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REGULATORY CONTROL OF NUCLEAR INSTALLATIONS

INTERNATIONAL ATOMIC ENERGY AGENCY
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FOREWORD

The International Atomic Energy Agency (IAEA) provides training courses and workshops on regulatory aspects of nuclear safety. The current publication has been issued to provide a complete introductory training course with some practical guidance from regulatory bodies of Member States on regulatory control of nuclear power plants. Since then there have been a number of significant developments that need to be taken into account.

Since the accident at the Fukushima Daiichi nuclear power plant, there have been many analyses of its causes and consequences, as well as detailed considerations of its implications and measures taken for nuclear safety by IAEA Member States. Unanimously endorsed by a Ministerial Conference on Nuclear Safety, the IAEA Action Plan on Nuclear Safety has since fostered international collaboration toward strengthening global nuclear safety. IAEA safety standards have since been reviewed to reflect lessons, IAEA safety peer review services have been strengthened, and the number of safety peer reviews for operating organizations and regulatory bodies in Member States has increased.

In addition, the IAEA has also published the Report on the Fukushima Daiichi Accident and its five Technical Volumes, which highlight observations and lessons to be taken into consideration so that they can be acted upon by governments, regulators and nuclear power plant operators throughout the world.

In the light of these events and developments, it was decided to review Training Course Series No. 15.

There has been a continuation and further development of subjects such as the importance of leadership, management and safety culture not only within operating organizations but also within regulatory bodies. Many regulatory bodies are now also responding to societal demand for greater openness and an effective dialogue with all parties interested in or affected by nuclear power.

This publication is designed to be used to support IAEA training courses and workshops on regulation to assure nuclear safety. It sets out general principles, referring to source material for more detailed explanations, in particular extensively to the IAEA Safety Standards which are used by Member States as a reference for their approach to regulating nuclear safety. It is closely linked to the IAEA Global Nuclear Safety and Security Framework and draws upon international good practices developed over many years of regulatory and operating experience. This publication also gives examples of regulatory control with reference to nuclear power plant applications.

The IAEA wishes to express its appreciation to all the experts, as well as the members of the Steering Committee on Regulatory Capacity Building and Knowledge Management, who contributed to the production of this publication. The IAEA officer responsible for this publication was M. J. Moracho Ramirez of the Division of Nuclear Installation Safety.

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1 INTRODUCTION

1.1 BACKGROUND

From 1994 to 2001, the IAEA conducted a number of training courses on regulatory control of nuclear power plants (NPPs). The presentations from these courses formed the basis for the first version of this publication, which was published in 2002. Since then, there have been a number of significant developments, the results of which have been incorporated into the current version.

This latest revision makes use of more modern approaches to training and development, in particular the systematic approach to training adopted by the IAEA in its Strategic Approach to Education and Training in Nuclear Safety 2013-2020. The learning objectives are in line with the competence framework, the quadrant model of competences for regulatory bodies, set forth by Safety Report Series No. 79 and used by the IAEA methodology for systematic assessment of the regulatory competence needs (SARCoN) for regulatory bodies of nuclear installations.

Within Member States, universities, training centres and nuclear safety regulatory bodies may use it in their education and training programmes. Users will develop an understanding of the main capabilities and competences that are needed for effective nuclear safety regulatory control.

1.2 OBJECTIVE

The objective of this publication is to provide the basis and source material for IAEA training courses and workshops, as well as a written background and references for others involved in training for regulatory bodies and technical support organizations (TSOs). It can also be used as training material for self-study.

As this publication is primarily concerned with the development and maintenance of competence within the regulatory body, it identifies learning objectives throughout the text. These learning objectives take into account the *Milestones in the Development of a National Infrastructure for Nuclear Power (IAEA Nuclear Energy Series No. NG-G-3.1)* [1] and the IAEA 'quadrant model of competences for regulatory bodies' set out in *Safety Reports Series No.79 on Managing Regulatory Body Competence* [2].

1.3 SCOPE

This publication primarily addresses nuclear safety. Nuclear safeguards are not covered and nuclear security is only covered where it affects nuclear safety. Its content set out on three levels:

- Global international framework (Level A);
- Organizational aspects (Level B); and
- Specific regulatory functions (Level C).

This publication is targeted mainly at professional staff members new to regulatory bodies. However, existing staff, including senior management, will find it a useful reference.

It provides a framework for the development of capabilities and competence of nuclear safety regulatory bodies and technical support organizations. It describes the Global Nuclear Safety and Security Framework, the organization and management of regulatory bodies and the activities involved in regulating nuclear installations.

Although the learning objectives are mostly applicable to NPPs, they also apply to other nuclear installations. This publication does not describe detailed expectations of operation.

1.4 STRUCTURE

This publication is structured to allow Member States to focus on developing competence in areas they consider necessary. Highlighting the importance of continuous improvement, it provides examples of how Member States meet international expectations and it sets out learning objectives for each section, allowing instructors and learners to focus on key areas. These learning objectives also reinforce the application of the IAEA safety standards.

Level A describes the strong international consensus that has developed around nuclear energy programmes, and the expectations for any national framework set up within this consensus. Level A will be of interest for those Member States contemplating a nuclear energy programme. Level A is also a useful reference for existing regulatory bodies, especially those that are regenerating capabilities that may not have been required for some time. Level A covers:

- Nuclear safety, security and liability conventions;
- IAEA safety standards;
- IAEA safety review and appraisal services;
- Building a national nuclear safety infrastructure.

Level B deals with the regulatory body as a whole and identifies the main elements of the organization including processes, management and approaches of the regulator. Level B does not cover the administrative aspects of regulatory body functions such as budgeting and finance, planning and procurement. Level B covers:

- Constitution of the regulatory body;
- Regulatory philosophies and relationships;
- Organization of the regulatory body;
- Independence of the regulatory body;
- Documentation of the management system;
- Continuous improvement and benchmarking;
- Support to national processes.

Level C describes the operational regulatory functions a regulatory body must manage. Implicit within the coverage in Level C are the key principles of defence in depth and the importance of human performance, both of which must be properly organized and controlled to ensure that nuclear safety is achieved. Level C covers:

— Authorization;
— Review and assessment;
— Inspection and enforcement;
— Drafting of national regulations and guides;
— Emergency preparedness and response;
— Communication with the public.

Throughout this publication, wherever appropriate, particular experiences of regulatory bodies from Member States are included. These experiences are drawn from publicly available information in particular good practices identified through Integrated Regulatory Review Service (IRRS) missions.

2 LEVEL A – GLOBAL NUCLEAR SAFETY FRAMEWORK

Experience has clearly demonstrated that the organizations and people involved in the peaceful use of nuclear energy and radiation sources are interdependent in such a way that the performance of one installation may have an impact on another. A serious nuclear accident could be of major significance around the world[1]. The recognition of this mutual dependence led to the development of the concept of the Global Nuclear Safety Framework.

The International Nuclear Safety Group[2] (INSAG) analyzed the concept and main characteristics of the Global Nuclear Safety Regime[3] in document INSAG-21 [3], which defines the concept as:

> "…the institutional, legal and technical framework for ensuring the safety of nuclear installations throughout the world. The objective of this regime is to lead to a world where all nuclear installations are operating safely".

Security was added later, resulting in the Global Nuclear Safety and Security Framework shown in Figure 1.



FIG. 1. Main elements of the Global Nuclear Safety and Security Framework.

The central and most important component continues to be a strong national nuclear infrastructure in each Member State. INSAG noted that by signing international conventions such as the Convention on Nuclear Safety and the Convention on Early Notification of a Nuclear Accident, each Member State committed to ensuring:

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[1] The 1979 Three Mile Island accident engendered the motto: *An accident anywhere is an accident everywhere*, as mentioned by IAEA Director General Hans Blix at his Statement to the fiftieth session of the United Nations General Assembly.

[2] More information on INSAG is provided in Appendix III.

[3] The term regime was changed to framework after the publication of INSAG-21.

— the highest possible levels of national safety and security, in harmony with those in other Member States;
— a continuous national and international review of the safety and security of installations and activities; and
— timely reporting by the licensee to the regulatory body and worldwide of anomalies, incidents and accidents with safety significance.

It adds that events do recur and this gives INSAG reason to believe that the mechanisms for operating experience feedback are not as effective as they could be. To solve the problem, INSAG recommends reinforcing the application of the existing regulations, increasing dedicated human resources within the operating organization and the regulatory body, reinforcing the Incident Reporting System, jointly operated by the IAEA and the Nuclear Energy Agency of the Organisation for Economic Co-operation and Development (OECD/NEA), and integrating already existing programmes within the World Association of Nuclear Operators (WANO)[4]. INSAG has also considered operating experience feedback in document INSAG-23 [4].

GSR Part 1 (Rev. 1): Governmental, Legal and Regulatory Framework for Safety [5], includes two requirements related to the Global Nuclear Safety and Security Framework.

Requirement 14 on international obligations and arrangements for international cooperation and assistance states:

> "The government shall fulfil its respective international obligations, participate in the relevant international arrangements, including international peer reviews, and promote international cooperation and assistance to enhance safety globally".

A variety of peer reviews is conducted by the IAEA at Member State request and by industry organizations, such as WANO. There is also a network of bilateral and multilateral agreements among regulatory bodies and licensees, and between licensees and reactor suppliers.

Requirement 15 on sharing of operating experience and regulatory experience states:

> "The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities".

Operating experience and feedback have led to significant corrective actions in equipment, human performance and the management system for safety, as well as changes to regulatory requirements and modifications to regulatory practices. The IAEA, in collaboration with the OECD/NEA, has established an incident reporting system under which incidents are reported by Member States and analyzed periodically.

As members of WANO, operators of NPPs have a very detailed system to share operating experience worldwide. The three major NPP accidents—Three Mile Island, Chernobyl and

[4] On 17 September 2012, in light of the Fukushima Daiichi accident, IAEA and WANO signed a Memorandum of Understanding to share information on operating experiences in NPPs.

Fukushima Daiichi—have been, and continue to be, thoroughly analyzed by international organizations such as the IAEA and the OECD/NEA, and by the regulatory bodies of many Member States. Many lessons have been, or are being, learned from these analyses and relevant changes are being introduced to equipment, operating procedures and training.

The Global Nuclear Safety and Security Framework also includes activities such as the application of international safety standards, codes of conduct, joint safety research and development programmes and participation in international conferences and workshops

2.1 NUCLEAR SAFETY, SECURITY AND LIABILITY CONVENTIONS

Learning Objective 1: To understand the role of international conventions in the Global Nuclear Safety and Security Framework.

Learning Objective 2: To understand the origin, development, obligations and implementation of relevant international safety conventions.

Learning Objective 3: To understand the origin, development, obligations and implementation of relevant international security conventions.

Learning Objective 4: To understand the origin, development, obligations and implementation of relevant third party liability conventions.

International conventions are one type of international legal instrument and are an essential component of the Global Nuclear Safety and Security Framework. The top level administrators of regulatory bodies and the staff members responsible for nuclear regulation and legal affairs need to have a comprehensive knowledge of the purpose, development and usage of international nuclear conventions, since national regulations need to reflect them. Other staff members concerned with compliance and enforcement also need to have some knowledge of the purpose of these conventions.

Member States operating nuclear installations or performing activities utilizing ionizing radiation have accepted and ratified specific safety related international conventions, mainly under the auspices of the IAEA. The conventions of interest to nuclear regulatory organizations are naturally divided into three major areas:

- Nuclear safety conventions;
- Nuclear security conventions; and
- Third party nuclear liability conventions.

There are various terms[5] for organizations that have ratified or acceded to international legal instruments. For simplicity, this book will use the term Contracting Party.

2.1.1 The nature of international legal instruments

International legal instruments such as treaties, conventions and codes of conduct require Contracting Parties to develop national regulations that properly reflect the obligations acquired from being a Contracting Party. Not all treaties and conventions induce the same

[5] Such as: State; State Party; Member State; Contracting Party; Contracting State.

type of internal and external obligations and requirements. Accordingly, international legal instruments may be regulative, incentive or assistance in nature. Regulative instruments include sanctions for non-compliance. Incentive instruments do not have sanctions for non-compliance, but provide reasons (incentives) for complying with the terms. Assistance conventions are just that, they provide methods for Contracting Parties to assist one another.

The main treaty associated with the nuclear industry is the Treaty on the Non-Proliferation of Nuclear Weapons[6], which is beyond the scope of this book. All international legal instruments associated with NPP safety are conventions.

2.1.2 International nuclear conventions

Adopting an international convention requires a Contracting Party to ensure that its internal laws and regulations conform to the terms of the convention. The Contracting Party also incurs obligations to all other Contracting Parties to the convention. This means that a Contracting Party's activities under the convention are subject to review and assessment by other Contracting Parties, through the processes and procedures required by the convention. Under this legal framework, Contracting Parties have a right to make judgments about how other Contracting Parties are conducting their activities, and whether they are in compliance with their obligations under the convention.

2.1.3 Conventions in the area of nuclear safety

Conventions in the area of nuclear safety include:

- The Convention on Nuclear Safety [6];
- Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management [7];
- Convention on Early Notification of a Nuclear Accident [8];
- Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency [8].

The IAEA is the promoter of these conventions, serves as their depositary and secretary and hosts the convention meetings. The Early Notification Convention and the Assistance Convention were adopted shortly after the Chernobyl accident. The Convention on Nuclear Safety and the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management required substantially more time and effort to enter into force.

2.1.3.1 Convention on Nuclear Safety

Background

The Convention on Nuclear Safety (CNS) [6], sometimes referred to as the Safety Convention, was adopted on 17 June 1994 and entered into force on 24 October 1996. As of March 2016, there were 78[7] Contracting Parties to the CNS.

[6] Treaty on the Non-Proliferation of nuclear Weapons, INFCIRC/140, IAEA, Vienna (1970).

An important result of the CNS was to bring the subject of nuclear safety within the ambit of international law for the first time. Appendix I to this book provides the historical and political background of the development of the CNS and provides detailed summaries of the results of the review and extraordinary meetings of the CNS.

The implementation of the CNS is based on a peer review process in which Contracting Parties prepare national reports demonstrating their compliance with the CNS. All Contracting Parties are given an opportunity to review and comment on those reports at periodic review meetings.

Provisions of the CNS

The CNS [6] includes a preamble and 35 articles divided into four chapters.

The preamble consists of ten paragraphs, only a few of which are described here. Paragraph (iv) establishes the desire of the Contracting Parties "to promote an effective nuclear safety culture" [6]. Although safety culture is a central concept for the enhancement of nuclear safety, this is the only place in the CNS where the term safety culture is mentioned. The Contracting Parties recognized the difficulties in introducing the concept as a specific international law obligation, but felt the need to promote the concept in the CNS preamble. Paragraph (v) recognizes that "accidents at nuclear installations have the potential for transboundary impacts" [6]. Paragraph (viii) describes the relationship of fundamental safety principles to the obligations contained in the CNS and recognizes that technical and management approaches evolve over time.



FIG. 2. Photo of a plenary session of the 6th Review Meeting of the CNS, March 2014.

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[7] INTERNATIONAL ATOMIC ENERGY AGENCY, Convention on Nuclear Safety – Latest Status, Registration No: 1676, https://www.iaea.org/Publications/Documents/Conventions/nuclearsafety_status.pdf

Chapter 1 includes three articles stating objectives, definitions and the scope of application. Article 1 identifies the following three objectives:

- "To achieve and maintain a high level of nuclear safety worldwide through the enhancement of national measures and international cooperation including, where appropriate, safety related technical cooperation;
- To establish and maintain effective defences in nuclear installations against potential radiological hazards in order to protect individuals, society and the environment from harmful effects of ionizing radiation from such installations;
- To prevent accidents with radiological consequences and mitigate such consequences should they occur" [6].

Article 3 limits the scope of application to the safety of nuclear installations, which are defined under article 2 as land-based civil NPPs, as well as storage, handling and treatment facilities for radioactive materials that are on the same site and directly related to the operation of the NPP.

Chapter 2, Obligations, includes sixteen articles divided into four major groups:

- General provisions (articles 4 to 6);
- Legislation and regulation (articles 7 to 9);
- General safety considerations (articles 10 to 16);
- Safety of installations (articles 17 to 19).

Article 4, implementing measures, requires each Contracting Party to take the steps necessary to implement its obligations under the CNS.

Article 5, reporting, requires each Contracting Party to submit, prior to each Review Meeting, a report on the measures it has taken to implement the obligations of the CNS.

Article 6, existing nuclear installations, deals with the question of how to ensure the safety of nuclear installations constructed to earlier standards. The requirements of Article 6 include:

- "Each Contracting Party shall take appropriate steps to ensure that the safety of nuclear installations existing at the time the Convention enters into force for that Contracting Party is reviewed as soon as possible" [6]. Although not explicit, the article implies that the review must be based on current standards;
- Each "Contracting Party shall ensure that all reasonably practicable improvements are made as a matter of urgency to upgrade the safety of the nuclear installations" [6]. This does not mean that all possible measures to improve safety must be taken, but that those that are reasonable from a technical, economic and management perspective should be implemented in a timely manner;
- "If such upgrading", to this new level of safety, "cannot be achieved" by a Contracting Party, "plans should be implemented to shut down the nuclear installation as soon as practically possible", taking into account "the whole energy context and possible alternatives as well as the social, environmental and economic impact" [6].

Contracting Parties must include information on their reviews of existing NPPs in their national reports and must justify any decision to continue to operate NPPs that do not meet current safety standards.

Article 7 requires a Contracting Party to "establish and maintain a legislative and regulatory framework to govern the safety of nuclear installations" [6]. It includes: safety requirements and regulations; a system of licensing; inspection and assessment, and an enforcement process.

Article 8 sets forth requirements for the regulatory body, including "adequate authority, competence and financial and human resources to fulfil its assigned responsibilities". This article also deals with regulatory independence, stating that Contracting Parties "shall take the necessary steps to ensure an effective separation between the functions of the regulatory body and those of any other body or organization concerned with the promotion or utilization of nuclear energy" [6].

Article 9 states that the operator of the NPP has the "prime responsibility for safety" [6]. Although other entities (architects, engineers, regulators, contractors, suppliers) have important safety roles, the operating organization is the entity that must finally ensure that a NPP is safe.

