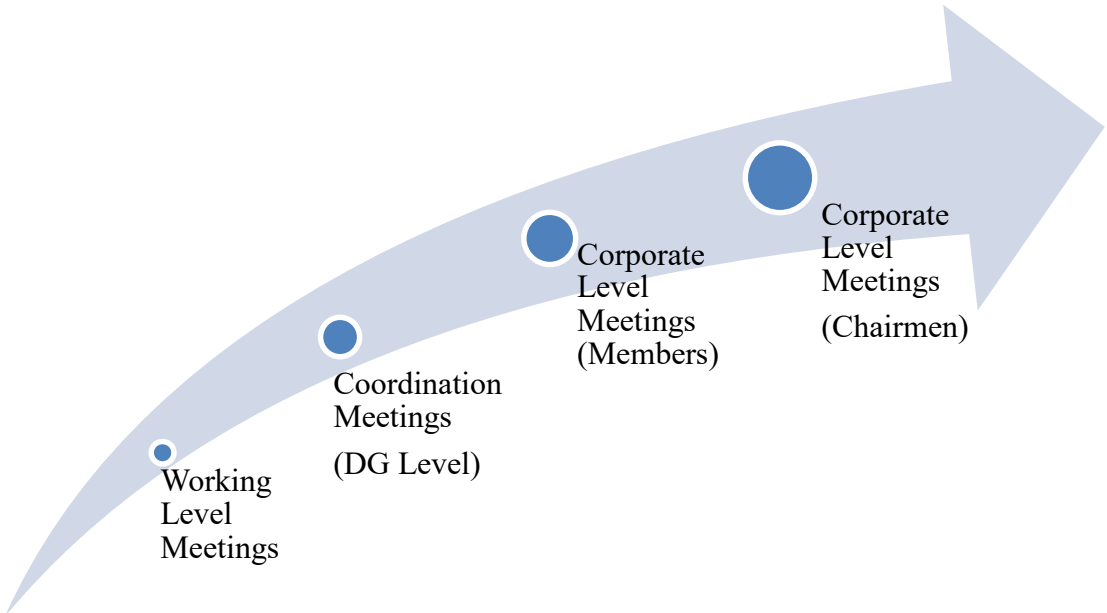

FIG. A–5. Other techniques of ensuring compliance.

A–2. UNITED KINGDOM

A–2.1. The Office for Nuclear Regulation

The Office for Nuclear Regulation (ONR) is the statutory regulatory body for safety for Great Britain's nuclear sites and regulates activities prescribed in the Energy Act 2013. The Act states that ONR has five purposes:

— The Nuclear Safety purpose (section 68 of Energy Act 2013);

— The Nuclear Site Health and Safety purpose (section 69 of Energy Act 2013);

— The Civil Nuclear Security purpose (section 70 of Energy Act 2013);

— The Nuclear Safeguards purpose (section 72 of Energy Act 2013); and

— The Nuclear Transport purpose (section 73 of Energy Act 2013).

The ONR mission is to protect society by securing safe nuclear operations. As the nuclear regulator, ONR takes enforcement action when licensees or duty holders are found to be failing to meet the safety and security standards required by law. To do this, ONR has been provided with a range of enforcement powers which range from providing advice to taking court proceedings.

A–2.2. The ONR enforcement policy statement

The ONR Enforcement Policy Statement (EPS) sets out the principles that inspectors apply when determining what enforcement action to take in response to breaches of health, safety, security and safeguards legislation. Fundamental to this is the principle that enforcement action is proportionate to the health, safety, security and safeguards risks and compliance gaps and/or the seriousness of the breach. The EPS is available from the ONR website.

All ONR staff who make enforcement decisions are required to follow ONR's Enforcement Policy Statement. It details the purposes of enforcement as well as the key principles for enforcement by ONR.

The purpose of enforcement is to:

— ensure that authorized parties take action to deal immediately with serious risks;

— promote, achieve and sustain compliance with the law;

— ensure that authorized parties who breach regulatory requirements, and directors or managers who fail in their responsibilities, are held to account, which may include bringing alleged offenders before the courts in England and Wales, or recommending prosecution in Scotland, in the circumstances set out later in this policy.

The EPS also provides a broad overview of applicable UK law as well as the different enforcement methods. Sometimes UK law is prescriptive; however, much of modern health and safety law is goal setting, setting out what needs to be achieved.

A–2.3. Enforcement guide (ONR-ENF-GD-006)

The enforcement guide sets out the principles that ONR inspectors apply when determining which enforcement action to take in response to breaches of legislation; it provides an overview of enforcement for all ONR purposes and guides inspectors through the key facets of determining the enforcement decision. The enforcement guide is available on the ONR website.

A–2.4. Enforcement management model

The guide describes the ONR Enforcement Management Model (EMM) which is a methodology which is intended to:

— ensure consistency in the enforcement decision making process;

— ensure proportionality and targeting by considering the risk-based criteria against which decisions are made;

— provide a framework for ensuring transparency in making enforcement decisions and for ensuring that those who make decisions are accountable for them;

— help inspectors assess their decisions in complex cases and allow peer review of enforcement action.

The EMM is a framework for making consistent enforcement decisions and not a mechanistic decision making tool. It is simple in structure, and thus cannot capture the nuances of each potential enforcement scenario. It identifies a range of enforcement options, but the regulatory response is not limited to these.

The key facets of the EMM are:

— Risk Analysis (determine the Risk/Compliance Level);

— Identify the Benchmark Standard;

— Confirm the Baseline Enforcement Level (BEL);

— Consider Duty Holder Factors;

— Consider Strategic Factors;

— Review the proposed decision.

The concept of Risk Level is not appropriate for administrative aspects of legal requirements, which, in themselves, do not relate directly to risk control e.g. the requirement to notify ONR of an incident. The ONR EMM refers to such cases as non-risk-based compliance with administrative issues and treats them separately from risk-based issues.

A–2.5. Enforcement level

The BEL is the minimum enforcement to secure compliance. The way in which ONR regulates nuclear licensees means that, in most cases, ONR has regular interactions with these authorized parties in terms of compliance with the law. As such, there are numerous opportunities for ONR to provide advice on safety, security and safeguards matters, and this will affect how authorized

party factors are used in determining proportionate enforcement action. In other cases, for example, transport, ONR has limited interactions with authorized parties, which also affects the application of authorized party factors. The inspector will be best placed to consider these factors given their ongoing interactions with the authorized party. Examples of authorized party factors include:

— Inspection history;

— Level of confidence in the authorized party;

— History of relevant formal enforcement;

— History of related incidents;

— Evidence of deliberate seeking of economic gain;

— Standard of general compliance.

There are a range of strategic factors which may impact on the enforcement decision. For example, inspectors ensures that the public interest and vulnerable groups (e.g. children and patients) are considered.

A–2.6. Enforcement decision

The inspector ensures that the enforcement recommendation takes account of the following principles in relation to the priorities for action:

— Does the enforcement action deal with the most serious risks in order of priority, and in appropriate timescales?

— Are underlying causes addressed?

— Does the enforcement action take account of the scale of the failures, e.g. isolated or multiple failures?

— Does the enforcement action deal with the fundamental cause of the problem(s), e.g. workplace precautions, risk control systems or management arrangements?

The application of the EMM is recorded in an Enforcement Decision Record (EDR), which has to be completed for any decision where formal enforcement is a realistic possibility. Formal enforcement is a written communication demanding or seeking improvement, or a legal instrument or process.

The Enforcement Decision Record (EDR) is subject to governance checks by ONR to ensure:

— that the application and evidence for authorized party factors has been appropriately applied if the BEL has been escalated;

— that the application of strategic factors is addressed by the proposed enforcement action;

— whether the proposed enforcement action meets the EPS;

— that, for consideration of prosecution, the enforcement action meets the Code for Crown Prosecutors in England and Wales or the Prosecutors Code in Scotland.

Once confirmed, the enforcement action is communicated to the authorized party, in line with ONR arrangements.

A–3. UNITED STATES OF AMERICA

The U.S. Nuclear Regulatory Commission (NRC) Enforcement Policy sets forth the general principles governing the NRC's enforcement programme and the Commission's expectations regarding the process to be used by the NRC to assess and disposition violations of NRC requirements. However, this is a policy statement and not a regulation. The Commission may deviate from this statement of policy, as appropriate, under the circumstances of a particular case. The NRC Enforcement Policy and Manual, which contains specific processes and guidance for implementing the Policy, can be found in their entirety on the NRC website (www.nrc.gov).

The NRC Enforcement Policy supports the NRC's mission to ensure adequate protection of public health and safety, promote the common defence and security, and protect the environment. Adequate protection is presumptively assured by compliance with NRC requirements. Compliance with NRC requirements, including regulations, technical specifications, licence conditions, and Orders, provides reasonable assurance to the NRC and the public that safety and security are being maintained. The application of this Policy ensures that associated enforcement actions properly reflect the safety or security significance of such violations. Consistent with this objective, the Enforcement Policy endeavours to do the following:

— Deter non-compliance by emphasizing the importance of compliance with NRC requirements;

— Encourage prompt identification and prompt comprehensive correction of violations of NRC requirements.

The Enforcement Policy applies to all NRC licensees and applicants, to various categories of non-licensees, and to individual employees of licensed and non-licensed entities involved in NRC-regulated activities.

It is NRC policy to hold licensees, certificate holders, and applicants responsible for the acts of their employees, contractors, or vendors and their employees, and the NRC may cite the licensee, certificate holder, or applicant for violations committed by its employees, contractors, or vendors and their employees. The NRC may use the term "licensee" in this Policy to generally refer not only to licensees, but also to certificate holders and applicants.

The NRC's enforcement process has the following basic steps:

(a) First, violations will be identified;

(b) Next, the NRC will assess the severity or significance of the violation;

(c) Finally, the NRC will disposition the violation.

The enforcement process begins with the identification of violations, either through NRC inspections or investigations, a licensee report, or substantiation of an allegation.

All violations are subject to consideration for civil enforcement action; some violations may also be considered for criminal prosecution by the U.S. Department of Justice. The NRC's enforcement assessment process is fact driven, performance based, and, when appropriate and possible, risk informed. The NRC reviews each case being considered for enforcement action

on its own merits to ensure that the severity of a violation is characterized at the level appropriate to the safety or security significance of the particular violation.

After a violation is identified, the NRC assesses its severity or significance (both actual and potential). Under traditional enforcement, the severity level (SL) assigned to the violation generally reflects the assessment of the significance of a violation. For most violations committed by NPP licensees, the significance of a violation is assessed using the Reactor Oversight Process (ROP) or the Construction Reactor Oversight Process (cROP). All other violations at power reactors or power reactor facilities under construction will be assessed using traditional enforcement. Violations identified at facilities that are not subject to an ROP or cROP are assessed using traditional enforcement.

In determining the appropriate enforcement response to a violation, the NRC considers the four specific factors discussed below.

(a) Whether the violation resulted in actual safety or security consequences;

(b) Whether the violation had potential safety or security consequences;

(c) Whether the violation impacted the ability of the NRC to perform its regulatory oversight function;

(d) Whether the violation involved wilfulness.

Whenever possible, the NRC uses risk information in assessing the safety or security significance of violations and assigning severity levels. A higher severity level may be warranted for violations that have greater risk, safety, or security significance, while a lower severity level may be appropriate for violations that have lower risk, safety, or security significance. The duration of the violation is also an appropriate consideration in assessing the significance of the violation.

A–3.1. Traditional enforcement

Recognizing that the regulation of nuclear activities in many cases does not lend itself to a mechanistic treatment, judgment and discretion will be exercised in determining the severity levels of the violations and the appropriate enforcement actions. This judgment and discretion include the decision to issue a Notice of Violation (NOV), or to propose or impose a civil penalty and the amount of this penalty, after considering the general principles of this statement of policy and the significance of the violations, as well as the surrounding circumstances.

Severity level designations reflect different degrees of significance depending on the activity area in which the severity level is designated. For example, the immediacy of any hazard to the public associated with SL I in reactor operations is not directly comparable to that associated with SL I violations in facility construction.

(a) SL I violations are those that resulted in or could have resulted in serious safety or security consequences (e.g. violations that created the substantial potential for serious safety or security consequences or violations that involved systems failing when actually called on to prevent or mitigate a serious safety or security event);

(b) SL II violations are those that resulted in or could have resulted in significant safety or security consequences (e.g. violations that created the potential for substantial safety or security consequences or violations that involved systems not being capable, for an extended period, of preventing or mitigating a serious safety or security event);

(c) SL III violations are those that resulted in or could have resulted in moderate safety or security consequences (e.g. violations that created a potential for moderate safety or security consequences or violations that involved systems not being capable, for a relatively short period, of preventing or mitigating a serious safety or security event);

(d) SL IV violations are those that are less serious, but are of more than minor concern, which resulted in no or relatively inappreciable potential safety or security consequences (e.g. violations that created the potential of more than minor safety or security consequences);

(e) Minor Violations are those that are less significant than a SL IV violation. Minor violations do not warrant enforcement action and are not normally documented in inspection reports. However, minor violations have to be corrected.

A–3.2. Assessment of violations identified under the reactor oversight process or construction oversight process

The assessment, disposition, and subsequent NRC action related to inspection findings identified at operating power reactors is determined by the ROP, as described in NRC Inspection Manual Chapter (IMC) 0305, 'Operating Reactor Assessment Program,' and IMC 0612, 'Power Reactor Inspection Reports.' The assessment, disposition, and subsequent NRC action related to inspection findings identified at power reactors under construction are determined by the cROP, as described in IMC 2505, 'Periodic Assessment of Construction Inspection Program Results' and in IMC 0613, "Power Reactor Construction Inspection Reports."

Inspection findings identified through the ROP are assessed for significance using the Significance Determination Process (SDP) described in IMC 0609, 'Significance Determination Process (SDP).' Inspection findings identified through the cROP are assessed for significance using the SDP described in IMC 2519, 'Construction Significance Determination Process.' The SDPs uses risk insights, where possible, to assist the NRC staff in determining the significance of inspection findings identified within the ROP or cROP. Inspection findings processed through the SDP, including associated violations, are documented in inspection reports, and are assigned one of the following colours, depending on their significance.

(a) Red: inspection findings with high safety or security significance;

(b) Yellow: inspection findings with substantial safety or security significance;

(c) White: inspection findings with low-to-moderate safety or security significance;

(d) Green: inspection findings with very low safety or security significance.

Violations associated with ROP or cROP inspection findings are not normally assigned severity levels, nor are they normally subject to civil penalties, although civil penalties are considered for any violation that involves actual consequences.

A–3.3. Using traditional enforcement to disposition violations identified at power reactors

Some aspects of violations at power reactors cannot be addressed solely through the SDP. In these cases, violations have to be addressed separately from any associated ROP or cROP findings. Accordingly, these violations are assigned severity levels and can be considered for civil penalties in accordance with this policy, while the significance of the associated ROP or cROP finding has to be dispositioned in accordance with the SDP. In determining the severity level assigned to such violations, the NRC will consider information in this policy, as well as SDP-related information, when available. Typically, the types of violation dispositioned using traditional enforcement include the following:

(a) violations that resulted in actual safety or security;

(b) violations that may impact the ability of the NRC to perform its regulatory oversight function;

(c) violations involving wilfulness;

(d) violations not associated with ROP or cROP findings.

A–3.4. Disposition of violations

The NRC can disposition violations in the following way:

A–3.4.1. Minor violation

Violations of minor safety or security concern generally do not warrant enforcement action or documentation in inspection reports but has to be corrected. Examples of minor violations can be found in the NRC Enforcement Manual, IMC 0612, Appendix E, 'Examples of Minor Issues', IMC 0613, Appendix E, 'Examples of Minor Construction Issues', and IMC 0617, Appendix E, 'Minor Examples of Vendor and Quality Assurance Implementation Findings.'

A–3.4.2. Non-cited violation

If a licensee or non-licensee has implemented a corrective action programme that is determined to be adequate by the NRC, the NRC will normally disposition SL IV violations and violations associated with green ROP or cROP findings as non-cited violations (NCVs).