The third group, general safety considerations, includes articles 10 to 16. They cover:

- Priority to safety;
- Financial and human resources;
- Human factors; quality assurance;
- Assessment and verification of safety;
- Radiation protection;
- Emergency preparedness.

These articles are written as broad principles. They codify well understood concepts in nuclear safety, such as the ALARA[8] principle for radiation protection. This section contains the only CNS provision specifically directed to Contracting Parties that do not operate NPPs. Article 16 requires these Contracting Parties to prepare and test emergency plans to cover possible radiological emergencies resulting from any problem at a NPP in the vicinity.

The fourth group, safety of installations, includes articles 17 to 19. They cover the familiar safety-related subjects siting, design and construction, and operation of NPPs.

Article 18, design and construction, codifies familiar safety principles, including defence in depth, human factors and the human-machine interface. Article 19, operation, is the longest technical article in the CNS, containing eight sub-articles that were originally drafted as separate articles. This article codifies a number of familiar nuclear safety principles, including operational limits (sub-article ii), incident reporting (sub-article vi), analysis of operating experience (sub-article vii), and waste minimization (sub-article viii).

[8] As low as reasonably achievable.

Chapter 3, Meetings of the Contracting Parties, contains articles 20 to 28. These provisions are general, leaving most of the detail of the form and content of the review process to the procedural rules. Several important provisions should be noted:

- Article 20 includes the requirement that "each Contracting Party shall have a reasonable opportunity to discuss the reports of other Contracting Parties and to seek clarification of such reports" [6];
- Article 21 includes the requirement that "the interval between review meetings shall not exceed three years" [6];
- Article 22 establishes that arrangements for the review meetings are to be contained in "Rules of Procedure and Financial Rules" [6];
- Article 23 allows for extraordinary meetings at the written request of a Contracting Party and the support of a majority of Contracting Parties;
- Article 24 requires Contracting Parties to attend Review and Extraordinary Meetings;
- Article 25 requires that the Contracting Parties adopt and make public the issues discussed and conclusions reached during a meeting.

Chapter 4, final clauses and other provisions, includes Articles 29 to 35. Article 29 states that disagreements must be resolved within a meeting of the Contracting Parties. Article 32 states that any Contracting Party may present amendments, which must be considered in a Review Meeting or in an Extraordinary Meeting. Article 34 nominates the IAEA Director General as Depositary of the CNS. The Depository must, among other things, inform the Contracting Parties of: deposits of instruments of ratification, acceptance, approval or accession; and, proposed amendments and their date of entry into force. The Depositary must also be responsible for keeping the authentic original text of the CNS in each of the official languages of the IAEA.

Implementation processes under the CNS

Following the entry into force of the CNS, a Preparatory Meeting was held to adopt the Rules of Procedure and Financial Rules[9], and other associated documents called for under Article 22 of the CNS, in order to support the peer review process. There are three main supporting documents:

- Guidelines regarding the Review Process under the CNS (INFCIRC/571): This document provides guidance on how the peer review process is managed;
- Guidelines regarding National Reports under the CNS (INFCIRC/572): This document describes what should be contained in the National Reports;
- CNS: Rules of Procedure and Financial Rules (INFCIRC/573): This document sets out the general rules of procedure and financial rules for the peer review process under the CNS.

Chapter 3 of the CNS gives the basis of the review process, which is divided into six phases:

- Phase 1: Contracting Parties prepare a national report, describing how it has met the obligations contained in the CNS;

[9] The most recent versions can be found at the IAEA website.

- Phase 2: Contracting Parties receive the national reports of all other Contracting Parties and review them;
- Phase 3: Contracting Parties develop questions and comments that are transmitted to the relevant Contracting Party through the CNS secure website not less than four months before the Review Meeting;
- Phase 4: Contracting Parties attend the Review Meeting, where they discuss the reports of other Contracting Parties in country groups, present their own national reports and respond to questions and comments submitted prior to the Review Meeting and those made during country group sessions;
- Phase 5: Country group rapporteurs develop an oral report to be delivered at the final plenary identifying main issues, themes or conclusions arising from country group discussions;
- Phase 6: The Review Meeting considers and approves by consensus a summary report of the Review Meeting prepared by the President.

2.1.3.2 The Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (Joint Convention)

Background

The Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (referred to as the Joint Convention) is the first international legal instrument to directly address the safety of spent fuel and radioactive waste [7]. It was adopted at a diplomatic conference on 5 September 1997 and entered into force on 18 June 2001. As of April 2016, there were 72[10] Contracting Parties to the Joint Convention.

The Joint Convention applies to spent fuel and radioactive waste resulting from civilian nuclear reactors and activities [7]. It also applies to spent fuel and radioactive waste from military or defence programmes, when these materials are transferred permanently to and managed within exclusively civilian programmes, or when declared as spent fuel or radioactive waste for the purpose of the Joint Convention by the Contracting Party. The Joint Convention also applies to planned and controlled releases into the environment of liquid or gaseous radioactive materials from regulated nuclear installations.

It should be noted that some Member States consider spent fuel to be radioactive waste to be ultimately disposed of, while other Member States consider spent fuel to be a resource to be reprocessed.

Provisions of the Joint Convention

The articles of the Joint Convention include a preamble and 44 articles, divided into seven chapters [7]. The most significant aspects are described below. The preamble reaffirms the need to manage spent nuclear fuel and dispose of radioactive waste in a safe and efficient manner, and that the ultimate responsibility for ensuring the safety of spent fuel and radioactive waste management rests within the Member State [7].

[10] : INTERNATIONAL ATOMIC ENERGY AGENCY, Latest Status of Signature and Ratification, Registration No: 1729, http://www.iaea.org/Publications/Documents/Conventions/jointconv_status.pdf

Chapter 1 states the main objectives, definitions and scope of application of the Joint Convention. The main objectives are:

- "To achieve and maintain a high level of safety worldwide in spent fuel and radioactive waste management";
- To ensure protection against potential hazards "that the needs and aspirations of the present generation are met without compromising the ability of future generations to meet their needs and aspirations"; and
- "To prevent accidents with radiological consequences and to mitigate their consequences" [7].

Chapter 2 includes Articles 4 to 10 and covers the complete life cycle of the spent fuel management. Article 4 requires each Contracting Party to "take the appropriate steps to ensure that at all stages of spent fuel management, individuals, society and the environment are adequately protected against radiological hazards" [7]. Article 5 requires existing installations to meet the requirements of Article 4. Articles 6, 7, 8 and 9 introduce the basic principles to be followed during siting, design and construction, assessment of safety, operation of installations and disposal of the spent fuel, respectively. Article 10 states that if a Contracting Party considers spent fuel to be radioactive waste, the provisions of Chapter 3 must be followed [7].

Chapter 3 parallels Chapter 2 but deals with radioactive waste and includes Articles 11 to 16. Additionally, Article 17 requires Contracting Parties to ensure that, after closure of a disposal facility, the necessary records are preserved, active or passive institutional controls are carried out and intervention measures are implemented, if necessary [7].

Chapter 4 includes Articles 18 to 26 and relates to "the legislative, regulatory and administrative measures and other steps necessary for implementing" a Contracting Parties' "obligations" under the Joint Convention [7].

Chapter 5 includes Articles 27 and 28, and deals with transboundary movement and disused sealed sources [7].

Chapter 6 includes Articles 29 to 37 and deals with meetings of the Contracting Parties. These provisions are similar to those of the CNS [7].

Chapter 7 includes Articles 38 to 43 and deals with some administrative aspects of the Joint Convention and again are similar to those of the CNS [7].

Appendix II to this book has more information on the Joint Convention, including a summary of the results of the review meetings [7].

2.1.3.3 Convention on Early Notification of a Nuclear Accident

The Convention on Early Notification of a Nuclear Accident (referred to as Early Notification Convention) was a result of the Chernobyl accident in April 1986 and was adopted by the IAEA General Conference at its special session, 24 to 26 September 1986. The Early Notification Convention entered into force on 27 October 1986 [8].

As of March 2016, there were 119[11] Contracting Parties to the Early Notification Convention, including all Member States with operating NPPs. Four international organizations are also Contracting Parties: European Atomic Energy Community (EURATOM), Food and Agriculture Organization of the United Nations (FAO), World Health Organization (WHO) and World Meteorological Organization (WMO).

The Early Notification Convention includes a preamble and 17 articles. Only the most salient ones are described below.

The Early Notification Convention establishes a notification system which requires in Article 1 Contracting Parties to report time, location, radiation releases, and other data essential for assessing the situation for any accident "from which a release of radioactive material occurs or is likely to occur and which has resulted or may result in an international transboundary release that could be of radiological safety significance for another State" and is applicable to "facilities or activities of a State Party or of persons or legal entities under its jurisdiction or control" [8]. It includes a comprehensive list of installations or activities:

- "Any nuclear reactor wherever located;
- Any nuclear fuel cycle facility;
- Any radioactive waste management facility;
- The transport and storage of nuclear fuels or radioactive wastes;
- The manufacture, use, storage, disposal and transport of radioisotopes for agricultural, industrial, medical and related scientific and research purposes; and
- The use of radioisotopes for power generation in space objects" [8].

Article 2 states that the Contracting Party in the event of an accident has to notify, directly or through the Agency, those States that "are or may be physically affected", as well as the IAEA. This notification may be directly to affected States, or through the IAEA.

Under Article 3, Contracting Parties may also voluntarily report other accidents with transboundary consequences than those associated with facilities and activities listed in Article 1 [8]. China, France, Russian Federation, United Kingdom, and United States of America have all declared their intent to voluntarily report other accidents involving transboundary consequences pursuant to Article 3.Article 4 requires the IAEA to immediately inform Contracting Parties, Member States and other States that may be affected and relevant international intergovernmental organizations of a notification received pursuant to Article 2. Article 4 also requires the IAEA to provide, on request, information to any Contracting Party, Member State or relevant international organization.

Article 5 requires the notifying Contracting Party to provide the following information, as available:

- "The time, exact location where appropriate, and the nature of the nuclear accident;
- The facility or activity involved;

[11] INTERNATIONAL ATOMIC ENERGY AGENCY, Convention on Early Notification of a Nuclear Accident – Latest Status, Registration No: 1532, https://www.iaea.org/Publications/Documents/Conventions/cenna_status.pdf.

- The assumed or established cause and the foreseeable development of the nuclear accident relevant to the transboundary release of the radioactive materials;
- The general characteristics of the radioactive release, including, as far as is practicable and appropriate, the nature, probable physical and chemical form and the quantity, composition and effective height of the radioactive release;
- Information on current and forecast meteorological and hydrological conditions, necessary for forecasting the transboundary release of the radioactive materials;
- The results of environmental monitoring relevant to the transboundary release of the radioactive materials;
- The off-site protective measures taken or planned;
- The predicted behaviour over time of the radioactive release" [8].

"Such information shall be supplemented at appropriate intervals by further relevant information on the development of the emergency situation, including its foreseeable or actual termination" and "may be used" by other Contracting Parties and the IAEA "without restriction, except when such information is provided in confidence" [8].

Article 6 requires notifying Contracting Parties to respond promptly to a request for further information or consultations sought by an affected Contracting Party.

Article 7 requires each Contracting Party to "make known to the Agency and to other State Parties, directly or through the Agency, its competent authorities and point of contact responsible for issuing and receiving notification and information". The IAEA "shall maintain an up-to-date list with such information and "shall provide it to State Parties and Member States, and relevant international organizations" [8].

Articles 8, 9 and 10 consider complementary requirements related to assistance to Contracting Parties with no nuclear activities, bilateral and multilateral arrangements between Contracting Parties, and relationship to other international agreements.

Article 11 states that any disputes between Contracting Parties should be settled by negotiation or by other peaceful means. In the event settlement cannot be reached, Article 11 allows a Contracting Party to, either go to arbitration or to refer the matter to the International Court of Justice for decision.

Article 16 designates the IAEA Director General as Depositary of the Early Notification Convention. The depositary shall promptly notify Contracting Parties of each signature, any protocol of amendment; each deposit of an instrument of ratification, or any declaration or withdrawal.

Article 17 establishes that the original documents of the convention shall be deposited, in all official IAEA languages, with the IAEA Director General who shall provide copies to the Contracting Parties and all other Member States.

2.1.3.4 Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency

The Convention on the Assistance in the Case of a Nuclear Accident or Radiological Emergency (referred to as the Assistance Convention) [8] enables a Contracting Party to request assistance from any other Contracting Party, the IAEA or other international

organizations, in case of a nuclear accident or radiological emergency. The Assistance Convention is a convention closely associated with the Early Notification Convention. Both were created as a result of the Chernobyl accident.

The Assistance Convention was adopted by the IAEA General Conference at its special session, 24 to 26 September 1986, and entered into force on 26 February 1987. As of March 2016, there were 112[12] Contracting Parties to the Assistance Convention, including all Member States with operating NPPs. The following four international organizations are also Contracting Parties: EURATOM, FAO, WHO and WMO.

The Assistance Convention includes a preamble and 19 articles. Only the most salient ones are described below.

Article 1 requires Contracting Parties to cooperate among themselves and with the IAEA to facilitate prompt assistance in the event of a nuclear accident or radiological emergency.

Article 2 establishes that in the event of a request for assistance, the obligations of Contracting Parties include:

- A requesting Contracting Party "shall specify the scope and type of assistance needed" [8];
- A Contracting Party to which a request is directed has to "promptly decide and notify" the requesting Contracting Party about whether it can render the requested assistance and about the scope and terms of the assistance [8];
- The IAEA shall respond to a request for assistance by "making available appropriate resources", "transmitting promptly the request to other States and international organizations" and "co-ordinating the assistance at international level" [8];

Article 3 sets out how the assistance is controlled and directed unless otherwise specified and includes:

- The assisting Contracting Party is required to designate in consultation with the requesting party, the person responsible for immediate operational supervision over provided personnel and equipment, coordination of related medical treatment when needed and organizing the release of information [8];
- The requesting Contracting Party is required to manage the assistance in its territory, provide local facilities and services, protect provided personnel and equipment, and provide necessary support to the assisting personnel [8].

Article 4 requires each Contracting Party to provide the IAEA and other Contracting Parties its designated competent authorities and authorized point of contact. The IAEA must maintain a continuously updated and readily available list of competent authorities and points of contact, and provide this list to Contracting Parties, Member States, and relevant international organizations [8].

Article 5 describes the functions of the IAEA. The Contracting Parties request the Agency to:

[12] https://www.iaea.org/Publications/Documents/Conventions/cacnare_status.pdf

- Collect and disseminate information concerning experts, equipment and materials which could be made available, as well as methodologies, techniques and available results of research relating to response to nuclear accidents or radiological emergencies [8];
- Assist, within the scope of its Statute, a Contracting Party or a Member State when requested [8];
- Make available, on request, appropriate resources for conducting an initial assessment of the accident or emergency [8];
- Establish and maintain liaison with relevant international organizations for the purposes of obtaining and exchanging relevant information and data [8].

Articles 6 to 12 mainly cover administrative matters related to:

- Confidentiality and public statements;
- Reimbursement of costs;
- Privileges, immunities and facilities; transit of personnel, equipment and property;
- Claims and compensation;
- Termination of assistance; and
- Relationship to other international agreements [8].

Article 13, dealing with settlement of disputes, has similar provisions as Article 11 of the Early Notification Convention [8].

Article 18 designates the IAEA Director General as Depositary of the Assistance Convention.

Article 19 establishes that the authentic documents in all IAEA official languages are deposited with the IAEA Director General, who must provide copies to the Contracting Parties and all other Member States [8].

2.1.3.5 The IAEA system to assure its functions under the Early Notification and Assistance Conventions

Both the Early Notification and the Assistance Conventions assign the IAEA several obligations. The IAEA has established a system to discharge its roles under the Early Notification and Assistance Conventions properly. The operational arrangements among the IAEA, its Member States, Contracting Parties and relevant international intergovernmental organizations (here-in-after: international organizations) set forth under these Conventions are documented in the IAEA EPR – IEComm 2012 [9] and EPR – RANET 2013 [10]. Section 4.5 provides further discussion of the IAEA roles in emergency preparedness and response.

Notification and official information exchange

Under the Early Notification Convention, the IAEA has established and has been maintaining a list of competent authorities and points of contact in Contracting Parties authorized to issue and receive notification and information in an emergency as well as of points of contact of relevant international organizations. The IAEA provides this list to the Contracting Parties and Member States and to relevant international organizations. In addition, the Early Notification Convention assigns the IAEA responsibility to inform States Parties, Member States, other States, which are or may be physically affected, and relevant international organizations, of a notification received from a State Party of the occurrence and location of a nuclear or radiological accident. Upon request, the IAEA is also required to provide any State

Party, Member State and relevant international organizations promptly with the information received relevant to minimizing the radiological consequences. For this purpose, the IAEA established a designated web portal named IAEA Unified System for Information Exchange in Incidents and Emergencies (USIE).

International assistance

Under the Assistance Convention, the IAEA has established and has been maintaining a list of competent authorities and points of contact in Contracting Parties authorized to make and receive requests and to accept offers of assistance. Each Contracting party is required, within the limits of its capabilities, to identify and notify the IAEA of experts, equipment and materials, which could be made available for the provision of assistance to other States Parties as well as the terms, especially financial, under which such assistance could be provided. To support the implementation of the Assistance Convention, the IAEA established a global network named Response Assistance Network (RANET) that also allows sharing of information of available teams with expertise and equipment to assist, upon request, in response to a nuclear or radiological emergency.

The IAEA has the specific response role to respond to a State Party's or a Member State's request for assistance in accordance with the Statute and the terms of the Convention by:

(1) Making available appropriate resources allocated for this purpose;
(2) Promptly transmitting the request to other States and international intergovernmental organizations which according to the IAEA's information, may possess the necessary resources;
(3) Coordinating assistance at the international level which may thus become available, if so requested by the requesting State;
(4) Making available, to a State Party or a Member State requesting assistance, appropriate resources allocated for the purpose of conducting an initial assessment of the emergency;
(5) Offering its good offices to the States Parties and Member States; and
(6) Establishing and maintaining liaison with relevant international organizations for the purposes of obtaining and exchanging relevant information and data, and making a list of such organizations available to States Parties, Member States and the aforementioned organizations.