For licensees and non-licensees that are not credited by the NRC as having adequate corrective action programmes, the NRC will normally disposition SL IV violations and violations associated with green ROP or cROP findings as NCVs. If the SL IV violation or violation associated with a Green ROP or cROP finding was identified by the NRC, the NRC will normally issue a Notice of Violation.

Inspection reports or inspection records document NCVs and briefly describe the corrective action the licensee or non-licensee has taken or plans to take, if known. Licensees and non-licensees are not required to provide written responses to NCVs.

(a) Licensees and non-licensees with a credited Corrective Action Programme:

(i) The licensee or non-licensee needs to place the violation into a corrective action programme to restore compliance and address recurrence;

(ii) The licensee or non-licensee needs to restore compliance (or demonstrate objective evidence of plans to restore compliance) within a reasonable period of time after a violation is identified;

(iii) For traditional enforcement, the violation is either not repetitive as a result of inadequate corrective action, or, if repetitive, the repetitive violation has not been identified by the NRC;

(iv) The violation is not wilful. Notwithstanding wilfulness, an NCV may still be appropriate if certain detailed criteria are met.

(b) All Other Licensees and Non licensees:

(i) The licensee or non-licensee identified the violation;

(ii) The licensee or non-licensee corrected or committed to correcting the violation within a reasonable period of time by specific corrective action committed to by the end of the inspection, including immediate corrective action and comprehensive action to prevent recurrence;

(iii) The violation is not repetitive as a result of inadequate corrective action;

(iv) The violation is not wilful. Notwithstanding wilfulness, an NCV may still be appropriate if certain detailed criteria are met.

A–3.4.3. Notice of violation

A Notice of Violation is a written notice setting forth one or more violations of a legally binding requirement and normally requires the recipient to provide a written response describing (1) the reasons for the violation or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken by the licensee or other person and the results achieved, (3) the corrective steps that will be taken, and (4) the date when full compliance will be achieved. The NRC may waive all or portions of a written response to the extent that relevant information has already been provided to the NRC in writing or documented in an NRC inspection report or inspection record. A civil penalty may be issued in conjunction with an NOV.

A–3.4.4. Civil penalty

A civil penalty is a monetary penalty that the NRC may impose for violations. Based on the circumstances of a specific case, the NRC may increase a civil penalty where application of the guidance would normally result in a zero penalty or a base civil penalty, to ensure that the proposed civil penalty reflects the safety significance of the case. The NRC's policy of imposing graduated civil penalties generally takes into account the severity of the violation as the primary consideration and the ability to pay as a secondary consideration. Thus, operations involving greater nuclear material inventories, significantly higher consequences resulting from a release of, or exposure to, radioactive material and consequences to the public and workers

receive higher civil penalties. Regarding the secondary factor of the ability of various classes of licensees to pay the civil penalties, it is not the NRC's intention that the economic impact of a civil penalty be so severe that it adversely affects a licensee's ability to safely conduct licenced activities or puts a licensee out of business (Orders, rather than civil penalties, are used when the NRC's intent is to suspend or terminate licenced activities).

Civil penalties are considered for all SL I, II, and III violations. Violations assessed under an SDP normally are not considered for civil penalties. However, civil penalties are considered for violations associated with inspection findings evaluated through an SDP that involve actual consequences.

The civil penalty assessment process considers the following four decision points:

(a) Did the licensee have any previous escalated enforcement action (regardless of the activity area) within the past two years of the inspection at issue, or the period between the last two inspections, whichever is longer?

(b) Can the licensee be given credit for actions related to identification of the violation? A stated purpose of this Policy is to encourage prompt identification of violations of NRC requirements.

(c) Were the licensee's corrective actions prompt and comprehensive?
The purpose of the corrective action factor is to encourage licensees to (1) take the immediate actions necessary upon discovery of a violation that will restore safety, security, and compliance with the licence, regulation(s), or other requirement(s) and (2) develop and implement (in a timely manner) the lasting actions that will not only prevent recurrence of the violation, but will be appropriately comprehensive, given the significance and complexity of the violation, to prevent occurrence of violations with similar root causes.

(d) In view of the circumstances of the violation, the NRC exercises enforcement discretion to either escalate or mitigate the amount of the civil penalty. Discretion may be exercised by either escalating or mitigating the amount of the civil penalty determined after applying the civil penalty adjustment factors to ensure that the proposed civil penalty reflects all relevant circumstances of the particular case.

A–3.4.5. Orders

An Order is a written NRC directive to modify, suspend, or revoke a licence; to cease and desist conduct of an activity; or to take such other action as may be proper. Orders may be issued in lieu of, or in addition to, civil penalties, as appropriate, for SL I, II, and III violations. Orders may be made immediately effective, without prior opportunity for a hearing, whenever the NRC determines that the public health, safety, interest, or common defence and security so requires, or if the violation or conduct causing the violation is wilful. In such cases, the Order may provide, for stated reasons, that the proposed action be immediately effective pending further action. Otherwise, the Agency grants a prior opportunity for a hearing on the Order.

The NRC may also issue Orders to non-licensees, including contractors and subcontractors, holders of NRC approvals (e.g. certificates of compliance, early site permits, standard design certifications, or applicants for any such approvals), and to employees of any of the foregoing and to licenced individuals, such as licenced reactor operators, and non-licensed individuals.

A–3.4.6. Demand for information

The Commission may also issue a 'demand for information (DFI)' to determine whether an Order under 10 CFR 2.202 has to be issued or whether other action will be taken.

A–3.4.7. Administrative actions

The NRC also uses administrative actions, such as confirmatory action letters, notices of deviation, and notices of non-conformance, to supplement its enforcement programme. The NRC expects licensees and other persons subject to the Commission's jurisdiction to adhere to any obligations and commitments resulting from administrative actions and will consider issuing additional Orders, as needed, to ensure compliance.

A–3.5. Participation in the enforcement process

Before making a final enforcement decision in cases where the NRC is considering taking escalated enforcement action (i.e. a SL III or higher NOV or a greater-than-green ROP or cROP finding), the NRC will typically offer the operating organization or individual subject to the enforcement action a conference with the NRC to present facts relevant to the assessment and disposition of the apparent violations. The NRC may also request a conference if additional information is needed to make a determination relevant to the assessment and disposition of the apparent violations (e.g. whether violations occurred, the severity level of the violations, wilfulness of any violations, and whether credit has to be given for corrective actions or self-identification). The conference is normally held at an NRC regional office and is normally open to public observation, except when the proposed enforcement action involves discussions of classified or safeguards information, an enforcement action against an individual, proprietary information, or other sensitive, non-public information. In addition, licensees, non-licensees, and individuals can be offered Alternative Dispute Resolution.

A–3.6. Use of enforcement discretion

The NRC may choose to exercise discretion and either escalate or mitigate enforcement actions or otherwise refrain from taking enforcement action within the Commission's statutory authority. After considering the general tenets of this policy and the safety and security significance of a violation and its surrounding circumstances, judgment and discretion may be exercised in determining the severity levels of violations and the appropriate enforcement sanctions to be taken. Categories include:

(a) Violations identified during extended shutdowns or work stoppages;

(b) Violations involving old design issues;

(c) Violations identified because of previous enforcement action;

(d) Violations involving certain discrimination issues;

(e) Violations involving special circumstances;

(f) Use of discretion in determining the amount of a civil penalty;

(g) Exercise of discretion to issue orders;

(h) Notices of enforcement discretion for operating power reactors and gaseous diffusion plants.

A–3.7. Enforcement actions involving individuals

Any individual may be subject to NRC enforcement action if the individual (1) deliberately causes or would have caused, if not detected, a licensee to be in violation of any regulation or Order, or any term, condition, or limitation of any licence issued by the Commission related to NRC-licenced activities or (2) deliberately submits materially inaccurate or incomplete information to the NRC, a licensee, an applicant or a licensee, or a contractor or subcontractor of a licensee or applicant for a licence.