Under the Assistance Convention, the IAEA is also required to collect and disseminate methodologies, techniques and available results of research relating to response to nuclear accidents or radiological emergencies. This is partly fulfilled through the publication of IAEA safety standards, and technical guidance and tools in the area of emergency preparedness and response. Upon request, the IAEA assists Contracting Parties or Member States to:

(1) Prepare both emergency plans in the case of nuclear accidents or radiological emergencies and the appropriate legislation;
(2) Develop appropriate training programmes for personnel to deal with nuclear accidents or radiological emergencies;
(3) Develop appropriate radiation monitoring programmes, procedures and standards; and
(4) Conduct investigations into the feasibility of establishing appropriate radiation monitoring systems. This is usually done through expert missions and various capacity building activities.

2.1.4 Conventions in the area of nuclear security

The history of the nuclear security concept has passed through three related issues and activities. In the early days in the development of nuclear technology, the major concern within the five nuclear weapon States was proliferation of nuclear devices. Next, the increasing use of nuclear materials for peaceful applications and the growing interest in many States for reprocessing spent fuel led to concern regarding the control of these materials. Finally, recent escalating acts of terrorism initiated the need to protect nuclear installations against malevolent acts causing the release of radioactive products.

2.1.4.1 Evolution of the nuclear security concept and related treaties and conventions

The non-proliferation concern

The non-proliferation concern was highlighted with President Eisenhower's Atoms for Peace speech to the UN General Assembly on 8 December 1953. Although the proposal was well received, concerns were expressed on the potential proliferation of nuclear explosives. To avoid that threat, the Treaty on the Non-Proliferation of Nuclear Weapons (NPT) entered into force in 1970. As of June 2016, the NPT had 191[13] Contracting Parties. To verify compliance with the NPT, the IAEA was charged with creating and verifying a comprehensive safeguards system.

The protection of strategic materials

As Member States began to take advantage of nuclear technology, substantial amounts of nuclear materials started to circulate, mainly in the form of enriched uranium for research reactors and low enriched uranium for NPPs. Amounts of plutonium also started to accumulate. In the late 1970s, the concern started to grow that there could be unauthorized removal, through theft or diversion, of nuclear strategic substances and radioactive materials from civil installations and activities for malevolent purposes. Those considerations stimulated the development and establishment in 1987 of the Convention on the Physical Protection on Nuclear Materials.

The protection of nuclear installations

The third phase of nuclear security started soon after, but was consolidated by the September 11th, 2001 multiple terrorist attacks in the USA. It became clear that the current protection system against terrorist intrusions in NPPs and fuel cycle facilities may not be sufficient. Member States started to reassess the protection of their nuclear installations and activities, while the IAEA increased its support to help Member States reinforce security in civil installations and activities such as transport. These actions stimulated the 2005 Amendment to the Convention on the Physical Protection on Nuclear Materials, not yet in force. The Amendment makes it legally binding for Contracting Parties to protect nuclear installations and material in peaceful domestic use, storage and transport.

[13] http://disarmament.un.org/treaties/t/npt

2.1.4.2 Convention on the Physical Protection of Nuclear Materials

The Convention on the Physical Protection of Nuclear Materials (CPPNM) [11] entered into force on 8 February 1987 and as of September 2015, there were 153[14] Contracting Parties . The CPPNM is the only international legally binding undertaking in the area of physical protection of nuclear material. It establishes measures related to the prevention, detection and punishment of offenses relating to nuclear material. The CPPNM includes 23 articles and two Annexes.

Article 1 limits the scope of the CPPNM to nuclear materials, defined as:

> "…nuclear material means plutonium except that with isotopic concentration exceeding 80% in plutonium-238; uranium-233; uranium enriched in the isotope 235 or 233; uranium containing the mixture of isotopes as occurring in nature other than in the form of ore or ore-residue; any material containing one or more of the foregoing" [11].

Article 2 limits the application of the CPPNM to nuclear material used for peaceful purposes while in international transport.

Article 3 requires each Contracting Party to take steps to ensure as far as practicable that, during international nuclear transport, nuclear material within its territory or on board a ship or aircraft under its jurisdiction is protected.

Articles 4 to 6 cover Contracting Party responsibilities; requirements to establish contact points and communication; and confidentiality of information related to the transport.

Articles 7 to 13 discuss in detail how to handle offences.

As in other Conventions, there are articles related to: handling disputes; duties and services of the Depositary (the IAEA Director General); entrance into force; and, handling of amendments.

The heart of the technical part of the CPPNM is the Annexes. Annex I describes the acceptable levels of physical protection for nuclear material during storage incidental to international nuclear transport and during international transport for each of the three categories defined in Annex II. Annex II includes a table defining, in three categories, the limiting amounts for each nuclear material. Table 1 reproduces Annex II.

[14] https://www.iaea.org/Publications/Documents/Conventions/cppnm_status.pdf

TABLE 1 CATEGORIZATION OF NUCLEAR MATERIAL[15]

Material	Form	Category		
		I	II	III
Plutonium[16]	Unirradiated[17]	2 kg or more	Less than 2 kg but more than 500 g	500 g or less but more than 15 g
Uranium-235	Unirradiated enriched to 20% ^{235}U or more	5 kg or more	Less than 5 kg but more than 1 kg	1 kg or less but more than 15 g
	enriched to 10% ^{235}U but less than 20%		10 kg or more	Less than 10 kg but more than 1 kg
	enriched above natural, but less than 10% ^{235}U			10 kg or more
Uranium-233	Unirradiated	2 kg or more	Less than 2 kg but more than 500 g	500 g or less but more than 15 g
Irradiated fuel			Depleted or natural uranium, thorium or low-enriched fuel (less than 10% fissile content)[18][19]	

For storage during transportation, the protective measures go from controlled access for Category III material to sophisticated storage for Category I material. Protection during transport, for all categories, must include special precautions. In addition, for Category I, the transport has to be under constant surveillance by escorts and in close communication with response forces.

2.1.4.3 Amendment to the CPPNM

The increase of terrorist threats in the 1990s resulted in Member States considering the need to amend the CPPNM. The physical protection of nuclear installations was an increasing concern. However, the CPPNM is limited to nuclear materials.

In September 2001, the IAEA Director General convened an open-ended group of legal and technical experts (the Group) to prepare a draft amendment to the CPPNM. In March 2003,

[15] Taken from Annex II in INFCIRC/274/Rev. 1
[16] All plutonium except that with isotopic concentration exceeding 80% in ^{238}P
[17] Material not irradiated in a reactor or material irradiated in a reactor but with a radiation level equal to or less than 100 rad/h at one metre unshielded.
[18] Although this level of protection is recommended, it would be open to Member States, upon evaluation of the specific circumstances, to assign a different category of physical protection.
[19] Other fuel which by virtue of its original fissile material content is classified as Category I and II before irradiation may be reduced one category level while the radiation level from the fuel exceeds 100 rad/h at one metre unshielded.

the Group adopted by consensus its final report. In June 2003, the Director General circulated the Group's report to all Contracting Parties to the CPPNM for their consideration. On July 8, 2005 a diplomatic conference adopted by consensus the *Nuclear Security - Measures to Protect Against Nuclear Terrorism Amendment to the CPPNM* [12]. The Amendment requires no signature but is subject to ratification, acceptance, or approval. In accordance with article 20 of the CPPNM, the amendment entered into force on 8 May 2016 after ratification by two-thirds of the Contracting Parties.

The amended title, *Convention on the Physical Protection of Nuclear Material and Nuclear Facilities* is a clear indication of the extended scope of the CPPNM. A new article 1A is added:

> "The purposes of this Convention are to achieve and maintain worldwide effective physical protection of nuclear material used for peaceful purposes and of nuclear facilities used for peaceful purposes; to prevent and combat offences relating to such material and facilities worldwide; as well as to facilitate cooperation among States Parties to those ends" [12].

The amended CPPNM binds Contracting Parties legally to protect nuclear installations and material in peaceful domestic use, storage and transport. It also provides for expanded cooperation between and among Contracting Parties regarding rapid measures to locate and recover stolen or smuggled nuclear material, mitigate any radiological consequences of sabotage, and prevent and combat related offences.

The new text also adds the prevention of radiological risks due to sabotages inflicted upon nuclear installations with the possibility of radioactive releases. In some cases, the text of articles was replaced, while in other cases new text was added to the original text. Article 16 was completely changed to establish that conferences of Contracting Parties have to be convened five years after the entry into force of the Amendment, and every five years afterwards, to review the implementation of the amended Convention. Some footnotes regarding irradiated fuel were added to the Annexes.

2.1.4.4 Fundamental principles of physical protection of nuclear material and nuclear installations

The fundamental principles of physical protection of nuclear material and nuclear installations are an important addition in the Amended CPPNM and read [12]:

> "FUNDAMENTAL PRINCIPLE A: *Responsibility of the State.* The responsibility for the establishment, implementation and maintenance of a physical protection regime within a State rests entirely with that State.
>
> FUNDAMENTAL PRINCIPLE B: *Responsibilities during international transport*. The responsibility of a State for ensuring that nuclear material is adequately protected extends to the international transport thereof, until that responsibility is properly transferred to another State, as appropriate.
>
> FUNDAMENTAL PRINCIPLE C: *Legislative and regulatory framework.* The State is responsible for establishing and maintaining a legislative and regulatory framework to govern physical protection. This framework should provide for the establishment of applicable physical protection requirements and include a system of evaluation and licensing or other procedures to grant authorization. This framework should include a

system of inspection of nuclear installations and transport to verify compliance with applicable requirements and conditions of the licence or other authorizing document, and to establish a means to enforce applicable requirements and conditions, including effective sanctions.

FUNDAMENTAL PRINCIPLE D: *Competent authority.* The State should establish or designate a competent authority which is responsible for the implementation of the legislative and regulatory framework, and is provided with adequate authority, competence and financial and human resources to fulfil its assigned responsibilities. The State should take steps to ensure an effective independence between the functions of the State's competent authority and those of any other body in charge of the promotion or utilization of nuclear energy.

FUNDAMENTAL PRINCIPLE E: *Responsibility of the licensees.* The responsibilities for implementing the various elements of physical protection within a State should be clearly identified. The State should ensure that the prime responsibility for the implementation of physical protection of nuclear material or of nuclear installations rests with licensees or the holders of other authorizing documents (e.g., operators or shippers).

FUNDAMENTAL PRINCIPLE F: *Security culture.* All organizations involved in implementing physical protection should give due priority to the security culture, to its development and maintenance necessary to ensure its effective implementation in the entire organization.

FUNDAMENTAL PRINCIPLE G: *Threat.* The State's physical protection should be based on the State's current evaluation of the threat.

FUNDAMENTAL PRINCIPLE H: *Graded approach.* Physical protection requirements should be based on a graded approach, taking into account the current evaluation of the threat, the relative attractiveness, the nature of the material and potential consequences associated with the unauthorized removal of nuclear material and with the sabotage against nuclear material or nuclear installations.

FUNDAMENTAL PRINCIPLE I: *Defence in depth.* The State's requirements for physical protection should reflect a concept of several layers and methods of protection (structural or other technical, personnel and organizational) that have to be overcome or circumvented by an adversary in order to achieve his objectives.

FUNDAMENTAL PRINCIPLE J: *Quality assurance.* A quality assurance policy and quality assurance programmes should be established and implemented with a view to providing confidence that specified requirements for all activities important to physical protection are satisfied.

FUNDAMENTAL PRINCIPLE K: *Contingency plans.* Contingency (emergency) plans to respond to unauthorized removal of nuclear material or sabotage of nuclear installations or nuclear material, or attempts thereof, should be prepared and appropriately exercised by all licensees and authorities concerned.

FUNDAMENTAL PRINCIPLE L: *Confidentiality.* The State should establish requirements for protecting the confidentiality of information, the unauthorized disclosure of which could compromise the physical protection of nuclear material and nuclear installations" [12].

2.1.5 Conventions in the area of civil nuclear liability

Civil liability for nuclear damage is the potential responsibility for payment to compensate for nuclear damage to third parties or to the environment following a lawsuit. It is distinguished from criminal liability, which involves possible punishment for a crime. Nuclear damage is defined in INFCIRC/500, the Vienna Convention on Civil Liability for Nuclear Damage (the Vienna Convention), as:

> "Nuclear damage means loss of life, any personal injury or any loss of, or damage to, property which arises out of or results from the radioactive properties or a combination of radioactive properties with toxic, explosive or other hazardous properties of nuclear fuel or radioactive products or waste in, or of nuclear material coming from, originating in, or sent to, a nuclear installation; any other loss or damage so arising or resulting if and to the extent that the law of the competent court so provides" [13].

The issue of civil liability for nuclear damage required special statutory provisions in most Member States since nuclear energy started to be used for civil purposes in the 1950s.[20]

In most legal systems, specific rules had already been adopted to govern third party liability for damage caused by dangerous activities. These rules could have been applied to civil nuclear liability. However, under the ordinary law of civil liability, several persons might have been liable for damage caused by a nuclear incident and victims might have had difficulty in establishing which of them was in fact liable. In addition, the person liable would have had unlimited liability without being able to obtain complete insurance cover.

In view of the fact that nuclear activities were generally deemed to be more hazardous than conventional dangerous activities, legislators felt that liability for nuclear damage should be subject to a specific legal regime, in order to ensure prompt and adequate compensation for nuclear damage without, at the same time, exposing the nuclear industry to excessive burdens. It was also felt that the adoption of an international regime for civil nuclear liability would facilitate the bringing of actions and the enforcement of judgements.

2.1.5.1 Convention on Third Party Liability in the Field of Nuclear Energy (Paris Convention)

The OECD/NEA, the former Organisation for European Economic Co-operation, was the first international organization to consider nuclear liability formally, when the Paris Convention [14] was adopted on 29 July 1960. The Paris Convention entered into force on 1 April 1964, with two additional protocols added in 1964 and 1982. A Brussels Supplementary Convention to the Paris Convention was established in 1963. It also included the additional protocols of 1964 and 1982. Contracting Parties are obliged to adapt their own nuclear civil liability regulations to the requirements of the Paris Convention.

[20] For a more complete discussion on civil nuclear liability, refer to *IAEA International Law Series No. 3 The 1997 Vienna Convention on Civil Liability for Nuclear Damage and the 1997 Convention on Supplementary Compensation for Nuclear Damage—Explanatory Texts*, from which this background is adapted.

2.1.5.2 Vienna Convention on Civil Liability for Nuclear Damage (Vienna Convention)

The IAEA, working together with Member States from Central and South America, Africa, Asia Pacific and Eastern Europe, adopted the Vienna Convention on 21 May 1963, which entered into force on 12 November 1977. After the Chernobyl accident, a Protocol to Amend the Vienna Convention [15] was added in 1997, and a Convention on Supplementary Compensation for Nuclear Damage (CSC) [16] was also added in 1997.

2.1.5.3 Principles on which the Paris and Vienna Convention are based

The Paris, as well as the Vienna Convention are based on the civil law concept and share the following main principles:

1. Strict or channelling liability. Operators of nuclear installations are exclusively liable for nuclear damage;
2. Liability of the operator is absolute, i.e. the operator is held liable irrespective of fault;
3. Liability is limited in amount. To cover potential claims, the licensee must engage an insurance policy or provide other financial security for an amount corresponding to the established liability, which is fixed by national law, generally in accordance with the Conventions[21]. In case of an accident, the total compensation is limited to the amount established for each installation. When the claims surpass the amount allocated, the court must adjust compensation accordingly. A national government may decide to add national resources for increased compensation[22];
4. Liability is limited in time. Although nuclear damage may be evident immediately, in many cases there is a latency period, which may vary from weeks to several decades, before nuclear damage is evident. In addition, in the vast majority of cases, delay effects and genetic damage are not unique to nuclear hazards (i.e. other agents or conditions completely unrelated to the nuclear accident may produce the same delay effects or genetic damage). Therefore, the Conventions fix a time limit by which a claim must be made;
5. The operator must maintain insurance of other financial security for an amount corresponding to his liability; if such security is insufficient, the installation State is obliged to make up the difference up to the limit of the operator´s liability;
6. Exclusive jurisdiction. Jurisdiction over actions lies exclusively with the courts of the Contracting Party in whose territory the nuclear incident occurred. A single court of justice must be assigned to consider and judge the claims formally requested by claimants from all affected countries. Since a nuclear accident may affect other countries, assigning a single court ensures equitable compensation and distribution of funds;
7. Non-discrimination of victims on the grounds of nationality, domicile or residence.[23]

[21] The 1997 Protocol to the Vienna Convention sets the operator's liability at not less than 300 million Special Drawing Rights (SDR). The 1983 Brussels Supplementary Convention to the Paris Convention created new ways of compensation up to 300 million SDR. SDR is the unit of account defined by the International Monetary Fund and used by it for its own operations and transactions.

[22] For example, Spanish regulations state that loss of life must be compensated first and completely with participation of the State if needed. Compensation for loss of property is then distributed prorated among the claimants.

[23] https://www.iaea.org/publications/documents/conventions/vienna-convention-on-civil-liability-for-nuclear-damage

2.1.5.4 Nuclear liability after the Chernobyl accident

Following the Chernobyl accident, the IAEA initiated work on all aspects of nuclear liability with a view to improving the basic Conventions and establishing a comprehensive liability regime. In 1988, as a result of joint efforts by the IAEA and OECD/NEA, the *Joint Protocol Relating to the Application of the Vienna Convention and the Paris Convention* [17] was adopted. The Joint Protocol established a link between the two Conventions combining them into one expanded liability regime. Parties to the Joint Protocol are treated as though they were Parties to both Conventions and a choice of law rule is provided to determine which of the two Conventions should apply to the exclusion of the other in respect of the same accident. However, the Joint Protocol did not address needed improvements to either the Paris or the Vienna Convention.

Developments by the IAEA

The loss of life, personal injuries and large contamination from the Chernobyl accident made it clear that the amount reserved for civil liability needed a revision. The Paris Convention had already considered such revision through the Brussels Supplementary Convention to the Paris Convention and by the additional Protocols of 1964 and 1982.