The Commission will normally take enforcement actions against non-licensed individuals only in cases involving deliberate misconduct by the non-licensed individual, in cases involving a lack of reasonable assurance, and in cases in which an individual violates any requirement directly imposed on him or her. However, the NRC may take enforcement action against NRC-licensed reactor operators even if the violation does not involve deliberate misconduct, since operators licenced by the NRC are subject to all applicable Orders, terms, conditions or limitations of a licence.

The primary factors considered by the NRC in considering whether to take action or what action to take are (1) the significance of the underlying violation or technical issue (not considered in discrimination cases) and (2) the individual's position within the organization (i.e. notwithstanding an individual's job title, consider the position of the individual within the licensee's organizational structure and the individual's responsibilities related to the oversight of licenced activities and to the use of licenced material).

A–3.8. Violation examples

The violation examples in this Policy are intentionally broad in scope so as to serve as a set of guiding examples that are neither exhaustive nor controlling for making severity level determinations.

Reactor operations examples include:

(a) SL I violations involve, for example:

(i) A system that is part of the primary success path and which functions or actuates to mitigate a Design Basis Accident (DBA) or transient that either assumes the failure of, or presents a challenge to, the integrity of a fission product barrier is unable to perform its licencing basis safety function when actually called on to function;

(ii) An inadvertent or unplanned criticality; or

(iii) A TS safety limit is exceeded.

(b) SL II violations involve, for example a system that is part of the primary success path and which functions or actuates to mitigate a DBA or transient that either assumes the failure of, or presents a challenge to, the integrity of a fission product barrier would be unable to perform its licencing basis safety function had it been called upon to function.

(c) SL III violations involve, for example:

(i) A licensee fails to shut down the reactor or follow remedial actions permitted by a TS action requirement when a Limiting Condition for Operation (LCO) is not met (i.e. non-compliance with 10 CFR 50.36(c)(2)(i));

(ii) A system that is part of the primary success path and which functions or actuates to mitigate a DBA or transient that either assumes the failure of, or presents a challenge to, the integrity of the fission product barrier not being able to perform its licencing basis safety function because it is not fully qualified (per the IMC 0326, 'Operability Determinations & Functional Assessment for Conditions Adverse to Quality or Safety') (e.g. materials or components not environmentally qualified);

(iii) A licensee fails to adequately oversee contractors, which results in the use of safety-significant products or services that are defective or of indeterminate quality;

(iv) Equipment failures caused by inadequate or improper maintenance substantially complicate recovery from a plant transient.

(d) SL IV violations involve, for example:

(i) A failure to comply with a TS action requirement demonstrates misapplication of the conventions in technical specifications Section 1.0, "Use and Application", or the allowances for LCO and surveillance requirement applicability in technical specifications Section 3.0;

(ii) Violations of 10 CFR 50.59 result in conditions evaluated as having very low safety significance (i.e. green) by the SDP;

(iii) A licensee fails to update the FSAR as required by 10 CFR 50.71(e) and the lack of up-to-date information has a material impact on safety of licenced activities.

The Enforcement Policy also has example severity levels for:

(a) Fuel cycle operations;

(b) Materials operations;

(c) Licenced reactor operators;

(d) Facility construction (10 CFR Parts 50 and 52 Licensees and Fuel Cycle Facilities);

(e) Emergency preparedness;

(f) Health physics;

(g) Transportation;

(h) Inaccurate and incomplete information or failure to make a required report;

(i) Discrimination;

(j) Reactor, independent spent fuel storage installation, fuel facility, and special nuclear material security;

(k) Materials security;

(l) Information security;

(m) Fitness for duty;

(n) Export and import activities.

A–4. UNITED ARAB EMIRATES

A–4.1. Legislative and regulatory framework

The United Arab Emirates (UAE) nuclear legislative framework consists of the Federal Law by Decree No. (6) of 2009 Concerning the Peaceful Uses of Nuclear Energy (referred to as the 'Nuclear Law'), and the Federal Law by Decree No. 4 of 2012 Concerning Civil Liability for Nuclear Damage (the 'Nuclear Liability Law'). The Nuclear Law is a comprehensive nuclear legislation that established the Federal Authority for Nuclear Regulation (FANR) as the nuclear regulatory authority with jurisdiction over nuclear and radiation safety, security, and safeguards. The Nuclear Law is supplemented by a set of regulations published by FANR that cover a wide range of activities carried out in the UAE and their related facilities within FANR's authority. In addition to the legally binding requirements included in FANR regulations, FANR has also issued regulatory guides that describe methods and/or criteria acceptable for meeting and implementing specific requirements contained in FANR regulations.

The Nuclear Law is supplemented by Cabinet Resolution No. 27 of 2015 that specifies administrative penalties for violation of the conditions of the licences issued by FANR. The Cabinet Resolution empowers FANR to apply a number of administrative penalties such as administrative fines, suspension or revocation of FANR licences, or enforcement actions against violators. FANR is currently revising the Cabinet Resolution in order to strengthen the list of violations and identify the corresponding administrative penalties using a graded approach.

A–4.2. Regulatory function: Enforcement

The UAE Nuclear Law requires FANR to conduct inspections of all regulated activities, covering all areas of regulatory responsibility to ensure that licensees and any other entity or individual subject to the Nuclear Law comply with the requirements and obligations contained in Nuclear Law as well the applicable FANR regulations and any relevant licence terms and conditions issued by FANR, as well as any other administrative decision or instructions issued by the Authority. Furthermore, the Nuclear Law provides FANR the power to execute enforcement actions in the event of commissions or omissions of an act which results in a violation of the requirements contained in the aforementioned legal documents.

Enforcement actions are defined under the Nuclear Law to include the following:

(a) Corrective actions;

(b) Written warnings;

(c) Revocation or suspension of a licence;

(d) Administrative penalties including fines.

The authorized party is required under Article (37) of the UAE Nuclear Law to comply with FANR administrative decisions to correct any violation, remedy any breach, carry out an investigation related to the breach and take any measures necessary to prevent recurrence. In the event that the authorized party fails to remedy a breach as required and within the time frame specified by FANR, the Authority may remove the breach in order to mitigate the consequences of such violation. In such a case, the authorized party would bear the necessary costs of such an intervention. Finally, as per Article 37(3) of the Nuclear Law:

"If there is evidence of a deterioration in the level of Safety, or in the event of serious violations the Authority requires the Operator to curtail activities and to take any further action necessary to restore an adequate level of Safety".

Chapter Ten of the Nuclear Law contains provisions related to penalties, describing in particular the criminal offences and corresponding enforcement actions applicable to certain violations of the Nuclear Law and relevant international legal instruments.

A–4.3. Procedure overview

FANR has established within its Integrated Management System (IMS) processes, procedures and instructions consistent with the provisions of the UAE Nuclear Law, the Cabinet Resolution No. 27 of 2015 and the related FANR regulations. These internal documents support the implementation of FANR's related enforcement activities.

The FANR enforcement procedure interfaces with FANR Regulatory Inspection Oversight Framework Procedure under Core Process CP.3, Assurance of Compliance for Safety, Security, Safeguards and Radiation Protection. The enforcement procedure describes the key steps of FANR enforcement, beginning with the identification of the violation through gathering of facts. Typically, potential violations are identified through regulatory inspections, event reporting, licensee performance assessments or allegations. This procedure provides detailed instructions supporting the assessment of the significance of a violation and describes steps to be taken to determine the appropriate enforcement action, taking into account the significance and severity of the breach, as well as the required corrective actions. It also identifies the responsibilities of the various departments within FANR for the implementation of enforcement tasks. The procedure concludes with instructions for handling contested violations, conduct of follow-up, closure of the violation, and documentation and records.

A–4.3.1. Significance determination

To identify the appropriate enforcement action, applying a systematic and graded approach to the application of the penalties and taking into account the fact that violations occur in a variety of activities and have varying levels of significance, the first step is for FANR to assess violations significance, which includes taking into account the following elements, but not limited to:

— Risk insight obtained from probabilistic risk assessments (PRA);

— Impact on workers, members of the public and the environment;

— Safety significance (see below);

— Extent of any corrective actions;

— Actual or potential consequences;

— Impact on the Authority's ability to perform its regulatory functions;

— Assessment of the corrective actions;

— Existence of misconduct or criminal violations;

— Violator's compliance history;

— Intention or negligence on the part of the violator.