The IAEA created a Standing Committee on Nuclear Liability in 1990 resulting in the *Protocol to Amend the Vienna Convention on Civil Liability for Nuclear Damage* (Vienna Convention Protocol) [15].

To establish a supplementary system to increase national and international liability funds, the Standing Committee decided to create a Supplementary Compensation Convention, which was adopted in September 1997. It included three major purposes: more money available to compensate victims, more people entitled to compensation and more damage to be compensated.

As of February 2016, there are 19[24] signatory countries, but only five[25] have ratified the Supplementary Compensation Convention, which will not enter into force until ratified by five countries with a minimum of 400 000 megawatts (thermal) of installed nuclear capacity.

Developments by the OECD/NEA

The work of the IAEA described above led the OECD/NEA to review the Paris Convention and the Supplementary Brussels Convention mainly to increase the amount of compensation, the number of claimants and the time to pose a request for compensation. The OECD/NEA asked Contracting Parties to make the revisions themselves, resulting in the 2004 Protocol to Amend the Paris Convention [18]. As of July 2015[26], only two[27] countries out of 16 original signatories have accepted the protocol. The parallel 2004 Protocol to the Brussels Convention has only been ratified by three countries[28] out of 13 signatories, as of March 2014[29], and is not yet in force.

[24] https://www.iaea.org/Publications/Documents/Conventions/supcomp_status.pdf
[25] Argentina, Morocco, Romania, United Arab Emirates and USA
[26] https://www.oecd-nea.org/law/paris-convention-ratification.html
[27] Norway and Switzerland
[28] Norway, Spain and Switzerland
[29] https://www.oecd-nea.org/law/brussels-convention-ratification.html

2.1.5.5 Third party liability and the Fukushima Daiichi accident

The Fukushima Daiichi accident has not produced loss of life or significant radiation induced injuries, but it has resulted in large contaminated land zones, a large number of evacuees, significant releases of radioactive contaminants and large monetary losses.

The Japan Nuclear Damage Act[30] was promulgated in 1961 and is based on a general tort law arranged to cover nuclear damages. It adheres to the principle of strict liability as only the operator assumes unlimited no-fault liability. The operator is exempted from no-fault liability in case of extraordinary natural catastrophe or social upheaval[31]. The operator is required to financially secure its liability up to ¥ 120 billion for each nuclear site[32]. Claims are extinguished 20 years following the date of the tort and the actions must be placed within three years from the date the person suffering damage had knowledge both of the damage and the liable operator.

If the amount of damages exceeds the amount of the insurance, the operator still remains liable, but the government, if approved by the Japanese National Diet, gives the operator the necessary aid to compensate the excess and maintain the unlimited liability required by the Compensation Act. The Ministry of Education, Culture, Sports, Science, and Technology (MEXT) is required to set up a Reconciliation Committee to establish the scale of the nuclear damage and to mediate disputes concerning compensation claims. In the case of the Fukushima Daiichi accident, MEXT established the Reconciliation Committee in early April 2011. Despite the official nature of the Reconciliation Committee, the final decision on what qualifies as nuclear damage rests with Japanese courts of justice.

The OECD/NEA Nuclear Law Committee has maintained closed contacts with the Reconciliation Committee on the legal procedures developed as a result of the Fukushima Daiichi accident. In 2012, the OECD/NEA published the results of these efforts [19].

In August 2011, the Japanese National Diet approved the creation of the Nuclear Damage Compensation Facilitation Corporation, which will be responsible for managing a fund that will help operators in providing compensation to victims of nuclear accidents. That fund is supported by the government through treasury bonds, with companies operating NPPs required to pay an insurance premium to the Facilitation Corporation every year. The Facilitation Corporation will decide on the premium amount. If a company receives financial support from the Facilitation Corporation, the company is required to pay an additional premium.

Tokyo Electric Power Company (TEPCO), the operator of the Fukushima Daiichi NPP, will use that fund to respond to claims for compensation. Provisional payments started in April 2011 to those ordered to evacuate, followed by agriculture, forestry and fishing operators, business operators and voluntary evacuees. It is estimated that the total compensation for the Fukushima Daiichi accident will be ¥ 4.5 trillion, of which ¥ 1.7 trillion have already been paid.

[30] Law No. 147 of 17 June 1961
[31] This exception did not apply because of the historical evidence of earthquakes and tsunamis of the magnitude experienced at Fukushima Daiichi.
[32] Independent of the number of nuclear reactors on the site.

2.2 IAEA SAFETY STANDARDS

Learning Objective 1: To understand the role of the IAEA Safety Standards in the Global Nuclear Safety and Security Framework.

Learning Objective 2: To understand the historical development of the IAEA Safety Standards.

Learning Objective 3: To understand the current long term structure of the IAEA Safety Standards based on fundamental safety principles, general and specific requirements and guides.

Learning Objective 4: To understand the fundamental safety objective and the ten fundamental safety principles.

Learning Objective 5: To understand the IAEA Safety Standards that are applicable to national governments and regulatory bodies.

Learning Objective 6: To be aware of the IAEA Safety Standards that are applicable to NPPs.

The IAEA has created a comprehensive set of harmonized international safety standards, which is an essential element of the global nuclear safety framework.

Traditionally, the development of a new technology[33] starts with research leading to a discovery. From this discovery, development work continues to test whether the discovery is useful. If it is, the development ends with the commercial deployment of the technology. Progressing through these stages, the potential of harm can increase. At the research stage, the potential for harm is very low and localized. The researchers themselves are the most likely (or the only ones) to be harmed. At the development stage, the potential for harm increases, but again those directly involved in the development are most likely to be harmed. As the technology reaches the commercial stage the potential for harm increases once more. However, at this stage, the potential for harm is not localized and the health and safety of the public and the environment may be the most likely to be affected. Controlling hazards at different steps must therefore be different.

Scientific research is mainly regulated by ethical principles, generally established by the research community itself. New technology development requires a minimum of regulation, generally of a precautionary nature, established and accepted by the developers. Regulations need to progress with the experience gained in the development of the technology in such a way that when the development process ends the existing regulation is satisfactory for the moment. The commercial deployment of a new technology usually requires regulation by an independent body. This independent regulatory body enhances the regulation by taking account of the experience gained in commercial operation. Figure 3 shows this pictorially.

[33] Or product or activity

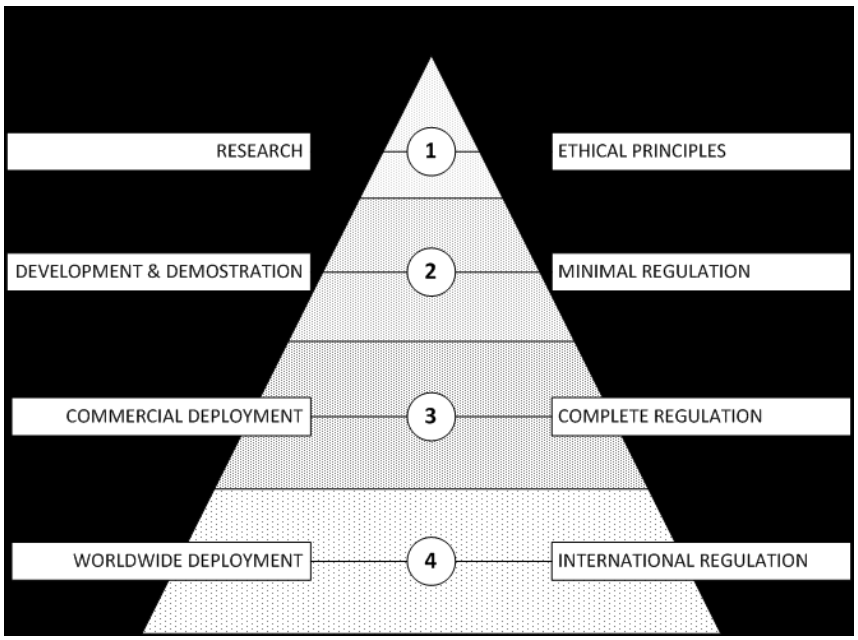


FIG. 3. Standards development for new technologies.

When the nature of the technology has global implications, international institutions are generally created to develop appropriate regulations or standards. In some cases, the regulations are mandatory, while others they are advisory. In the case of nuclear power, the relevant international institution is the IAEA.

From the very beginning of nuclear energy research and development, safety was a concern and prevention against radiation hazards was identified as essential. Nuclear energy was one of the first instances where those in charge of research, development and commercial operation were aware of the need to consider safety as a condition for further deployment.

The IAEA Statute includes the objective:

> "To establish or adopt, in consultation and, where appropriate, in collaboration with the competent organs of the United Nations and with the specialized agencies concerned, standards of safety for protection of health and minimization of danger to life and property (including such standards for labour conditions), and to provide for the application of these standards to its own operation as well as to the operations making use of materials, services, equipment, facilities, and information made available by the Agency or at its request or under its control or supervision; and to provide for the application of these standards, at the request of the parties, to operations under any bilateral or multilateral arrangements, or, at the request of a State, to any of that State's activities in the field of atomic energy" [20].

The IAEA is mandated to provide standards of safety for protection of health and minimization of danger to life and property and to provide assistance on how these standards should be applied.

2.2.1 History of the IAEA safety standards

Shortly after its inception in 1957, the IAEA began developing and setting safety standards; the very first IAEA publication (STI/PUB/1) was Safety Series No. 1 on the *Safe Handling of Radioisotopes*, published in December 1958. Around 200 publications were subsequently

issued in the Safety Series including the worldwide accepted *Regulations for the Safe Transport of Radioactive Material* (1961), the *Basic Safety Standards for Radiation Protection* (1962) and *Safe Radioactive Waste Disposal into the Ground* (1965).

The IAEA is not an international regulatory body, therefore its efforts on developing safety standards are aimed at providing advice on how nuclear energy should be regulated. IAEA safety standards are written in such a way that Member States can introduce the IAEA standards in their regulations.

IAEA safety standards represent an international consensus and generally minimum requirements. Each Member State must define its own acceptable safety level on the basis of local conditions and governmental practices.

Current IAEA safety standards and information on the status of the standards development is available on the IAEA website.

2.2.1.1 Early IAEA safety standards for NPPs

As nuclear power expanded globally in the 1970s, the need for a comprehensive set of safety standards for NPPs emerged, and in 1974, the IAEA launched its Nuclear Safety Standards (NUSS) programme. A Senior Advisory Group (SAG) was entrusted with the task of supervising, reviewing and advising on the programme and proposing draft documents for approval by the IAEA Director General. The SAG selected topics to be covered by Codes of Practice and drew up a provisional list of subjects for Safety Guides. A series of technical documents, called Safety Practices, were also part of the NUSS programme.

After the Three Mile Island accident, and especially after the Chernobyl accident, the IAEA safety standards focused on realistic steps to increase the levels of safety and radiation protection in the growing number of NPPs in operation. The IAEA persisted in particular that:

— Member States develop national safety regulation;
— Basic safety Codes of Practice and Safety Guides were in force;
— National regulatory bodies were truly independent from promoters;
— Radiation dosimetry was in place;
— Emergency preparedness and response were provided for.

With strong international cooperation, by 1986 the IAEA had completed the NUSS programme with five Codes of Practice and 58 Safety Guides for NPPs published in the IAEA Safety Series. These Codes of Practice and Safety Guides set out the objectives and minimum requirements which must be fulfilled to provide adequate safety for NPPs. The five Codes of Practice dealt with the following topics:

— Governmental organization for the regulation of NPPs (50-C-G);
— Safety in NPP siting (50-C-S);
— Design for safety of NPPs (50-C-D);
— Safety in NPP operation (50-G-O);
— Quality assurance for safety in NPPs (50-G-QA).

Each Code of Practice was expanded upon in a number of Safety Guides. The Codes of Practice were all published in 1978 and the 58 Safety Guides were published from 1979 to 1986.

The NUSS programme contributed to the development of a complete and satisfactory set of safety regulations for the advanced designs of NPPs that constitute the bulk of the current world nuclear fleet.

2.2.1.2 A revised system for developing IAEA safety standards

In 1990, following the substantial growth in the IAEA's safety related work and the need to consider fuel cycle installations and new nuclear activities, the IAEA introduced a new structure for safety related publications. The IAEA Safety Series was replaced by two new series of safety related publications, the IAEA Safety Standards Series and the Safety Reports Series. The purpose was to make a distinction between safety standards, which were intended to spell out objectives, concepts and principles; serve as a basis for national regulations; or indicate how various safety requirements may be met, and publications in the Safety Reports Series, which were issued for informational purposes. The IAEA Safety Standards Series set of documents was divided into three categories: Safety Fundamentals, Safety Requirements Standards and Safety Guides. Safety Fundamentals and Safety Requirements needed approval of the IAEA Board of Governors, while Safety Guides and Safety Practices were published under the authority of the Director General.

TABLE 2. THE NATURE AND OBJECTIVES OF THE DOCUMENTS IN THE SAFETY STANDARDS SERIES

Safety Fundamentals	The Safety Fundamentals publications establish the fundamental safety objective and principles of protection and safety. The Safety Fundamentals publications are drafted in a language that is understandable to non-specialists. They convey the basis and rationale for the safety standards to persons at senior level in governments and regulatory bodies.
Safety Requirements	The Safety Requirements publications establish the requirements that must be met to ensure the protection of people and the environment, both now and in the future. The requirements are governed by the objective and principles of the Safety Fundamentals. The format and style of the requirements facilitates the use of the safety requirements by Member States for the establishment, in a harmonized manner, of their regulatory framework.
Safety Guides	The Safety Guides provide recommendations and guidance on how to comply with the Safety Requirements, indicating an international consensus on the measures recommended. The Safety Guides present international good practices to help users striving to achieve high levels of safety.
Safety Reports	The Safety Reports on safety and protection in nuclear activities are issued in the Safety Reports Series. They may complement and be directly related to Safety Requirements or Safety Guides. They may give practical examples and detailed methods that can be used to ensure the observance of Safety Requirements or Safety Guides. They may describe good practices but they do not establish requirements or present recommendations and therefore they do not contain prescriptive 'shall' statements and generally do not contain prescriptive 'should' statements.

Three Safety Fundamentals were issued from 1993 to 1996: The Safety of Nuclear Installations (Safety Series No. 110, 1993); The Principles of Radioactive Waste Management (Safety Series No. 111-F, 1995); and Radiation Protection and the Safety of Radiation Sources (Safety Series No. 120, 1996). These Safety Fundamentals described the basic

objectives, concepts and principles involved, while Safety Requirements and Safety Guides provided technical details and discussed application of the principles.

As part of the revised system, the IAEA created a set of advisory bodies with harmonized terms of reference. The Commission on Safety Standards (CSS) is a standing body of senior government officials holding national responsibilities for standards related to nuclear, radiation, waste and transport safety. It advises the Director General on the Safety Standards programme, ensures consistency and coherence and resolves issues referred to it. Under the CSS are four specific committees as shown in Figure 4. These specific committees are made up of senior Member State experts.

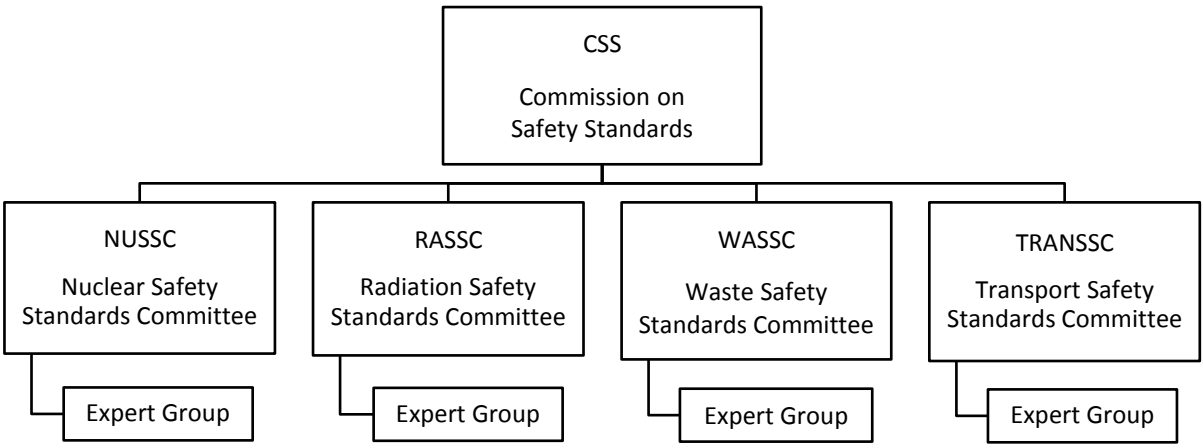


FIG. 4. Organization chart for the CSS and Committees for IAEA safety standards.

IAEA safety standards are developed on the basis of international consensus and as such they reflect widely accepted safety levels. During the development or revision of a safety standard all Member States have the opportunity to present their comments, which are taken into account before approval by the IAEA Board of Governors or the Director General. Figure 5 shows this development process.

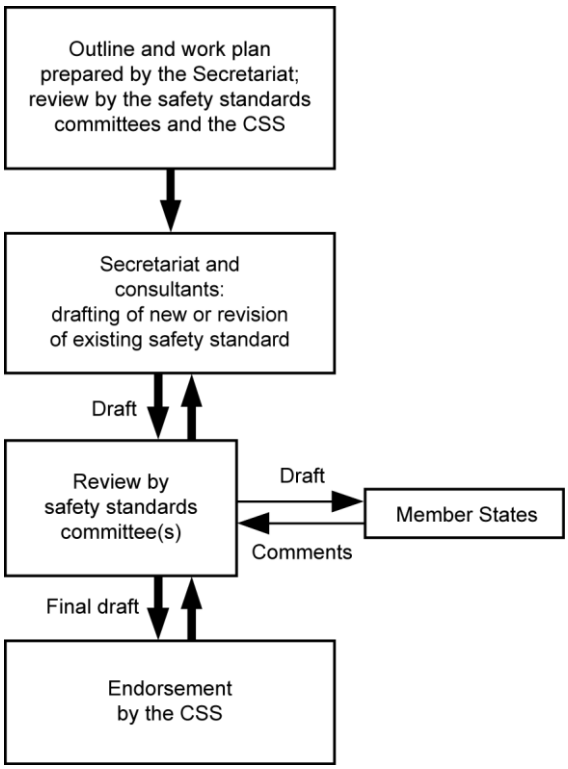


FIG. 5. Process for developing or revising an IAEA Safety Standard.

The revised process resulted in a significant increase in the quality and relevance of the IAEA safety standards. Not only did this result in more Member States using the IAEA safety standards, but there was also increased participation in the production and review of safety standards. However, a new challenge arose: Member States were now also interested in regulatory stability.

2.2.1.3 The long term structure for IAEA safety standards

In the early 2000s the IAEA began to consider the idea of integrating the three existing Safety Fundamentals into a single document. After much effort, the IAEA published the *Fundamental Safety Principles* as *IAEA Safety Standards Series No. SF-1* [21] in 2006, formulating for the first time a unified philosophy of nuclear safety and protection against ionizing radiation with a broad international consensus.

SF-1 is the basis for the IAEA safety standards and provides the rationale for its wider safety programme. The enthusiasm created by the publication of SF-1 led to a new vision for the IAEA safety standards on their 50th anniversary in 2008. It also initiated a complete review of the integrated standards programme[34]. The new approach, the IAEA Safety Standards Series, maintains the hierarchy of the safety standards with three categories, Safety Fundamentals, Safety Requirements and Safety Guides, although with a revised formulation.

[34] Strategies and Processes for the Establishment of IAEA Safety Standards (SPESS) version 2.1, March 2013

A new vision for the IAEA Safety Standards

Outcome: A harmonized high level of protection for people and the environment worldwide based on the IAEA Safety Standards Series as global reference.

Output: IAEA safety standards will be seen as the global reference for protecting people and the environment from harmful effects of ionizing radiation. They will constitute an integrated, comprehensive and consistent set of up-to-date, user friendly and fit-for-purpose safety standards of high quality, which through their use and application in Member States will provide for a harmonized high level of protection for people and the environment from harmful effects of ionizing radiation worldwide.

The publication of SF-1 [21] allowed the IAEA to restructure the Safety Requirements. Figure 6 shows the new long-term structure of the IAEA Safety Standards Series. The Safety Fundamentals provide the basis for the Safety Requirements. General Safety Requirements are applicable to all types of installations and activities, while Specific Safety Requirements cover relevant installations. The Safety Guides provide help on how to comply with the Safety Requirements. Each Safety Guide is associated with a corresponding Safety Requirement.

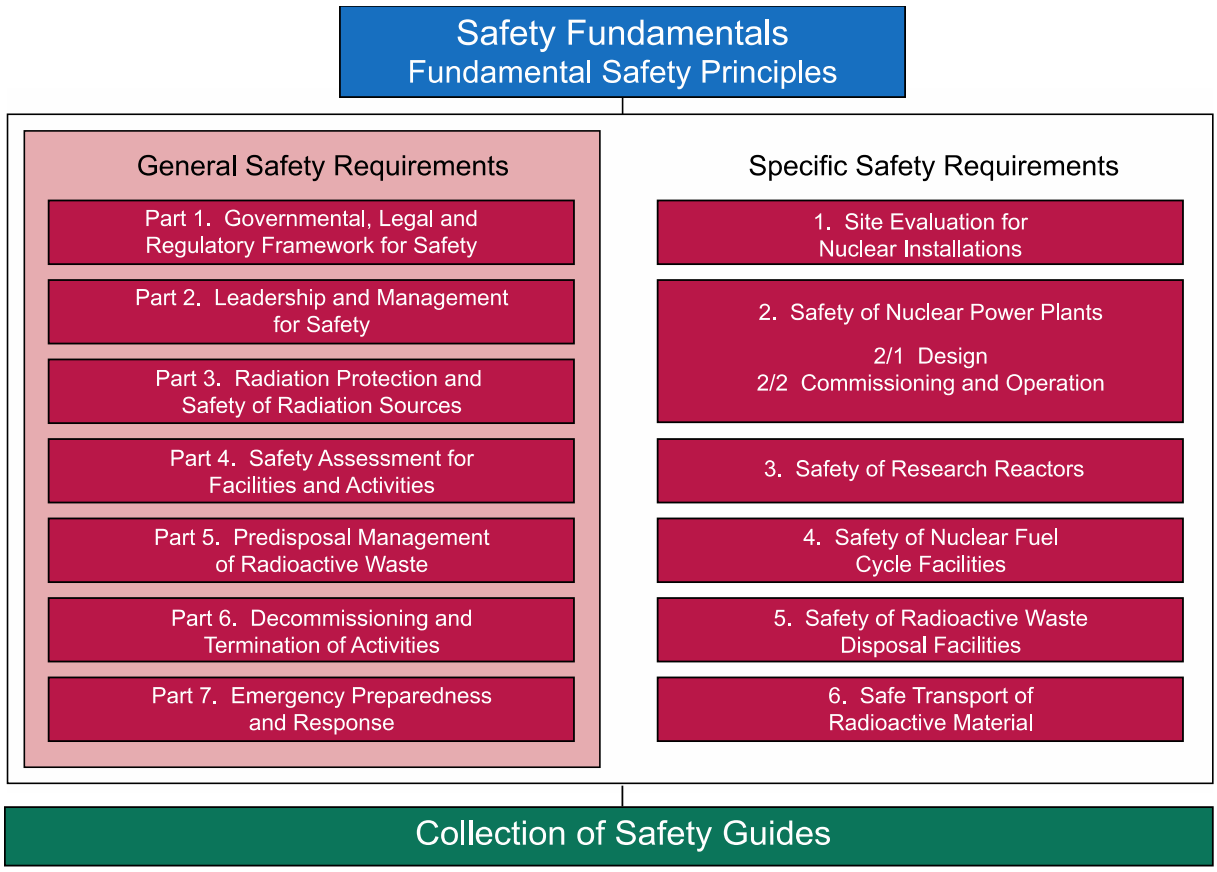


FIG. 6. The long term structure of the IAEA Safety Standards Series.

The infrastructure described in Figure 4 on the CSS and Safety Standard Committees and the process for developing standards shown in Figure 5 remain in place. The intention is to develop some 130 documents, mainly based on the already existing documents. Some have already been published. The status of the IAEA safety standards can be found at the IAEA website.

2.2.2 Safety Fundamentals

SF-1 presents the fundamental safety objective and the ten principles of protection and safety.

> "The fundamental safety objective is to protect people and the environment from harmful effects of ionizing radiation" [21].

SF-1 states that this objective "has to be achieved without unduly limiting the operation of installations or the conduct of activities that give rise to radiation risks" [21].

The ten fundamental safety principles are shown in full in Table 3. These principles are applicable to all peaceful uses of nuclear energy and materials, and, if obeyed, they will ensure that installations and activities achieve the highest standards of safety.

TABLE 3. FUNDAMENTAL SAFETY PRINCIPLES

Principle 1	Responsibility for safety	The prime responsibility for safety must rest within the person or organization responsible for facilities and activities that give rise to radiation risks.
Principle 2	Role of government	An effective legal and governmental framework for safety, including an independent regulatory body, must be established and sustained.
Principle 3	Leadership and management for safety	Effective leadership and management for safety must be established and sustained in organizations concerned with, and facilities and activities that give rise to, radiation risks.
Principle 4	Justification of facilities and activities	Facilities and activities that give rise to radiation risks must yield an overall benefit.
Principle 5	Optimization of protection	Protection must be optimized to provide the highest level of safety that can reasonably be achieved.
Principle 6	Limitation of risks to individuals	Measures for controlling radiation risks must ensure that no individual bears an unacceptable risk of harm.
Principle 7	Protection of present and future generations	People and the environment, present and future, must be protected against radiation risks.
Principle 8	Prevention of accidents	All practical efforts must be made to prevent and mitigate nuclear or radiation accidents.
Principle 9	Emergency preparedness and response	Arrangements must be made for emergency preparedness and response for nuclear or radiation incidents.
Principle 10	Protective actions to reduce existing or unregulated radiation risks	Protective actions to reduce existing or unregulated radiation risks must be justified and optimized.

2.2.3 Safety Requirements

An integrated and consistent set of Safety Requirements establishes the requirements that must be met to ensure the protection of people and the environment, both now and in the future. The requirements are governed by the objective and principles of the Safety

Fundamentals. If the requirements are not met, measures must be taken to reach or restore the required level of safety. The format and style of the requirements facilitate their use for the establishment, in a harmonized manner, of a national regulatory framework. Requirements, including numbered 'overarching' requirements, are expressed as 'shall' statements. Many requirements are not addressed to a specific party, the implication being that the appropriate parties are responsible for fulfilling them.

The development status of the general and specific safety requirements and the documents they supersede is summarized in Tables 4 and 5, respectively.

TABLE 4. GENERAL SAFETY REQUIREMENTS AND THE DOCUMENTS THEY SUPERSEDE

General Safety Requirements	**Superseded Documents**
GSR Part 1 (Rev. 1): Government Legal and Regulatory Framework for Safety (2016).	GSR Part 1: Government Legal and Regulatory Framework for Safety (2010); GS-R-1: Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety (2000).
GSR Part 2: Leadership and Management for Safety (2016).	GS-R-3: The Management System for Facilities and Activities (2006).
GSR Part 3: Radiation Protection and the Safety of Radiation Sources (2014).	GSR Part 3 (Interim): Radiation Protection and the Safety of Radiation Sources (2011); SS115: International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (1996).
GSR Part 4 (Rev. 1): Safety Assessment for Facilities and Activities (2016).	GSR Part 4: Safety Assessment for Facilities and Activities, (2009); NS-G-1.2: Safety Assessment and Verification for Nuclear Power Plants (2001).
GSR Part 5: Predisposal Management of Radioactive Waste (2009).	WS-R-2: Predisposal Management of Nuclear Fuel Including Decommissioning (2000).
GSR Part 6: Decommissioning and Termination of Activities (2014).	WS-R-5: Decommissioning of Facilities Using Radioactive Material (2006).
GSR Part 7: Emergency Preparedness and Response, (2015).	GS-R-2: Preparedness and Response for a Nuclear or Radiological Emergency (2002).

TABLE 5. SPECIFIC SAFETY REQUIREMENTS AND THE DOCUMENTS THEY SUPERSEDE

Specific Safety Requirements	**Superseded Documents**
SSR-1: Site Evaluation for Nuclear Installations (In preparation)	NS-R-3: Site Evaluation for Nuclear Installations (2003)
SSR-2/1 (Rev. 1): Safety of Nuclear Power Plants: Design and Construction (2012)	NS-R-1: Safety of Nuclear Power Plants: Design (2000)
SSR-2/2 (Rev. 1): Safety of Nuclear Power Plants: Commissioning and Operation (2011)	NS-R-2: Safety of Nuclear Power Plants: Operation (2000)

SSR-3: Safety of Research Reactors (2016)	NS-R-4: Safety of Research Reactors (2005)
SSR-4: Safety of Nuclear Fuel Cycle Facilities (In preparation)	NS-R-5 (Rev. 1): Safety of Nuclear Fuel Cycle Facilities (2014) NS-R-5: Safety of Nuclear Fuel Cycle Facilities (2008)
SSR-5: Safety of Radioactive Waste Disposal Facilities (2011)	WS-R-1: Near Surface Disposal of Radioactive Waste (1999) WS-R-4: Geological Disposal of Radioactive Waste (2006)
SSR-6: Safe Transport of Radioactive Material (2012)	TS-R-1: Regulations for the Safe Transport of Radioactive Material, 2009 Edition

2.2.4 Safety Guides

Safety Guides provide recommendations and guidance on how to comply with the Safety Requirements; they also present international good practices to help users achieve high levels of safety. The recommendations provided in Safety Guides are expressed as 'should' statements.

In establishing and maintaining the list of safety guides, the following criteria were adopted:

- The overall picture is a matrix, which allows for Safety Guides that implement several requirements;
- To the extent practicable, Safety Guides in the general safety area cover all installations and activities. The objective was to have one safety guide for each relevant issue where possible;
- For Safety Guides in a specific area, the preferred approach is to integrate the necessary guidance material on all topics and for each type of installation. This was not possible for NPPs and research reactors due to the large number of topics that need to be covered.

2.2.5 IAEA safety standards for the governmental, legal and regulatory framework for safety

Safety standards related to organization and management of regulatory bodies, and operational functions are covered extensively in Sections 3 and 4 of this publication respectively. They provide in-depth information with extensive references to the IAEA Safety Standards Series.

2.2.5.1 Governmental, Legal and Regulatory Framework for Safety (IAEA Safety Standards Series No. GSR Part 1 (Rev. 1))

IAEA Safety Standards Series No. GSR Part 1 (Rev. 1) on Governmental, Legal and Regulatory Framework for Safety (2010) [5] includes 36 requirements, all of which are applicable to NPPs, divided into three major groups: responsibilities and functions of the government; the global safety regime; and responsibilities and functions of the regulatory body. GSR Part 1 (Rev. 1) addresses Fundamental Safety Principle 2.

Requirements on responsibilities and functions of the government

GSR Part 1 (Rev. 1) [5] includes 13 requirements on the responsibilities and functions of the government as shown in Table 6.

TABLE 6. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

Requirement 1	National policy and strategy for safety	The government shall establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals.
Requirement 2	Establishment of a framework for safety	The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated.
Requirement 3	Establishment of a regulatory body	The government, through the legal system, shall establish and maintain a regulatory body, and shall confer on it the legal authority and provide it with the competence and the resources necessary to fulfil its statutory obligation for the regulatory control of facilities and activities.
Requirement 4	Independence of the regulatory body	The government shall ensure that the regulatory body is effectively independent in its safety related decision making and that it has functional separation from entities having responsibilities or interests that could unduly influence its decision making.
Requirement 5	Prime responsibility for safety	The government shall expressly assign the prime responsibility for safety to the person or organization responsible for a facility or an activity, and shall confer on the regulatory body the authority to require such persons or organizations to comply with stipulated regulatory requirements, as well as to demonstrate such compliance.
Requirement 6	Compliance with regulations and responsibility for safety	The government shall stipulate that compliance with regulations and requirements established or adopted by the regulatory body does not relieve the person or organization responsible for a facility or an activity of its prime responsibility for safety.
Requirement 7	Coordination of different authorities with responsibilities for safety within the regulatory framework for safety	Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties.
Requirement 8	Emergency preparedness and response	The government shall make provision for emergency preparedness to enable a timely and effective response in a nuclear or radiological emergency.
Requirement 9	System for protective actions to reduce existing or unregulated radiation risks	The government shall establish an effective system for protective actions to reduce undue radiation risks associated with unregulated sources (of natural or artificial origin) and contamination from past activities or events, consistent with the principles of justification and optimization.
Requirement 10	Provision for the decommissioning of	The government shall make provision for the safe decommissioning of facilities, the safe management and disposal of radioactive waste

	facilities and the management of radioactive waste and of spent fuel	arising from facilities and activities, and the safe management of spent fuel.
Requirement 11	Competence for safety	The government shall make provision for building and maintaining the competence of all parties having responsibilities in relation to the safety of facilities and activities.
Requirement 12	Interfaces of safety with nuclear security and with the State system of accounting for, and control of, nuclear material	The government shall ensure that, within the governmental and legal framework, adequate infrastructural arrangements are established for interfaces of safety with arrangements for nuclear security and with the State system of accounting for, and control of, nuclear material".
Requirement 13	Provision of technical services	The government shall make provision, where necessary, for technical services in relation to safety, such as services for personal dosimetry, environmental monitoring and the calibration of equipment.

When developing requirement 2, GSR Part 1 (Rev. 1) [5] notes that the government must take into account the Fundamental Safety Objective, the binding international conventions, the scope of the regulatory framework for safety, the provision for human and financial resources, the framework for research and development, the social and economic developments and the promotion of leadership and management for safety, including safety culture.

Section 2.4 provides in-depth information on building a national nuclear safety infrastructure with extensive references to the IAEA safety standards.

Requirements for the Global Safety Regime

International cooperation in relation to safety, including the safety of nuclear installations, radiation safety, the safety of radioactive waste management and safety in the transport of radioactive material, has contributed to the development of a global safety regime. The organizations and persons involved in the utilization of nuclear energy and radiation sources for peaceful purposes are interdependent in that the performance of one may have implications for all, and a serious nuclear accident would be of major significance around the world. Recognition of this mutual dependence has led to a number of international arrangements that are intended to enhance safety in all States. The requirements for the Global Safety Regime are listed in Table 7.

TABLE 7. THE GLOBAL SAFETY REGIME

Requirement 14	International obligations and arrangements for international cooperation and assistance	The government shall fulfil its respective international obligations, participate in the relevant international arrangements, including international peer reviews, and promote international cooperation and assistance to enhance safety globally.
Requirement 15	Sharing of operating experience and regulatory experience	The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities.
Requirement 15	Organizational structure of the regulatory body and allocation of resources	The regulatory body shall structure its organization and manage its resources so as to discharge its responsibilities and perform its functions effectively; this shall be accomplished in a manner commensurate with the radiation risks associated with facilities and activities.

Requirements for the responsibilities and functions of the regulatory body

As Table 8 shows, GSR Part 1 (Rev. 1) [5] includes 21 requirements on the responsibilities and functions of the regulatory body, covering three basic subjects:

— The organization and management of the regulatory body;
— The responsibilities of the regulatory body;
— The functions of the regulatory body.

TABLE 8. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

Requirement 16	Organizational structure of the regulatory body and allocation of resources	The regulatory body shall structure its organization and manage its resources so as to discharge its responsibilities and perform its functions effectively; this shall be accomplished in a manner commensurate with the radiation risks associated with facilities and activities.
Requirement 17	Effective independence in the performance of regulatory functions	The regulatory body shall perform its functions in a manner that does not compromise its effective independence.
Requirement 18	Staffing and competence of the regulatory body	The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities.
Requirement 19	The management system of the regulatory body	The regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement.