For nuclear facilities, FANR has developed a set of instructions that provide a practical method to determine the severity level (hence significance) of the violations consistently over different assessment areas (also called cornerstones) such as barrier integrity, mitigating systems, initiating events, management systems, operating experience and hazard assessment, emergency preparedness and response, protection of the public and the environment from undue radiation hazards, and protection of workers from undue radiation hazards. Violations are assigned with a colour code based on the safety significance as follows:

— GREEN: corresponds to an issue with very low safety significance. The issue represents a normal deviation in performance. Green issues do not significantly increase operational risk and do not need to be analysed further.

— WHITE: corresponds to an issue with low-to-moderate safety significance. The issue represents an above-normal deviation in performance.

— YELLOW: represents an issue with substantial safety significance. The issue indicates a decline in licensee performance.

— RED: indicates an issue with high safety significance. The issue indicates significant decline in licensee performance that is associated with an unacceptable loss of safety margin.

A–4.3.2. Enforcement decision

The implementation of enforcement action is not an automatic process and discretion is used to determine and assess the benefits of the implementation of such actions. Enforcement action decisions are based on a graded approach and are proportional to the severity of the violation. Multiple factors are considered to determine the most appropriate enforcement strategy for any given situation. Enforcement action can be applied individually or combined. In a situation where the initial enforcement action does not result in timely compliance, other actions could be used such as escalation to a higher enforcement action.

FANR uses four primary enforcement actions, depending on the significance of the violation:

(a) Written warning: Non-Cited Violation (NCV), identifies a requirement and how it was violated and normally does not require a written response;

(b) Written warning: Notice of Violation (NOV), identifies a requirement and how it was violated and requires a written response from licensees within 30 days;

(c) Administrative penalties: Significant violations as described below may lead to significant enforcement action such as the application of administrative penalties in the form of administrative fines including administrative fines, suspension, or revocation of a licence. Administrative Penalties are imposed in accordance with the applicable Cabinet Resolution No. 27 of 2015, Concerning Administrative Penalties issued by the Federal Authority for Nuclear Regulation;

(d) Criminal Penalties: As specified in Chapter 10 of the nuclear law some significant violations may lead to criminal penalties.

A–4.3.3. Significant enforcement actions

A violation that could result in safety (potential or actual), security or safeguards consequences is considered as a Significant Violation that could be considered for a Significant Enforcement Action (SEA). These cases are evaluated by an Enforcement Review Panel (ERP). The ERP is chaired by the Deputy Director General responsible for operations. The ERP also includes the director of the legal affairs department and the relevant directors of the departments in charge of radiation safety, nuclear safety, security or safeguards.

When considering a SEA, FANR will offer to meet with the violator to discuss the underlying violation. The purpose of the meeting is to ensure that FANR staff have all the relevant facts concerning the violation. Following the meeting with the violator, FANR ERP will reassess the significance of the violation based on any additional information obtained and make a final recommendation on the categorisation of the violation and the associated recommended enforcement action.

In instances where a meeting could not be held prior to issuing the SEA, FANR will offer to meet with the violator after the SEA is issued. The purpose of the meeting is to discuss the SEA, any relevant mitigating information the violator intends to raise, the violator's right to appeal, and any corrective action taken by the violator that may mitigate the ongoing need for the SEA.

As noted previously, the significant enforcement actions may range from the imposition of administrative penalties, such as administrative fines, and could also include a suspension or revocation of a FANR licence.

Furthermore, pursuant to Articles 60, 61, 62 and 63 of the Nuclear Law specific criminal violation call for criminal penalties. In such cases, following consideration of the case by the Enforcement Review Panel, a recommendation for referral to public prosecution or the Federal Prosecution for Emergencies, Crises and Disasters may be recommended. Referral to public prosecution based on the Nuclear Law follows a graded approach and has to be justified by considering, inter alia, the nature or the severity of the violation, and has to be fully documented and substantiated.

A–4.3.4. Follow-up

Following the issuance of an enforcement action, FANR may organize a follow-up regulatory inspection to assess the effectiveness of the authorized party's deficiency identification associated corrective actions. The schedule for assessing the corrective action associated with an NOV is included within the NOV itself.

A–4.3.5. Resolution of contested violations

Included in FANR's implementing documents is an instruction that establishes a mechanism for evaluating and making decisions to process a violator's objection to issued Administrative Penalties. In such cases, the violator is required to provide supporting documents to FANR specifying the rationale for their objection, within a specified time. A Review Panel is formed to re-evaluate the facts and circumstances surrounding the violation, as well as the additional supporting documentation. Following the review, the Panel will provide recommendation to

FANR management on a regulatory position for their consideration. Recommendations can range from, but not limited to:

— Upholding the enforcement action;

— Reconsidering the enforcement action; or

— Recommending further inspection.

A–5. REPUBLIC OF ARGENTINA

A–5.1. Introduction

The Act N° 24.804, known as the ‘National Nuclear Activity Law’, (interchangeably referred to as Nuclear Law) sanctioned by the National Congress in 1997, created the Nuclear Regulatory Authority (ARN) as an independent regulatory body under the jurisdiction of the Executive Branch. The National Nuclear Law empowered the ARN to regulate and control nuclear activities to ensure radiological and nuclear safety, personal protection, a controlled use of nuclear materials, licensing and surveillance of nuclear facilities, and compliance with international safeguards. The ARN controls ionizing radiation sources, except for X ray equipment, which falls under the purview of the federal and provincial departments in charge of public health.

The ARN has the power to set regulatory requirements on nuclear safety, nuclear security, and safeguards. Inspections to verify compliance with requirements are periodically conducted by the ARN, based on the associated radiological risks.

Authorizations to operate installations using radioactive sources in medicine, industry, research, and teaching are issued by the Authority to applicants who fulfil the requirements. Individual authorizations (Permits) are issued to those individuals who fulfil the requirements and demonstrate knowledge and training in radiological safety.

A–5.2. Regulatory policy and strategy

Licensees are responsible for the safety and security of radioactive sources and have to implement measures to prevent accidents. Compliance monitoring and enforcement actions by ARN control these measures. If necessary, the intervention of the authority precludes the development of conditions that could give rise to radiological accidents. In addition, an effective enforcement policy and actions imposed on persons responsible for non-compliance with the regulations contributes to the prevention of accidents.

The regulatory control of radioactive sources requires effective licensing, compliance monitoring and enforcement actions. Effective regulatory control of radioactive sources include the following elements:

— Standards and regulations are effective in the description of what is acceptable and what is not; enforcement actions are clearly specified and have sound legal support;

— A compliance monitoring programme that is able to detect deviations from the conditions established in the licences or to detect sequences of adverse events that may give rise to radiological accidents and will lead to timely enforcement actions, as applicable.

The regulatory control of radioactive sources and radioactive material requires effective compliance monitoring and enforcement actions aimed at controlling the radiological safety of sources and compliance with requirements. As necessary, the licensee implements actions not only to prevent, but also to interrupt, the development of conditions that could give rise to radiological accidents.