Requirement 20	Liaison with advisory bodies and support organizations	The regulatory body shall obtain technical or other expert professional advice or services as necessary in support of its regulatory functions, but this shall not relieve the regulatory body of its assigned responsibilities.
Requirement 21	Liaison between the regulatory body and authorized parties	The regulatory body shall establish formal and informal mechanisms of communication with authorized parties on all safety related issues, conducting a professional and constructive liaison.
Requirement 22	Stability and consistency of regulatory control	The regulatory body shall ensure that regulatory control is stable and consistent.
Requirement 23	Authorization of facilities and activities by the regulatory body.	Authorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all those facilities and activities that are not either explicitly exempted or approved by means of a notification process.
Requirement 24	Demonstration of safety for the authorization of facilities and activities	The applicant shall be required to submit an adequate demonstration of safety in support of an application for the authorization of a facility or an activity.
Requirement 25	Review and assessment of information relevant to safety	The regulatory body shall review and assess relevant information—whether submitted by the authorized party or the vendor, compiled by the regulatory body, or obtained from elsewhere—to determine whether facilities and activities comply with regulatory requirements and the conditions specified in the authorization. This review and assessment of information shall be performed prior to authorization and again over the lifetime of the facility or the duration of the activity, as specified in regulations promulgated by the regulatory body or in the authorization.
Requirement 26	Graded approach to review and assessment of a facility or an activity	Review and assessment of a facility or an activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.
Requirement 27	Inspection of facilities and activities	The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization.
Requirement 28	Types of inspection of facilities and activities	Inspections of facilities and activities shall include programmed inspections and reactive inspections; both announced and unannounced.
Requirement 29	Graded approach to inspections of facilities and activities	Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.
Requirement 30	Establishment of an enforcement policy	The regulatory body shall establish and implement an enforcement policy within the legal framework for responding to non-compliance by authorized parties with regulatory requirements or with any conditions specified in the authorization.
Requirement 31	Requiring of corrective action by authorized parties	In the event that risks are identified, including risks unforeseen in the authorization process, the regulatory body shall require corrective actions to be taken by authorized parties.

Requirement 32	Regulations and guides	The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based.
Requirement 33	Review of regulations and guides	Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical standards and of relevant experience gained.
Requirement 34	Promotion of regulations and guides to interested parties	The regulatory body shall notify interested parties and the public of the principles and associated criteria for safety established in its regulations and guides, and shall make its regulations and guides available.
Requirement 35	Safety related records	The regulatory body shall make provision for establishing, maintaining and retrieving adequate records relating to the safety of facilities and activities.
Requirement 36	Communication and consultation with interested parties	The regulatory body shall promote the establishment of appropriate means of informing and consulting interested parties and the public about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body.

2.2.5.2 Safety Guides for regulatory bodies

There are seven Safety Guides specifically for the regulatory body:

- IAEA Safety Standards Series No. GS-G-1.1 on Organization and Staffing of the Regulatory Body for Nuclear Facilities (2002) [22];
- IAEA Safety Standards Series No. GS-G-1.2 on Review and Assessment of Nuclear Facilities by the Regulatory Body (2002) [23];
- IAEA Safety Standards Series No. GS-G-1.3 on Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body (2002) [24];
- IAEA Safety Standards Series No. GS-G-1.4 on Documentation for Use in Regulating Nuclear Facilities (2002) [25];
- IAEA Safety Standards Series No. SSG-12 on Licensing Process for Nuclear Installations (2010) [26];
- IAEA Safety Standards Series No. SSG-16 on Establishing the Safety Infrastructure for a Nuclear Power Programme (2012) [27];
- IAEA Safety Standards Series No. GSG-4 on Use of External Experts by the Regulatory Body (2013) [28].

The first four Safety Guides were issued prior to the publication of GSR Part 1 (Rev. 1) [5], but are broadly consistent with its requirements.

2.2.6 IAEA safety standards for NPP operators[35]

Many of the IAEA safety standards are directed towards the organizations using nuclear technology. The main Safety Requirements and Safety Guides applicable to NPPs are discussed here[36].

2.2.6.1 GSR Part 2 on Leadership and Management for Safety

Principle 3 of the Fundamental Safety Principles [SF-1] states that effective leadership and management for safety must be established, sustained and continuously improved. IAEA Safety Standards Series No. GSR Part 2 on Leadership and Management for Safety [REF MISSING] provides guidance on how licensees can establish, implement, assess and continuously improve an integrated management system for safety.

Leadership and management are two different but complementary concepts: leadership is a relation by which a leader improves the conduct of the members of a team in properly completing an activity; management is a function through which an activity is properly completed in accordance with the established plans and resources. Fundamental Safety Principle 3 states that there must be:

- "Individual and collective commitment to safety on the part of the leadership, the management and personnel at all levels;
- Accountability of organizations and of individuals at all levels for safety;
- Measures to encourage a questioning and learning attitude and to discourage complacency with regard to safety" [21].

Other elements in leadership and management for safety include: the recognition of the entire range of interactions of individuals at all levels with technology and with organizations; the conduct of safety assessments for each one of the phases in the life of the installation and in a continuing and periodic manner during operation; and the conduct of safety reassessments to consider the application of new standards, scientific and technological developments and ageing. The feedback of operating experience is also a substantial part of leadership and management. Most of those attributes are included in the safety culture concept.

GSR Part 2 includes overarching requirements and associated requirements both expressed as "shall" statements. In addition, the publication will also include explanatory text in support of these requirements. GSR Part 2 includes the information contained in *GS-R-3 on The Management System for Facilities and Activities* [29], updated to reflect up-to-date concepts and experiences. GSR Part 2 also includes new chapters on responsibility for safety, responsibility for leadership and culture for safety (as shown in Tables 9 to 11) and it is envisaged that a number of Safety Guides will elaborate on the requirements of GSR Part 2.

TABLE 9. RESPONSIBILITY FOR SAFETY

Requirement 1	Achieving the fundamental safety	The registrant or licensee — starting with the senior management — shall ensure that the fundamental safety objective of protecting people

[35] Please note that some of the IAEA Safety Requirements referred to in this section, such as GSR Part 2, are applicable not only to NPP operators but also to other types of facilities and activities that give rise to radiation risks.

[36] The Safety Standards applicable for nuclear technology in relation to emergency preparedness and response are discussed in Section 4.5.

	objective	and the environment from harmful effects of ionizing radiation is achieved.

TABLE 10. LEADERSHIP FOR SAFETY

Requirement 2	Demonstration of leadership for safety by managers	Managers shall demonstrate leadership for safety and commitment to safety.

TABLE 11. CULTURE FOR SAFETY

Requirement 12	Fostering a culture for safety	Individuals in the organization, from senior managers downwards, shall foster a strong safety culture. The management system and leadership for safety shall be such as to foster and sustain a strong safety culture.

2.2.6.2 GSR Part 4 (Rev. 1) on Safety assessment for facilities and activities

IAEA Safety Standards Series No. GSR Part 4 (Rev. 1) on Safety Assessment for Facilities and Activities [30], published in 2009, applies to both NPP licensees and the regulatory body. GSR Part 4 (Rev. 1) describes the work a licensee must complete to demonstrate that the NPP is safe and meets the requirements of the regulatory body.

The objective of GSR Part 4 (Rev. 1) is:

> "[…] to establish the generally applicable requirements to be fulfilled in safety assessment for facilities and activities, with special attention paid to defence in depth, quantitative analyses and the application of a graded approach to the ranges of facilities and of activities that are addressed. The publication also addresses the independent verification of the safety assessment that needs to be carried out by the originators and users of the safety assessment. This publication is intended to provide a consistent and coherent basis for safety assessment across all facilities and activities, which will facilitate the transfer of good practices between organizations conducting safety assessments and will assist in enhancing the confidence of all interested parties that an adequate level of safety has been achieved for facilities and activities" [30].

GSR Part 4 (Rev. 1) defines safety assessment[37] as a systematic process conducted throughout the lifetime of the installation to ensure that relevant safety requirements are actually met. Each stage of the lifetime of an NPP—siting, design, construction, commissioning, operation and dismantling—should be assessed individually. In addition, there must be continuous oversight of the safety of the NPP. GSR Part 4 (Rev. 1) includes 24 requirements as shown in Tables 12 to 16.

While GSR Part 4 (Rev. 1) is applicable to a wide range of nuclear installations and activities, the resources devoted to safety must be commensurate with the magnitude of the possible radiation risks. This leads to the first requirement in GSR Part 4 (Rev. 1).

[37] Definitions included in IAEA Safety Standards are generally taken from the IAEA Safety Glossary [38].

TABLE 12. GRADED APPROACH

Requirement 1	Graded approach	A graded approach shall be used in determining the scope and level of detail of the safety assessment carried out in a particular State for any particular facility or activity, consistent with the magnitude of the possible risks arising from the facility or activity.

The safety assessment requirements are divided into overall, specific, defence in depth and safety analysis and documentation, independent verification, management, use and maintenance of safety assessment.

TABLE 13. OVERALL REQUIREMENTS

Requirement 2	Scope of the safety assessment	A safety assessment shall be carried out for all applications of technology that give rise to radiation risks; that is, for all types of facilities and activities.
Requirement 3	Responsibility for the safety assessment	The responsibility for carrying out the safety assessment shall rest with the responsible legal person; that is, the person or organization responsible for the facility or activity.
Requirement 4	Purpose of the safety assessment	The primary purposes of the safety assessment shall be to determine whether an adequate level of safety has been achieved for a facility or activity and whether the basic safety objectives and safety criteria established by the designer, the operating organization and the regulatory body, in compliance with the requirements for protection and safety as established in the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, have been fulfilled.

The IAEA Safety Glossary distinguishes safety assessment from safety analysis. It defines safety analysis as:

> "Evaluation of the potential hazards associated with the conduct of an activity" [31].

And adds:

> "Safety analysis is often used interchangeably with safety assessment. However, when the distinction is important, safety analysis should be used for the study of safety, and safety assessment for the evaluation of safety-for example, evaluation of the magnitude of hazards, evaluation of the performance of safety measures and judgment of their adequacy, or quantification of the overall radiological impact or safety of a facility or activity" [31].

The text explaining Requirement 4 stresses the need to include:

> "…a set of safety quantitative analysis for evaluating and assessing challenges to safety in various operational states, anticipated operational occurrences and accident conditions, by means of deterministic and also probabilistic methods. Determination of the scope and level of detail of the safety analysis is an integral part of the safety assessment".

The calculation methods and computer codes to be used in the safety analyses must be verified, tested, benchmarked and accepted by the regulatory body and generally used by accredited users within strict quality assurance.

TABLE 14. SPECIFIC REQUIREMENTS

Requirement 5	Preparation for the safety assessment	The first stage of carrying out the safety assessment shall be to ensure that the necessary resources, information, data, analytical tools as well as safety criteria are identified and are available.
Requirement 6	Assessment of the possible radiation risks	The possible radiation risks associated with the facility or activity shall be identified and assessed.
Requirement 7	Assessment of safety functions	All safety functions associated with a facility or activity shall be specified and assessed.
Requirement 8	Assessment of site characteristics	An assessment of the site characteristics relating to the safety of the facility or activity shall be carried out.
Requirement 9	Assessment of the provisions for radiation protection	It shall be determined in the safety assessment for a facility or activity whether adequate measures are in place to protect people and the environment from harmful effects of ionizing radiation.
Requirement 10	Assessment of engineering aspects	It shall be determined in the safety assessment whether a facility or activity uses, to the extent practicable, SSCs[38] of robust and proven design.
Requirement 11	Assessment of human factors	Human interactions with the facility or activity shall be addressed in the safety assessment, and it shall be determined whether the procedures and safety measures that are provided for all normal operational activities, in particular those that are necessary for implementation of the operational limits and conditions, and those that are required in response to anticipated operational occurrences and accidents, ensure an adequate level of safety.
Requirement 12	Assessment of safety over the lifetime of a facility or activity	The safety assessment shall cover all the stages in the lifetime of a facility or activity in which there are possible radiation risks.

Requirement 7 introduces the concept of safety function. In the case of a NPP, there are three main safety functions:

— *Reactivity control*. Capability to safely shut down the reactor and maintain it in a safe shutdown condition under all operational states and accident conditions;
— *Cooling the core*. Capability to remove heat from the reactor core under all operational states and accident conditions;
— *Confine radioactive material*. Capability to reduce the potential for the release of radioactive material and to ensure that any releases are within prescribed limits under all operational states and within acceptable limits during and after design basis accidents.

[38] SSCs stands for systems, structures and components

Requirement 11 refers to the assessment of human factors. The Three Mile Island accident demonstrated the importance of understanding and optimizing the human-machine interface. The Chernobyl accident confirmed the importance of the human-machine interface and added the concept of safety culture. The Fukushima Daiichi accident raised the relevance of human decisions before the accident and human training to operate the NPP under stress. These accidents, as well as many other observations in NPP operation, have clearly indicated that the assessment of human reliability is as important as any other technical safety issue. The human assessment must consider the individuals and their training and competence, NPP management and its commitment to safety, as well as the organizational environment in the operating organization.

TABLE 15. DEFENCE IN DEPTH AND SAFETY ANALYSIS

Requirement 13	Assessment of defence in depth	It shall be determined in the assessment of defence in depth whether adequate provisions have been made at each of the levels of defence in depth.
Requirement 14	Scope of the safety analysis	The performance of a facility or activity in all operational states and, as necessary, in the post-operational phase shall be assessed in the safety analysis.
Requirement 15	Deterministic and probabilistic approaches	Both deterministic and probabilistic approaches shall be included in the safety analysis.
Requirement 16	Criteria for judging safety	Criteria for judging safety shall be defined for the safety analysis.
Requirement 17	Uncertainty and sensitivity analysis	Uncertainty and sensitivity analysis shall be performed and taken into account in the results of the safety analysis and the conclusions drawn from it.
Requirement 18	Use of computer codes	Any calculational methods and computer codes used in the safety analysis shall undergo verification and validation.
Requirement 19	Use of operating experience data	Data on operational safety performance shall be collected and assessed.

The concept of defence in depth constitutes the basis of the deterministic approach to safety. INSAG-10 [32] defines five levels of protection: prevention of abnormal operation and failures; control of abnormal operation and detection of failure; control of accidents within the design basis; control of severe NPP conditions; and mitigation of radiological consequences of significant releases of radioactive material.

The IAEA Safety Glossary has the following definition:

> "Defence in depth: A hierarchical deployment of different levels of diverse equipment and procedures to prevent the escalation of anticipated operational occurrences and to maintain the effectiveness of physical barriers placed between radiation source or radioactive material and workers, members of the public or the environment, in operational states and, for some barriers, in accident conditions" [31].

The scope of the safety analysis defined in Requirement 14 has changed considerably over time and from the lessons learned from accidents and incidents. The analysis must consider all anticipated operational occurrences and accident conditions that challenge the safety of the NPP. They include internal and external events and processes with the potentiality of impairing the activation or operation of the foreseen safety functions. The internal events include the many possible combinations of equipment failures and human errors. External events include extreme natural events and combinations of those, as in the Fukushima Daiichi accident, as well as human induced events associated with nearby activities such as nearby transport of explosive or poisonous materials or falling flying objects.

Any quantitative analysis of complex physical phenomena requires developing physical and computational models. These models may not be a perfect representation of reality and will include uncertainties. Requirements 17, 18 and 19

TABLE 16. DOCUMENTATION, INDEPENDENT VERIFICATION, MANAGEMENT, USE AND MAINTENANCE OF SAFETY ASSESSMENT

Requirement 20	Documentation of the safety assessment	The results and findings of the safety assessment shall be documented.
Requirement 21	Independent verification	The operating organization shall carry out an independent verification of the safety assessment before it is used by the operating organization or submitted to the regulatory body.
Requirement 22	Management of the safety assessment	The processes by which the safety assessment is produced shall be planned, organized, applied, audited and reviewed.
Requirement 23	Use of the safety assessment	The results of the safety assessment shall be used to specify the programme for maintenance, surveillance and inspection; to specify the procedures to be put in place for all operational activities significant to safety and for responding to anticipated operational occurrences and accidents; to specify the necessary competences for the staff involved in the facility or activity and to make decisions in an integrated, risk informed approach.
Requirement 24	Maintenance of the safety assessment	The safety assessment shall be periodically reviewed and updated.

2.2.6.3 SSR 2/1 (Rev. 1) on Safety of Nuclear Power Plants: Design

IAEA Safety Standards Series No. SSR-2/1 (Rev. 1) on Safety of Nuclear Power Plants: Design [33] takes into account the experience gained in the design of new NPPs, considers severe accidents scenarios and strategies for their management and integrates safety and security measures to ensure that neither compromises the other.

SSR-2/1 (Rev. 1) states that to achieve highest possible level of safety it is necessary:

— "To prevent accidents with harmful consequences resulting from a loss of control over the reactor core or other sources of radiation, and to mitigate the consequences of any accidents that do occur;

— To ensure that for all accidents taken into account in the design of the installation, any radiological consequences would be below the relevant limits and would be kept ALARA;
— To ensure that the likelihood of occurrence of an accident with serious radiological consequences is extremely low and that the radiological consequences of such an accident would be mitigated to the fullest extent practicable" [33].

The safety assessment of the design must show that the safety of workers, the public and the environment is satisfactory for performance during:

— Normal operation;
— Anticipated operational occurrences;
— Accident conditions.

SSR-2/1 (Rev. 1) includes 82 requirements divided into four major groups: management of safety in design (3 requirements); principal technical requirements (9 requirements); general plant design (30 requirements); and design of specific plant systems (40 requirements). Many of these requirements are based on INSAG-12 [34].

The 70 requirements included in general plant design and design of specific plant systems cover the entire NPP and are beyond the scope of this book.

The three requirements on management of safety design are shown in Table 17.

TABLE 17. MANAGEMENT OF SAFETY IN DESIGN

Requirement 1	Responsibilities in the management of safety in NPP design	An applicant for a licence to construct and/or operate a NPP shall be responsible for ensuring that the design submitted to the regulatory body meets all applicable safety requirements.
Requirement 2	Management system for NPP design	The design organization shall establish and implement a management system for ensuring that all safety requirements established for the design of the NPP are considered and implemented in all phases of the design process and that they are met in the final design.
Requirement 3	Safety of the NPP design throughout the lifetime of the NPP	The operating organization shall establish a formal system for ensuring the continuing safety of the NPP design throughout the lifetime of the NPP.

It is clear that when a NPP is under commissioning and in operation that the operating organization has the prime responsibility for safety. However, there is the need to define the responsibility during design and construction. In many Member States the authorization of the site is the first activity for the regulatory body; in other cases the construction authorization also includes site acceptance. In any case, prior to an application for construction authorization, the responsibility for the design will rest with the design organization, i.e. the vendor.

Once the application has been submitted, the prime responsibility for safety will lie with the applicant, although detailed knowledge of the design will rest with the design organization. The challenge is for the design organization to successfully transfer this detailed knowledge to the operating organization through the Safety Analysis Report, the design manuals and other

design documentation prior to commissioning. This will only be possible if Requirement 2 is met. The operating organization should, at the same time, establish its management system to receive the information. The operating organization will be responsible for establishing a management system for construction and procurement activities.

Once operating, Requirement 3 ensures the safety of the NPP design is maintained during its operating lifetime up to and including decommissioning. In support of this requirement, SSR-2/1 (Rev. 1) [33] refers to INSAG-19 [35]. INSAG suggested that the operating organization could set up a formal process, including the designation of a competent entity, to maintain the integrity of design of the NPP throughout its lifetime.

The nine requirements on principal technical requirements for design are shown in Table 18.

TABLE 18. PRINCIPAL TECHNICAL REQUIREMENTS

Requirement 4	Fundamental safety functions	Fulfilment of the following fundamental safety functions for a NPP shall be ensured for all NPP states: (i) control of reactivity, (ii) removal of heat from the reactor and from the fuel store and (iii) confinement of radioactive material, shielding against radiation and control of planned radioactive releases, as well as limitation of accidental radioactive releases.
Requirement 5	Radiation protection	The design of a NPP shall be such as to ensure that radiation doses to workers at the NPP and to members of the public do not exceed the dose limits, that they are kept as low as reasonably achievable in operational states for the entire lifetime of the NPP, and that they remain below acceptable limits and as low as reasonably achievable in, and following, accident conditions.
Requirement 6	Design for a NPP	The design for a NPP shall ensure that the NPP and items important to safety have the appropriate characteristics to ensure that safety functions can be performed with the necessary reliability, that the NPP can be operated safely within the operational limits and conditions for the full duration of its design life and can be safely decommissioned, and that impacts on the environment are minimized.
Requirement 7	Application of defence in depth	The design of a NPP shall incorporate defence in depth. The levels of defence in depth shall be independent as far as is practicable.
Requirement 8	Interfaces of safety with security and safeguards	Safety measures, nuclear security measures and arrangements for the State system of accounting for, and control of, nuclear material for a NPP shall be designed and implemented in an integrated manner so that they do not compromise one another.
Requirement 9	Proven engineering practices	Items important to safety for a NPP shall be designed in accordance with the relevant national and international codes and standards.
Requirement 10	Safety assessment	Comprehensive deterministic safety assessments and probabilistic safety assessments shall be carried out throughout the design process for a NPP to ensure that all safety requirements on the design of the NPP are met throughout all stages of the lifetime of the NPP, and to confirm that the design, as delivered, meets requirements for manufacture and for construction, and as built, as operated and as modified.

Requirement 11	Provision for construction	Items important to safety for a NPP shall be designed so that they can be manufactured, constructed, assembled, installed and erected in accordance with established processes that ensure the achievement of the design specifications and the required level of safety.
Requirement 12	Features to facilitate radioactive waste management and decommissioning	Special consideration shall be given at the design stage of a NPP to the incorporation of features to facilitate radioactive waste management and the future decommissioning and dismantling of the NPP.

Regarding defence in depth, SSR-2/1 (Rev. 1) states:

> "The design shall be such as to ensure, as far as is practicable, that the first, or at most the second, level of defence is capable of preventing an escalation to accident conditions for all failures or deviations from normal operation that are likely to occur over the operating lifetime of the NPP" [33].

SSR-2/1 (Rev. 1) mentions taking into account relevant experience from the construction of other similar NPPs. SSR-2/1 (Rev. 1) also mentions avoiding materials that could be easily activated, producing energetic radioactive nuclides, which will impair access and complicate the handling of wastes.

2.2.6.4 SSR 2/2 (Rev. 1) on Safety of Nuclear Power Plants: Commissioning and operation

IAEA Safety Standards Series No. SSR-2/2 (Rev. 1) on Safety of Nuclear Power Plants: Commissioning and Operation [36] takes into account the experience gained in the operation of NPPs, and reflects current practices, new concepts and technical developments; reconsiders severe accidents scenarios and strategies for their management; and integrates safety and security measures to ensure that neither compromise the other. SSR-2/2 (Rev. 1) provides requirements for the safe commissioning and operation of a NPP, including maintenance and modifications made throughout the lifetime of the NPP. It also covers the preparation for decommissioning, but not the decommissioning phase itself. SSR-2/2 (Rev. 1) includes 33 requirements, shown in Tables 19 to 23.

TABLE 19. MANAGEMENT AND STRUCTURE OF THE OPERATING ORGANIZATION

Requirement 1	Responsibilities of the operating organization	The operating organization shall have the prime responsibility for safety in the operation of a NPP.
Requirement 2	Management system	The operating organization shall establish, implement, assess and continually improve an integrated management system.
Requirement 3	Structure and functions of the operating organization	The structure of the operating organization and the functions, roles and responsibilities of its personnel shall be established and documented.
Requirement 4	Staffing of the operating organization	The operating organization shall be staffed with competent managers and sufficient qualified personnel for the safe operation of the NPP.

The prime responsibility for safety covers all direct and indirect activities related to the operation of the NPP, i.e. the operating organization itself and the activities of designers, suppliers, manufacturers and constructors and contractors providing continuous work and

during refuelling outages or NPP overhauls. The management system is an integrated set of interrelated or interacting components for establishing policies and objectives and enabling the objectives to be achieved in an efficient and effective manner.

During all operation phases there should be an established liaison between the operating organization and the regulatory body. The operating organization must submit periodic reports to the regulatory body on the safety of the NPP and notify of anomalies or defects which have appeared or have been discovered.

The management system:

> "…shall integrate all the elements of management so that processes and activities that may affect safety are established and conducted coherently with other requirements, including requirements in respect of leadership, protection of health, human performance, protection of the environment, security and quality, and so that safety is not compromised by other requirements or demands" [36].

This management system must also apply to all contractors supplying services to the NPP.

The regulatory body maintains oversight of the operating organization to ensure compliance with safety requirements. To do this efficiently, the operating organization must provide the regulatory body with all necessary assistance to enable it to perform its duties, including unhindered access to the NPP and documentation.

Requirement 3 demands a clear definition of the structure and functions of the operating organization. This includes written allocation of functional responsibilities, lines of authority and internal and external communication links to assure the safe operation of the NPP under normal and abnormal circumstances.

TABLE 20. MANAGEMENT OF OPERATIONAL SAFETY

Requirement 5	Safety policy	The operating organization shall establish and implement operational policies that give safety the highest priority.
Requirement 6	Operational limits and conditions	The operating organization shall ensure that the NPP is operated in accordance with the set of operational limits and conditions.
Requirement 7	Qualification and training of personnel	The operating organization shall ensure that all activities that may affect safety are performed by suitably qualified and competent persons.
Requirement 8	Performance of safety related activities	The operating organization shall ensure that safety related activities are adequately analyzed and controlled to ensure that the risks associated with harmful effects of ionizing radiation are kept as low as reasonably achievable.
Requirement 9	Monitoring and review of safety performance	The operating organization shall establish a system for continuous monitoring and periodic review of the safety of the NPP and of the performance of the operating organization.
Requirement 10	Control of NPP configuration	The operating organization shall establish and implement a system for NPP configuration management to ensure consistency between design requirements, physical configuration and NPP documentation.
Requirement 11	Management of	The operating organization shall establish and implement a programme

	modifications	to manage modifications.
Requirement 12	Periodic safety review	Systematic safety assessments of the NPP, in accordance with the regulatory requirements, shall be performed by the operating organization throughout the NPP's operating lifetime, with due account taken of operating experience and significant new safety related information from all relevant sources.
Requirement 13	Equipment qualification	The operating organization shall ensure that a systematic assessment is carried out to provide reliable confirmation that safety related items are capable of the required performance for all operational states and for accident conditions.
Requirement 14	Ageing management	The operating organization shall ensure that an effective ageing management programme is implemented to ensure that required safety functions of SSCs are fulfilled over the entire operating lifetime of the NPP.
Requirement 15	Records and reports	The operating organization shall establish and maintain a system for the control of records and reports.
Requirement 16	Programme for long term operation	Where applicable, the operating organization shall establish and implement a comprehensive programme for ensuring the long term safe operation of the NPP beyond a time-frame established in the licence conditions, design limits, safety standards and/or regulations.

Requirement 5 insists on the predominance of safety in NPP operation overriding the demands of production, from which maintaining a strong and sustainable safety culture is an essential part as described in INSAG-4 [37] and INSAG-15 [38]. Management must ensure that this safety predominance is efficiently transmitted to the entire organization, as well as to external support organizations.

The operating limits and conditions discussed in Requirement 6 must include: safety limits; limiting settings for safety systems; limits and conditions for normal operation; surveillance and testing requirements; and action statements for deviations from normal operation.

TABLE 21. OPERATIONAL SAFETY PROGRAMMES AND COMMISSIONING

Requirement 17	Consideration of objectives of nuclear security in safety programmes	The operating organization shall ensure that the implementation of safety requirements and security requirements satisfies both safety objectives and security objectives.
Requirement 18	Emergency preparedness	The operating organization shall prepare an emergency plan for preparedness for, and response to, a nuclear or radiological emergency.
Requirement 19	Accident management programme	The operating organization shall establish an accident management programme for the management of beyond design basis accidents.
Requirement 20	Radiation protection	The operating organization shall establish and implement a radiation protection programme.
Requirement 21	Management of radioactive waste	The operating organization shall establish and implement a programme for the management of radioactive waste.

Requirement 22	Fire safety	The operating organization shall make arrangements for ensuring fire safety.
Requirement 23	Non-radiation-related safety	The operating organization shall establish and implement a programme to ensure that safety related risks associated with non-radiation-related hazards to personnel involved in activities at the NPP are kept as low as reasonably achievable.
Requirement 24	Feedback of operating experience	The operating organization shall establish an operating experience programme to learn from events at the NPP and events in the nuclear industry and other industries worldwide.
Requirement 25	Commissioning programme	The operating organization shall ensure that a commissioning programme for the NPP is established and implemented.

TABLE 22. NPP OPERATIONS

Requirement 26	Operating procedures	Operating procedures shall be developed that apply comprehensively (for the reactor and its associated facilities) for normal operation, anticipated operational occurrences and accident conditions, in accordance with the policy of the operating organization and the requirements of the regulatory body.
Requirement 27	Operation control rooms and control equipment	The operating organization shall ensure that the operation control rooms and control equipment are maintained in a suitable condition.
Requirement 28	Material conditions and housekeeping	The operating organization shall develop and implement programmes to maintain a high standard of material conditions, housekeeping and cleanliness in all working areas.
Requirement 29	Chemistry programme	The operating organization shall establish and implement a chemistry programme to provide the necessary support for chemistry and radiochemistry.
Requirement 30	Core management and fuel handling	The operating organization shall be responsible and shall make arrangements for all activities associated with core management and with on-site fuel handling.

TABLE 23. MAINTENANCE, TESTING, SURVEILLANCE AND INSPECTION AND PREPARATION FOR DECOMMISSIONING

Requirement 31	Maintenance, testing, surveillance and inspection programmes	The operating organization shall ensure that effective programmes for maintenance, testing, surveillance and inspection are established and implemented
Requirement 32	Outage management	The operating organization shall establish and implement arrangements to ensure the effective performance, planning and control of work activities during outages.
Requirement 33	Preparation for decommissioning	The operating organization shall prepare a decommissioning plan and shall maintain it throughout the lifetime of the NPP, unless otherwise approved by the regulatory body, to demonstrate that decommissioning can be accomplished safely and in such a way as to meet the specified end state.

The IAEA Safety Glossary defines maintenance as:

> "The organized activity, both administrative and technical, of keeping SSCs in good operating condition, including both preventive and corrective (or repair) aspects and surveillance testing as periodic testing to verify that SSCs continue to function or are capable of performing their functions when called upon to do so" [31].

Maintenance, surveillance, testing and inspection should be conducted by following established procedures. All data collected should be recorded, stored and analyzed to confirm that systems, structures and components (SSCs) comply with the design and meet all requirements.

During outages, the number of workers at a NPP grows substantially and many activities are undertaken, many by outside contractors. The operating organization must balance the desire to reduce the outage time with the need to ensure all essential work is completed in accordance with approved procedures.

Decommissioning is generally not conducted by the operating organization. However, the operating organization must ensure that a preliminary decommissioning plan is in place. Once commercial operation of the NPP has finished, the operating organization must arrange for the efficient turnover of the NPP to the decommissioning organization. During this time, which may take several years, the operating organization is responsible for the safety of the NPP until the NPP is formally transferred to the decommissioning organization.

2.3 IAEA SAFETY REVIEW AND APPRAISAL SERVICES

Learning Objective 1: To understand the role of IAEA safety review and appraisal services in the Global Nuclear Safety and Security Framework.

Learning Objective 2: To understand the types of safety review and appraisal services available to Member States using or considering the use of nuclear power.

Learning Objective 3: To understand how IRRS, OSART, SALTO, ISCA, EPREV and ETRES missions are organized, conducted and reported, as well as international experience related to IAEA safety review and appraisal services.

Learning Objective 4: To understand the importance of reporting operating experience and implementing feedback.

Under the terms of Article III of its Statute, the IAEA has the mandate:

> "…to establish standards of safety for protection of health and minimization of danger to life and property and to provide for the application of these standards to its own operations as well as to assist operations at the request of a State on activities concerning peaceful nuclear and radiation activities" [20].

To provide for the application of the IAEA safety standards, the IAEA has established a number of safety review and appraisal services. These services are available, at Member State request, to evaluate a Member State's compliance with the IAEA safety standards. The safety review and appraisal services relevant to the regulation of NPPs are listed in Table 24.

TABLE 24. IAEA SAFETY REVIEW AND APPRAISAL SERVICES

DRS	Design Safety Review
EPREV	Emergency Preparedness Review
ETReS	Education and Training Review Service
GRSR	Generic Reactor Safety Review
INSARR	Integrated Safety Assessment of Research Reactors
IPPAS	International Physical Protection Advisory Services
IPSART	International Probabilistic Safety Assessment Review Team
IRRS	Integrated Regulatory Review Service
ISCA	Independent Safety Culture Assessment
ORPAS	Occupational Radiation Protection Appraisal
OSART	Operational Safety Review Team
RAMP	Review of Accident Management Program

SALTO	Safe Long Term Operation
SEED	Site & External Events Design Review Service

This section will discuss in detail IRRS, OSART, SALTO, ISCA, EPREV and ETRES. In addition, this section will discuss the reporting and use of operating experience. Information on all IAEA safety review and appraisal services is available on the IAEA website.

In addition to the safety review and appraisal services, the IAEA also provides assistance for many other issues related to nuclear power development. Again, the IAEA website provides details on these services.

2.3.1 International Regulatory Review Service

2.3.1.1 Background

The International Regulatory Review Service (IRRS) concept was developed within the IAEA, and discussed at the 3rd Review Meeting of the CNS in 2005 and within the Joint Convention. It was proposed and strongly supported by the Board of Governors and the IAEA General Conference in 2006:

> "The General Conference recognizes the importance of an effective regulatory body as an essential element of national nuclear infrastructure, urges Member States to continue their efforts to increase regulatory effectiveness in the field of nuclear, radiation and transport safety and waste management, and consider availing themselves of the Secretariat's new Integrated Regulatory Review Service (IRRS) and notes with satisfaction the increased interest of the Member States in the IRRS".

The IRRS replaced the International Regulatory Review Team (IRRT), the Radiation Safety and Security Infrastructure Appraisal (RaSSIA) and the Transport Safety Appraisal Service (TranSAS), and includes elements from IPPAS and emergency preparedness and response.

Using the IAEA safety standards and other international good practices where appropriate, the IRRS objectively evaluates a Member State's regulatory infrastructure for safety. The process identifies existing gaps and provides recommendations and suggestions for improvement. The IRRS draws directly upon the wide-ranging international experience and expertise of the team members.

Through continuous improvement, the IRRS has matured since 2006 and the IAEA strives to ensure that the IRRS remains an up-to-date and state-of-the art service, ensuring that regulatory effectiveness is always appropriately addressed.

In 2013, the IAEA published *IAEA Services Series No. 23 on Integrated Regulatory Review Service (IRRS) Guidelines for the Preparation and Conduct of IRRS Missions* [39], hereafter referred to as IRRS Guidelines. This publication is a compilation of IAEA staff guidance for host Member States, peer reviewers and IAEA coordinators on the preparation, execution, and reporting of initial and follow-up IRRS missions. Although not official, the IRRS Guidelines create a consistent and systematic methodology for the efficient conduct of the IRRS missions.

“The objective of the IRRS is to enhance nuclear and radiation safety and regulatory effectiveness” [39]. Some of the benefits of the IRRS include:

- “An enhanced global nuclear safety framework through sharing of information between international reviewers and the host Member State, experience feedback and insights on contemporary issues of relevance;
- Greater openness and transparency of the governmental, legal and regulatory system;
- Improved regulatory management systems emphasizing continuous improvement through periodic assessment of safety performance, and encouraging broader consideration and application of lessons learned from international experience and thereby enhancing safety culture;
- More effective use of information and knowledge management networks to share relevant information on regulatory issues among and between Member States having common interests” [39].

“Critical feedback collected as part of the review of regulatory technical and policy issues helps to improve IAEA safety standards and enhance understanding of regulatory issues having a widespread impact on nuclear and radiation safety” [39].