A–5.3. Effective compliance monitoring and enforcement actions

The following characteristics of an effective compliance monitoring and enforcement programme, based on the Argentine experience, include:

— Regulations emphasize the responsibilities of both licensees and individuals directly responsible for the safety and security of radioactive sources and nuclear material, and the Authority, by the Nuclear Law 24.804 and Decree 1390/98 has the power to impose penalties for violations of regulations;

— Managers encourage the use of the 'correct from the very beginning' concept in regulatory tasks. This helps avoid oversights by the inspection staff and facilitates the follow-up;

— The Authority is empowered to impose penalties on a safety officer, licensee or any unauthorized individual who has caused unnecessary exposures or potential exposures of persons to ionizing radiation. Penalties such as curtailment, suspension or revocation of permits and authorizations to operate installations, or fines, will be imposed, in accordance with the regulations. The exercise of the rights of the persons prosecuted for violations by the Authority will be guaranteed;

— Regulations have to be clear enough to emphasize the responsibilities of both licensees and individuals who are directly responsible for the safety of radioactive sources used or stored in installations. If the Authority determines that harm has been caused to an individual because of a regulatory violation, the finding is reported to a criminal court;

— Enforcement actions have to be carried out by experienced staff and have to be imposed, in writing, to the individual directly responsible for the safety of the installation or the legal representative of the licensee. As necessary, these actions have to be followed by interviews (in person or by telephone) with the individual responsible for safety, to obtaining their commitment to comply with the requirements of the enforcement actions;

— The following factors exert influence on the enforcement actions: relevance of the detected deviation for the safe performance of the installation and complexity of the necessary corrections, severity of the violation, repeated or wilful violations, attitude and course of action taken by the safety officer;

— The inspectors have to be empowered to carry out enforcement actions during inspections. If safety is degraded and urgent enforcement actions are needed at the site, inspectors have to make every attempt to inform their managers in order to obtain approval for the enforcement action, especially if curtailment or suspension of operations will affect patients undergoing medical treatment. Enforcement actions carried out in medical centres need to consider the protection of the patients and any detriment that could be caused by the actions;

— Licensees have to be required to take spent sources out of their installations and to dispose of, or deposit, the sources at an authorized site. If urgent actions are necessary because unsecured radioactive sources threaten the health or the properties of persons, the Authority takes actions to secure the sources in situ or to sequester and transfer them to a safe site. In case of a deliberate obstruction to such actions, Authority managers have to be entitled to

petition the judge to provide police assistance to gain access to the premises and sources considered;

— To detect deviations from safe conditions in potentially risky practices such as gamma radiography or teletherapy, the Authority performs inspections to assess specific features of the installations, such as radiation beam calibration or safety interlocks in radiotherapy and maintenance of gamma radiography equipment;

— Enforcement actions have to be registered, and inspectors verify compliance shortly after the deadlines established. For repeated cases of non-compliance, experienced staff carries out upgraded enforcement actions. These actions guarantee the credibility of the enforcement policy.

A–5.4. Enforcement actions

Communications, requirements, and enforcement actions by the Authority are addressed to the legally responsible individual in charge of organization (radiological/nuclear facility) and to the individual designated as 'responsible for safety' (the 'Safety Officer' of Facilities Class II and III and to the 'Prime Responsible' of Facilities Class I). The licensee supervises the activities carried out by the safety officer and provides him or her with all the resources needed to discharge his/her responsibilities. The enforcement actions by the Authority can be categorized as follows:

— Impositions to correct minor deviations from the requirements set in the regulations. These actions are usually imposed during inspections and after a meeting with the safety officer;

— Impositions to correct safety or security issues, or for repeated violations of minor importance. The commitment of the licensee with respect to safety and security culture, or the ability of the safety officer to address issues safety or security is reviewed. These actions are imposed as soon as possible after a review of safety and security of the site, and corrections have to be carried out within a short time frame;

— Impositions to curtail or suspend operations in installations due to risks to the health of the workers or the public. Actions taken during inspections are imposed to urgently secure or shield radioactive sources, or to decontaminate the installation. As necessary, the Authority petitions a judge to order the preventive sequester of the sources, or any other appropriate measures.

A–5.5. Legal and regulatory framework

The regulatory enforcement policy, compliance monitoring and enforcement actions are documented and supported by provisions in the national legislation, regulations, and procedures.

As provided by the National Nuclear Law, ARN is responsible for the regulation and control of nuclear activities on matters of nuclear safety and security, as well as the control and use of nuclear materials, licensing and supervision of nuclear facilities and international safeguards.

The Nuclear Law (Article 8) establishes that ARN has regulatory and control responsibilities, as stated in this Law, to: a) Protect human beings from harmful effects of ionizing radiation. b)

Ensure that nuclear installations in Argentina comply with radiological and nuclear safety requirements. c) Ensure that no nuclear activities are performed for purposes other than those authorized by this Law, regulations issued in the future, international commitments and Argentina's policy on non-proliferation of nuclear activities and d) Prevent intentional actions that could have severe radiological consequences and any unauthorized removal of nuclear materials, or other materials, or equipment, which are regulated and controlled, as stated in this Law.

Law No. 24804 (Article 16) assigns the following faculties and responsibilities to the ARN to carry out enforcement actions:

(a) Granting, suspending, and revoking construction licences, commissioning, and operation and decommissioning licences for nuclear power generation plants;

(b) Granting, suspending, and revoking licences, permits or authorizations concerning uranium mining, conversion and enrichment, safety of research reactors, relevant accelerators, relevant radioactive facilities, including the facilities for waste or radioactive waste management, and nuclear applications in medical and industrial activities;

(c) Performing regulatory inspection and evaluations of facilities subject to regulation of the Nuclear Regulatory Authority, with the periodicity it deems necessary;

(d) Proposing to the Executive Power the transfer, extension, or replacement of a licence or authorization for the use of a State-owned nuclear facility, as necessary, or for the expiration of a licence or authorization, as necessary, due to non-compliances with regulatory requirements;

(e) Bringing civil or criminal lawsuits before the appropriate courts when there is a non-compliance from licensees or authorized party subject to this Law. or for requesting search warrants and aid of the police when such actions are deemed necessary for exercising the authority granted by this Law;

(f) Applying enforcement actions, following a graded approach based on the severity of the violation, such as warnings, fines, the suspension of a licence, permit or authorization or their revocation. Such actions are only appealable for the purpose of remand before the National Administrative Contentious Court of Appeals;

(g) Establishing procedures for the application of enforcement actions for the violation of rules issued while exercising its competence, while maintaining the principle of due process of Law;

(h) Disposing the seizure of nuclear or radioactive materials, as well as the preventive closure of facilities subject to regulations of the Nuclear Regulatory Authority, when they lack the required licence, permit or authorization, or when gross negligence is detected with respect to compliance with radiological and nuclear safety requirements.

In this context, gross negligence means acts involving a serious risk to the safety of the population or the environment, or whenever the application of physical protection or safeguards measures cannot be guaranteed.

A–5.5.1. Prohibition to Operate without a licence

Law No. 24804, establishes that conduct of a nuclear activity, any natural or legal person , has to comply with ARN regulations in its scope of competence and request a licence, permit or authorization that will enable them to perform the activities and comply with the obligations in safeguards or non-proliferation matters that Argentina has subscribed to or will subscribe to in the future.

A–5.5.2. Control system

Since the beginning of nuclear activities in the country and to verify that nuclear and radioactive facilities comply with the standards, licenses and requirements in force, the Regulatory Authority has determined a control system. Currently, the control system includes regulatory evaluations, inspections, and audits. If necessary, the ARN could require the implementation of corrective measures and in case they are not complied with may lead, as a last resort, to the imposition of sanctions provided in the regulatory system.

A–5.5.3. Documentation and reports during the licensing process

The Licensee has to submit documentation related to radiological and nuclear safety to the ARN. The scope of the documentation to be sent to ARN and the timeline for its presentation is set in specific procedures. This documentation has to be updated following changes or modifications and the modification proposals have to be forwarded to the Regulatory Authority for approval. The licence and the aforementioned documentation constitute the Mandatory Documentation. On one hand, any other standard or requirement issued by the Nuclear Regulatory Authority in connection with radiological and nuclear safety, safeguards and security is also mandatory. On the other hand, requirements related to the Mandatory Documentation and Reports are graded in accordance with the hazard involved. In addition, the licence, granted by the ARN, determines the periodic reports that the authorized party has to submit to the Nuclear Regulatory Authority, which includes all evidence or information which, in the criteria of the Licensee, shows weakness or degradation in the quality of components, equipment and systems which are important for safety or different risks in magnitude or nature from those foreseen in the Final Safety Report or in the Probabilistic Safety Assessment.

A–5.5.4. Regulatory inspections and audits

Act N° 24804 authorizes the ARN to perform regulatory inspections and evaluations to be carried out by regulatory body in the following manner:

A-5.5.4.1 Planned inspections

Programmed inspections offer the opportunity to examine the operating organization’s compliance and allows for the detection of possible problems at an early stage. These inspections consist of observation and evaluation of routine activities, in terms of safety, to assess the effectiveness of the licensee’s performance.

A-5.5.4.2 Reactive inspections

Reactive inspections by individuals or teams are usually performed by the regulatory body in response to an unexpected, unplanned, or unusual event or an incident, in order to assess its significance and implications and the adequacy of corrective actions.

A-5.5.4.3 Specific enforcement actions

Enforcement actions that may be taken by the ARN regarding a particular facility may originate from:

(a) The results of regulatory inspections and evaluations performed at the facility;

(b) The knowledge of abnormal events that have occurred at the facility or at a similar facility;

(c) The results of independent technical evaluations. In such cases, the ARN sends a regulatory document to the Licensee in the form of a requirement, recommendation, or request for additional information. In this document, the ARN urges the Licensee to take the required corrective actions within a specified time. These documents have the following scopes:

- Requirement: It is a regulatory order that the Licensee has to comply with in the requested manner;

- Recommendation: It is an order that ARN regards as advisable to be implemented by the Licensee. The Licensee has certain flexibility for compliance (for example, engineering alternatives) which ensures the result required by the recommendation. These alternative corrective actions have to be proposed to the ARN for their evaluation;

- Request for additional information**:** It is a regulatory order whereby more details on the basis of the documentation provided are required such as, the explanation of an assertion, the demonstration of the result of calculations or additional documentation.

A–5.5.5. Sanction regime

Act 24.804, (Nuclear Law) in Article 16 g) authorizes ARN to impose the appropriate Sanction System in case of non-compliance with the Nuclear Law, AR Standards and requirements, as established in the respective licences or permits.

Likewise, Article 16 h) of authorizes ARN to establish the procedures for the implementation of sanctions in relation to the breach of regulation as its attributions, guaranteeing the principle of due process. It is also be noted that Annex I to Decree No. 1390/98, which regulates the aforementioned Nuclear Law, authorizes ARN to establish a penalty system.

The authority conferred by the government to the ARN in the Nuclear Act has been ruled through the approval by ARN Board of Directors of the following Sanctions Regimes:

(a) Sanctions Regime for Nuclear Power Plants; approved by Resolution N ° 63/99 of ARN Board of Directors.

(b) Sanctions Regime for Failure to Comply with Radiological and Nuclear Safety Regulations, Physical Protection, Safeguards and Non-Proliferation of Nuclear in Relevant Installations, approved by Resolution N ° 24/99 of ARN Board of Directors.

(c) Sanctions Regime for Facilities Classes II and III, Non-Routine Practices and Transport of Radioactive Materials; approved by Resolution N ° 32/02 of ARN Board of Directors.

All deviations from the requirements established in the regulatory standards, regulatory requirements and operating licences, detected by ARN, warrant follow up actions that include formal communications between different levels of responsibility, to encourage the licensee to take the necessary corrective actions as soon as possible, while the safety of the public, workers, and the facility itself is not affected. Only in case of resistance or non-compliance with the corrective actions by the Responsible Entity the sanctions regime is applied.

Severe violations to the regulatory requirements imply immediate actions to re-establish the safety conditions and to prevent any potential damage, and the regulatory body's inspectors are vested by the legal framework with authority to mandate such immediate actions on the spot. In these cases, despite the corrective actions implemented, the corresponding sanction regime is applied.

The ARN since 1999 implements a Procedure for non-compliance with regulatory standards on radiation, physical safety, and safeguards" a new revision was approved by Resolution of the Board ARN No. 159/2022. It guarantees due process. This procedure is complemented by the internal management procedure G-DIR- 03 that establishes the methodology for the application of sanctions when an act, action or omission known by the Nuclear Regulatory Authority — through the inspections of its personnel or by the complaint of a third party— may mean the breach or violation to the regulatory standards, to the regulatory requirements, or to the conditions established in the licenses, authorizations or permits granted by the ARN. Also establishes the responsibilities of the ARN´s staff involved. This procedure applies to all sanction's regimes approved by the Board Resolutions N ° 24/99, 63/99 and 32/02.

Consequently, in the framework of the enforcement policy the sanction regimes are complemented with the following internal procedures:

(a) G-DIR- 03: Procedure to apply regulatory sanctions;

(b) P-AJ-03: Complaints management;

(c) G-1XX-09: Procedure to authorize the removal or restitution of radioactive sources;

(d) G-1XX-12: Procedure to issue regulatory requirements for Class II and III facilities;

(e) G-1XX-14: Procedure for closing or suspending the operation license for Class II and III facilities;

(f) P-LCRN-10: Procedure to issue and control compliance with regulatory requirements in nuclear reactors.

In the definition of the sanction, a graded approach is taken under consideration, regarding the severity of the infraction committed, the potentiality of the damage in terms of radiological and nuclear safety and the consequences that may arise in terms of security or safeguards.

Depending on the severity of the violation, a sanction will consist of:

— A formal warning;

— A penalty fee that will be graded according to the severity of the infraction and potentiality of the damage;

— The suspension of a license, permit or authorization;

— The revocation of the licence, permit or authorization;

— Seizure of radioactive materials.

The sanction system represents the last link of the safety chain. ARN considers that if the regulatory system is effective and the Licensee fully exercises their responsibilities, the application of sanctions and fines normally occur only in exceptional cases. In this sense, ARN´s strategy is to make the Licensee, Safety Officer and/ or Primary Responsible aware of their responsibility regarding safety and security, to increase the communication of safety culture at all levels of the organization structure.

A–6. STATE OF QATAR

A–6.1. Enforcement Policy

A–6.1.1. Objective

The objective of the enforcement policy is to support the mission of the Department of Radiation Protection in protecting individuals by ensuring that licensees comply with all safety requirements, in all steps of licensing process and at all stages of the operating lifetime of the facility or the duration of the activity, and that the licensee corrects non-compliances with safety requirements.

The objective of the enforcement policy is not to apply punitive measures against licensees, but to promote compliance with the regulatory requirements and conditions associated with any licence.

The following sections show only an extract from the enforcement policy of Qatar.

A–6.2. Penalties

The assessment of penalties is subject to approval by the Radiation Protection Department. The Department imposes different levels of penalties for different non-compliances, depending on the level of severity and the type of authorized party. Table A–1 shows examples of basic penalties according to the different types of non-compliance. The table establishes primary considerations to evaluate the severity of non-compliances, with regard to safety. As a second consideration, the financial capacity of the licensee may be considered, since the primary objective of the regulatory body is to ensure safety and not to create financial conditions that may compel the licensee to close the facility or stop the activity (orders are used in place of penalties when the intention is to close facilities or suspend activities) or adversely affect the licensee's ability to conduct the activity safely.

Operations involving large numbers of radioactive sources and greater potential consequences due to radiation exposure for the public and workers carry higher penalties.

TABLE A–1. TYPES OF VIOLATIONS VS. NON-COMPLIANCE

Sr. No.	Non-Compliance	Type
1.	The person responsible of radiation protection, non-compliance due to the licensee did not appoint a qualified expert; lack of written operating procedures	Organizational
2.	Facility construction;, relocation (source transfer documents incomplete, source movement record outdated, source record inaccurate); protection department not notified of new sources for licence modification; source record outdated or non-existent; insufficient emergency training for workers and/or not planned to conduct practical emergency drills; lack of annual monitoring records for personnel; and no record of accidents that might affect the safety of workers, patients, the public or the environment	Records
3.	— Operation of the facility: non-compliance with operating limits and conditions, failure to renew the safety analysis report, endangering the	Radiation safety and facility

Sr. No.	Non-Compliance	Type
	safety of radioactive sources;, improper storage or unsafe storage of other hazardous materials;, endangering labour protection; — Area classification: the controlled area is not properly marked, or warning signs are missing; — Standards and Supervision: standards and equipment are outdated, standards and equipment are missing, standards or equipment are not used in accordance with established operating procedures, monitoring is not implemented, monitoring equipment is not provided, leakage test periods are not appropriate; — Radioactive waste: There is no plan to dispose of unused sources or NORM, violation of the terms and conditions of the export licence, no control of radioactive discharges to the environment in cases of pollution or leakage, and no notification to the Radiation Protection Department regarding non-recoverable or abandoned sources in warehouses.	security verification
4.	Lack of emergency preparedness; emergency plan does not cover all practices; outdated emergency contact information (e.g. incorrect telephone numbers); unavailable emergency equipment (e.g. to handle radioactive sources); lack of training on the emergency plan; lack of emergency preparedness training for emergency personnel	Emergency preparedness and response
5.	Public protection is not good: insufficient visual and/or audible warning signs; no visitor control over controlled or supervised areas; missing warning signs or posters	Verification of public protection

A–6.3. Policy to be followed in case of different levels of severity of the non-compliance

In the case of non-compliances, and according to their level of severity, the Radiation Protection Department applies a graded approach to the enforcement policy that depends on the level of severity of the non-compliance and the number of times it has occurred. Tables A–2, A–3 and A–4 show the enforcement action that will be applied, based on the number of times it has occurred for each non-compliance and according to the level of severity.

TABLE A–2. POLICY FOR SERIOUS NON-COMPLIANCES

Enforcement action	Occurrence
Non-compliance letter is sent to the licensee; Immediate suspension of the licence; Imposing appropriate penalties according to the law, such as fines and others; Licensee meets with the Department to discuss corrective actions; The possibility of resorting to judicial procedures according to the severity of the non- compliance and the consequences thereof.	1st time
Non-compliance letter is sent to the licensee; Immediate suspension of the licence;	2nd time or more

Enforcement action	Occurrence
Imposing appropriate penalties according to the law, such as fines and others; The licensee meets with the Radiation Protection Department to discuss permanent revocation of the licence; The possibility of resorting to judicial procedures according to the severity of the non-compliance and the consequences thereof.	

Response letters are to be sent within one week of the date of the non-compliance letter and/or meeting with the Department. Failure to respond to the non-compliance or comply with any part of the enforcement policy will result in the immediate suspension of the licence. Alternatives may be presented in extenuating circumstances.

TABLE A–3. POLICY FOR MEDIUM NON-COMPLIANCE

Enforcement action	Occurrence
— Non-compliance letter sent to the licensee; — Imposing appropriate penalties according to the law, such as fines and others; — Licensee responds in writing to the inspector summarizing corrective actions to be taken. The results are reported to the inspector.	1st time
— Non-compliance letter sent to the licensee; — Licensee meets with inspector to discuss corrective actions to be taken, if necessary; — Imposing appropriate penalties according to the law, such as fines and others; — Licensee responds to the inspector in writing to document the implementation of corrective actions. The results are reported to the Department.	2nd time
— Non-compliance letter sent to the licensee; — Immediate suspension of the licence; — Imposing appropriate penalties according to the law, such as fines and others; — Licensee meets with the Radiation Protection Department to discuss corrective actions to be taken; — The possibility of resorting to judicial procedures according to the severity of the non-compliance and the consequences thereof.	3rd time or more

Response letters are to be sent within one week of the date of the non-compliance letter and/or meeting with the Department. Failure to respond to a non-compliance or comply with the enforcement policy will result in immediate suspension of the licence. Alternatives may be presented in extenuating circumstances.

TABLE A–4. POLICY FOR MINOR NON-COMPLIANCES

Enforcement action	Occurrence
Verbal notice may be given; The violation letter has been sent to the licensee; The licensee responds in writing to the inspector summarizing the corrective actions to be taken.	1st Time
The non-compliance letter is sent to the licensee; Licensee meets with the inspector to discuss corrective actions to be taken, if necessary; Licensee responds to the inspector in writing to document the implementation of corrective actions. The results are reported to the Department.	2nd Time
The non-compliance letter is sent to the licensee; Licensee meets with the Radiation Protection Department to discuss corrective actions to be taken; Imposing appropriate penalties according to the law, such as fines and others.	3rd Time
The non-compliance letter is sent to the licensee; Immediate suspension of the licence; Licensee meets with the Radiation Protection Department to ensure that corrective actions have been taken; Imposing appropriate penalties according to the law, such as fines and others.	4th time or more

Response letters are to be sent within one week of the date of the non-compliance letter and/or meeting with the Department. Failure to respond to the non-compliance or comply with the enforcement policy will result in the immediate suspension of the licence. Alternatives may be offered in extenuating circumstances.

A–6.4. Types of non-compliances and the penalties according to Radiation Protection Law No. 31 of 2002

Radiation Protection Law No. 31 of 2002 provides for different penalties according to the type of violation, in Articles 10 to 14. Table A–5 shows the types of non-compliance addressed in the law and the associated penalties.

TABLE A–5. TYPES OF NON-COMPLIANCES ADDRESSED IN THE LAW AND THE ASSOCIATED PENALTIES

Penalties according to Law 31 for the year 2002	Types of non-compliances
Imprisonment for a period of not less than one year, not to exceed three years and a fine of not less than fifty thousand riyals, not to exceed two hundred thousand riyals, or either of these two penalties	Submits a false testimony, or an incorrect statement or report

Penalties according to Law 31 for the year 2002	Types of non-compliances
Imprisonment for a period not to exceed one year and a fine not to exceed one hundred thousand riyals, or by one of these two penalties The penalty is doubled	– Failure to observe the necessary precautions to ensure the safety of individuals and radiation workers and to protect the environment from risks resulting from exposure to radiation, and to comply with the requirements established by the Radiation Protection Department; – The absence of a detailed radiation protection plan and procedures for radiation protection for the licensed radioactive materials in order to prevent accidents, or to mitigate the consequences of accidents,, or the absence of approval of the radiation protection plan or procedures by the Radiation Protection Department; – Unavailability of the necessary technical equipment for radiation monitoring, dosimetry, and personal protective equipment, in proportion to the nature of the hazards associated with the activities; – The lack of technical and health services necessary to protect workers and the public, and not maintaining adequate records in the manner required by the Radiation Protection Department; – The absence of a ROP to oversee implementation of radiation protection rules and procedures; – Contracts for importing radioactive material or sources do not include a provision to return the radioactive material or sources to the supplier when the need for the material or source ends.
Imprisonment for a period not to exceed five years, and a fine not to exceed two hundred thousand riyals, or one of these two penalties. The penalty is doubled in case of repetition	Conduct of any of the following activities and practices without a licence: – Importing, exporting, possessing, handling, or transporting radioactive material; – Application, introduction, procedure, modification, discontinuation or termination of any activity or practices involving radioactive material, sources, or radiation-emitting devices; – Designing, manufacturing, producing, acquiring, owning, importing, exporting, buying, selling, delivering, receiving, lending, borrowing, operating, discharging, or disposing of any radioactive material, sources or radiation-emitting devices; – Choosing any site for the conduct of activities that involve the use of radioactive substances or sources or a device that emits radiation, or constructing any buildings related to this activity or making any modifications to the site or buildings; – Activities involving the use of ionizing radiation, or activities requiring provisions for radiation protection; – Practicing activities related to medical radiation applications without a licence in accordance with the provision of Article (3) of the Law.

Penalties according to Law 31 for the year 2002	Types of non-compliances
The penalty is doubled	If the crime resulted in a person suffering from any disease, disability, or total or partial disability resulting from exposure to radiation
The Radiation Protection Department administratively seizes these sources and deposit them in the warehouses of the concerned authority or in any other place it deems appropriate	Import, possession, or handling of radioactive material, sources or radioactive devices without a licence.

ABBREVIATIONS

ARN	Nuclear Regulatory Authority of Argentina
BEL	Baseline enforcement level
cROP	Construction reactor oversight process
DG (I&E)	Director General Inspection and Enforcement
EMM	Enforcement management model
EPS	Enforcement policy statement
ERP	Enforcement review panel
FANR	Federal Authority for Nuclear Regulation
HPU	Hydraulic power unit
IMC	Inspection manual chapter
LMP	Last menopause period
MOV	Motor operated valve
NCV	Non cited Violation
NOV	Notice of Violation
NI	Nuclear instrument
NPP	Nuclear power plant
NRC	Nuclear Regulatory Commission
OLA	Office of Legal Affairs
ONR	Office for Nuclear Regulation
PNRA	Pakistan Nuclear Regulatory Authority
ROP	Reactor oversight process
RPO	Radiation protection officer
SL	Severity level
SDP	Significance determination process
SEA	Significant enforcement action
TS	Technical specification

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