2.3.1.2 IRRS provisions, contributions and promotions to enhance nuclear and radiation safety and regulatory effectiveness

The IRRS facilitates the enhancement of nuclear and radiation safety and regulatory effectiveness by [39]:

- “Providing an opportunity for continuous improvement of the national regulatory body through an integrated process of self-assessment and review;
- Providing the host Member State (regulatory body and governmental authorities) with a review of its regulatory technical and policy issues;
- Providing the host Member State (regulatory body and governmental authorities) with an objective evaluation of its regulatory infrastructure with respect to IAEA safety standards;
- Promoting the sharing of experience and exchange of lessons learned among senior regulators;
- Providing key staff in the host Member State with an opportunity to discuss regulatory practices with IRRS review team members who have experience of other regulatory practices in the same field;
- Providing the host Member State with recommendations and suggestions for improvement;
- Providing other Member States with information regarding good practices identified in the course of the review;
- Providing reviewers from Member States and IAEA staff with opportunities to observe different approaches to regulatory oversight and to broaden knowledge in their own field (mutual learning process);
- Contributing to the harmonization of regulatory approaches among Member States;
- Promoting the application of IAEA Safety Requirements;
- Providing feedback on the use and application IAEA safety standards” [39].

2.3.1.3 The IRRS structure and process

"The IRRS Structure is described in Chapter 4 of the Guidelines and includes both technical and policy issues. The technical issues are subdivided into 12 modules designed to address both generic and Member State specific needs and to accommodate variations in scope and size among regulatory frameworks. The technical issues verify compliance with the IAEA safety standards related to the nuclear safety and security infrastructure and the functions of the regulatory body and regulatory processes. The policy issues review the Member State's nuclear safety and security policies for conformance with the IAEA safety standards and international best practices" [39].

Figure 7 shows the modular form of the IRRS.

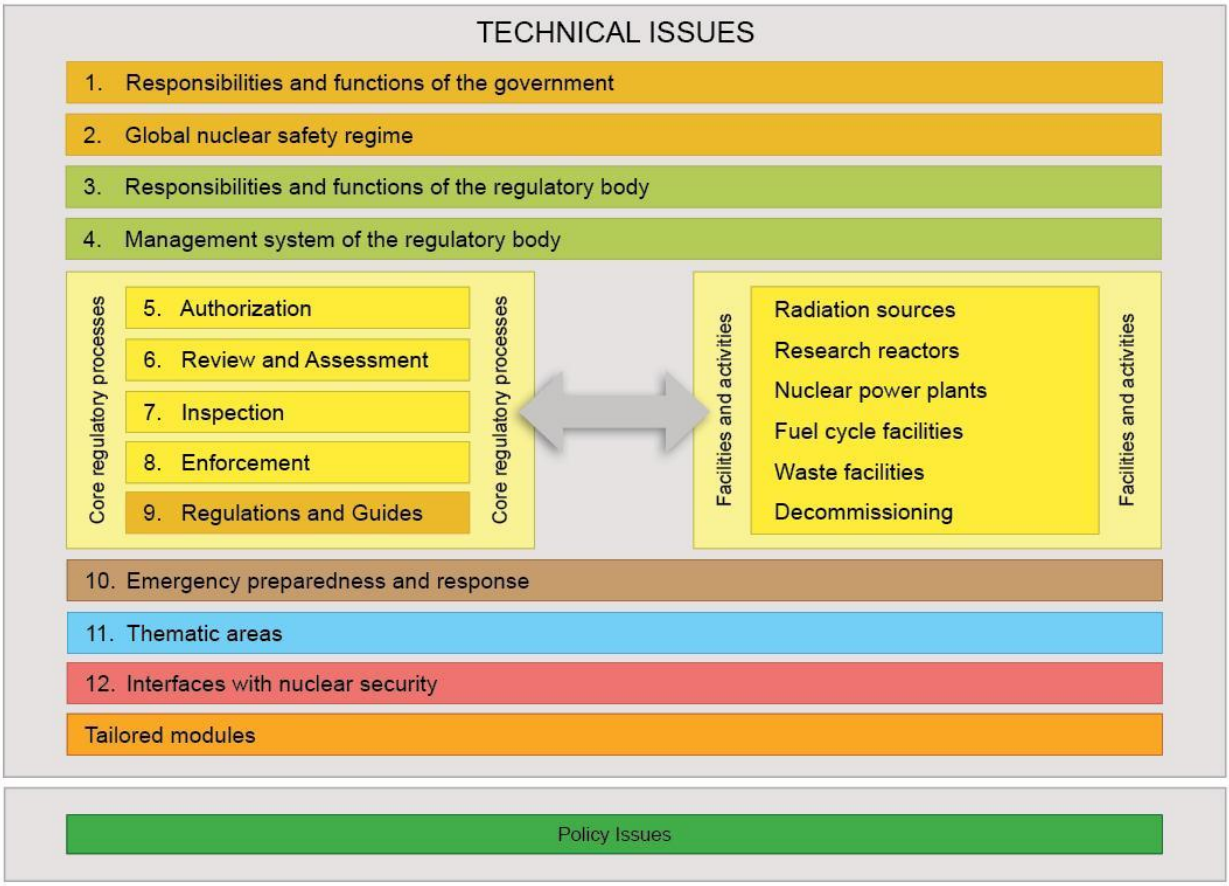


FIG. 7. Modular structure of the IRRS.

"Modules 1 to 4 cover the various elements of the framework for safety needed at the Member State level, regardless of the range and number of installations and activities to be regulated.

Modules 5 to 9 cover the five core regulatory processes and how the regulatory body applies these to its regulated installations and activities.

Module 9 comprises two levels of review:

— The first level is a core module of the IRRS and is related to the process of developing regulations and guides;

— The second level is optional and addresses compliance of regulations and guides with the corresponding IAEA safety standards.

Module 10 deals with the regulatory aspects of the nuclear and radiological emergency preparedness and response in the Member State and with emergency arrangements of a regulatory body to fulfil its role in emergency preparedness and response.

Module 11 includes a number of additional technical areas related to transport of radioactive materials, radiation protection, control of exposure, discharges and clearance, and environmental monitoring.

Module 12 considers the interfaces between safety and security" [39].

There are also two tailored modules. The first is for Member States embarking on a nuclear power programme, while the second addresses the regulatory implications of the Fukushima Daiichi accident. This is a core module for IRRS missions to Member States with NPPs.

2.3.1.4 The basis for the technical and policy issues

The IRRS addresses Fundamental Safety Principle 2. GSR Part 1 (Rev. 1) [5] describes the requirements associated with Fundamental Safety Principle 2 and forms the basis for the IRRS. Other requirements of interest are included in GSR Part 2 [29], and GSR Part 7 [40]. Other IAEA safety requirements are used, as appropriate, to cover the detailed scope of regulatory control for safety of nuclear installations and for radiation, radioactive waste and transport safety. Figure 2 on page 6 of the IRRS Guidelines shows each IRRS module and its corresponding IAEA safety standards.



FIG. 8. The three basic documents on which the IRRS is based.

The policy issues are not part of the IAEA standards. Each Member State's political, social and economic characteristics are unique and these characteristics shape nuclear safety and security policies, resulting in different approaches. The policy issues discussions allow Member States to discuss these different approaches and exchange ideas and best practices.

2.3.1.5 The IRRS process

As shown in Figure 9, the IRRS process is divided into a preparatory phase, the actual IRRS mission, post-mission activities and the follow-up IRRS mission.

The preparatory phase

The activities in the preparatory phase ensure that the IRRS mission is conducted effectively and meets the needs of the host Member State. Typical activities in the "preparatory phase include:

- "Development of an agreement between the IAEA and the host Member State on the scope of the proposed IRRS;
- A preparatory meeting usually conducted in the host Member State;
- Completion of a self-assessment by the host Member State (the IAEA will organize a self-assessment seminar on request);
- Agreement on and preparation for policy issue discussions;
- Completion and submission of the of the Advance Reference Material (ARM) by the host Member State, including the self-assessment and the resulting action plan;
- Identification of information that must remain confidential;
- Selection of the IRRS Review Team;
- Pre-mission preparation by Review Team members and IAEA participating officers;
- Mission agenda and logistics".

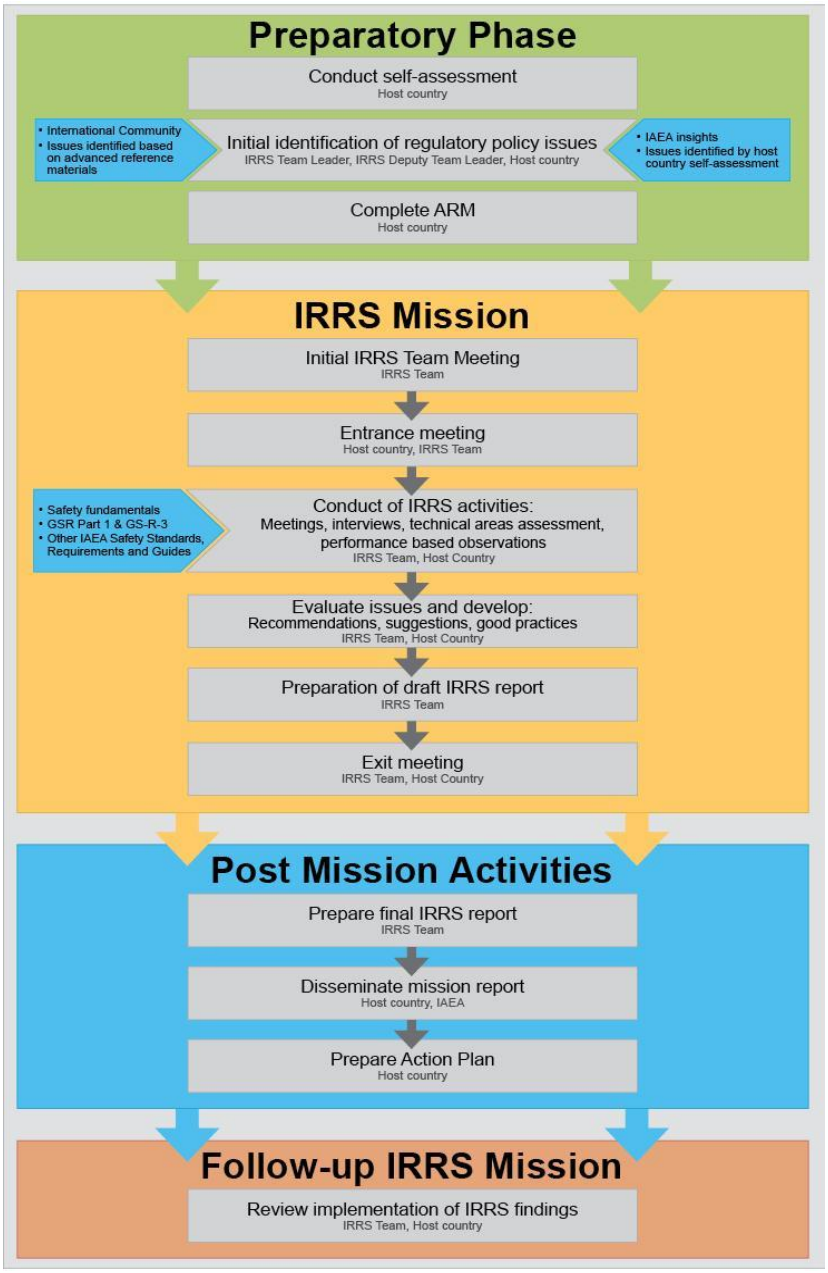


FIG. 9. The phases of the IRRS process.

After preliminary discussions between host Member State officials and IAEA staff, the host Member State must formally request the IAEA to conduct an IRRS Mission. The IAEA Coordinator and a Member State liaison officer then work through the activities of the preparatory phase.

An important and mandatory part of the preparatory phase is the self-assessment. To assist host Member States in completing this self-assessment, the IAEA has developed a self-assessment methodology and associated software, called SARIS[39]. SARIS includes questions for each IRRS module. The host Member State should use the results of the self-assessment to initiate a corrective action plan to address any revealed deficiencies or gaps.

[39] SARIS is provided to the regulatory body with training services upon request.

Another significant requirement is the preparation of the ARM, which must be submitted in English and may take months to assemble. The IRRS Guidelines include a complete list of material that must be submitted.

The size of the IRRS review team will vary depending on the scope of the IRRS. Team members[40] are recruited in accordance with established procedures and include:

- "IRRS Team Leader, who will be recruited from a Member State;
- IRRS Deputy Team Leader, also recruited from a Member State;
- IAEA Coordinator, who will be an IAEA staff member;
- IAEA Deputy Coordinator, also an IAEA staff member;
- IAEA Review Area Facilitators(for large or complex review missions; typically one for nuclear installations and one for radiation, transport and waste safety), drawn from IAEA staff, and;
- IRRS Review Team members recruited from Member States and who may additionally include, where necessary, experts drawn from IAEA staff.
- IAEA Administrative Support as appropriate.
- Observers from other states may participate with the agreement of the host state".

The Team Leader will be a senior regulator from a Member State, since the personal experience and attributes of the Team Leader are core to ensuring the success of a mission. In addition to relevant professional and technical expertise, the person must have attributes such as leadership qualities and a clear vision of the mission. The Deputy Team Leader will also have regulatory experience and the ability to work under pressure and reconcile varying points of view.

The preparatory meeting takes place six to nine months prior to the mission. The Team Leader, Deputy Team Leader (if necessary), IAEA Coordinator and participating IAEA divisions representatives will attend this meeting, which will last two to three days. The preparatory meeting should be held at the regulatory body's headquarters to allow for the participation of senior management and other interested organizations. The IRRS Guidelines provide additional details on the elements of the preparatory meeting, which is usually the last major activity of the preparatory phase.

The IRRS mission

The conduct of the mission, from its initiation through to the exit meeting and delivery of the final report, is described in Chapters 8 and 9 of the IRRS Guidelines.

To start the actual mission, the review team will hold a day-long meeting to ensure there is a common understanding of the context and objectives of the IRRS mission, as well as for the bases for the review. The review team will also begin to exchange opinions with Member State counterparts on analysis of the ARM. A shorter meeting is conducted the following day where the Team Leader presents an outline of the plan, approach and expectations for the mission. It should be noted that the IRRS mission is not an inspection or audit, but a peer review.

[40] No members of the host Member State may be part of the team, but a host Member State liaison officer should be assigned to attend the needs of the team.

The IRRS Guidelines provide a full description of the review methodology. Review team members use their expertise to compare the host Member State's legal infrastructure and the functions, procedures, organization and characteristics of the regulatory body with IAEA Safety Standards and Security Guidance and best international practices.

The review methodology includes interviews, visits to installations and direct observations of regulatory body activities. Interviews allow the review team to gather information not covered by the written material and, where necessary, to seek clarification of written information provided. Site visits, for instance during a scheduled regulatory inspection, allow team members to observe how the regulatory body discharges its responsibilities. Site visits also allow team members to have discussions with licensees and the review team should interview the senior manager at the visited installation to discuss the nature of the relationship with the regulatory body. Direct observation of regulatory work activities provides an opportunity to observe first-hand how the regulatory body's implements its written processes, practices and procedures.

The policy issues discussions are a unique and valuable feature of the IRRS. As part of the process, the host Member State must present written information of its own appraisal on policy issues by the time the mission starts. The Team Leader will schedule meetings on policy issues. These meetings should be open to host Member State counterparts and attended by as many team members as possible.

The review team will meet daily to present observations and propose findings; discussions are maintained to agree on the findings, identify gaps to be covered and solve any discrepancy that may exist. Once all of the information has been collected, the review team will sort the findings into one of the three categories shown in Table 25.

TABLE 25. CATEGORIES OF FINDINGS FOR IRRS MISSIONS

Recommendations	Findings where aspects relative to the IAEA Safety Requirements are missing, incomplete, or inadequately implemented.
Suggestions	Findings where the reviewers identify opportunities for improvement not directly related to inadequate conformance with IAEA Safety Requirements, but which should be shared with the host Member State.
Good practices	Findings where the reviewers recognize an outstanding organization, arrangement, programme or performance superior to those generally observed elsewhere.

At the conclusion of the Mission, the review team will then produce a preliminary report, highlighting the work and findings of the mission. This preliminary report will form the basis for the exit meeting. The host Member State is invited to make written comments on the factual correctness of the preliminary report, which the review team will take into account when drafting the final report.

Post mission activities

Post mission activities include the preparation and issue of the final report, under the responsibility of the IRRS Team Leader. The final report is submitted to the Member State concerned, IRRS team members and designated IAEA staff. Further distribution of the final report is the responsibility of the host Member State and the IAEA encourages host Member

States to make final reports available to the public. The IAEA uses the final reports internally to improve the IRRS process.

The host Member State is expected to initiate an action plan to address the recommendations and suggestions in the final report. Nevertheless the decision to define and implement a corrective action plan lies entirely with the host Member State.

The follow-up mission

The IAEA recommends that the host Member State request a follow-up mission two to four years after the IRRS mission. The purposes of the follow-up mission are to:

- Review the progress in implementing improvement resulting from the IRRS mission recommendations and suggestions;
- Where appropriate, to address areas of significant change since the IRRS mission including new topics requested.

The follow-up mission follows the same process than the first mission. For continuity, where possible the follow-up team should include members from the IRRS mission. If the request includes new areas, additional members with appropriate knowledge will also be recruited. The host Member State must update the ARM to include the status of findings from the IRRS mission.

The follow-up mission will focus on the findings from the IRRS mission, updating the status of recommendation and suggestions to one of:

- Recommendation/suggestion remains open;
- Recommendation/suggestion closed, or,
- Recommendation/suggestion closed on the basis of progress made and confidence in effective completion.

2.3.1.6 International IRRS experience

Since its inception in 2006 up to December 2014 more than 50 IRRS Mission have been conducted worldwide; many were full-scope mission, while some had a reduced scope. In some cases, follow-up missions have also been completed. Figure 10 shows the IRRS missions conducted between 2006 and 2014. The first IRRS mission was conducted in Romania in January 2006 as a follow-up to 2002 IRRT and 2004 RaSSIA missions, demonstrating the usefulness of the integrated IRRS approach.

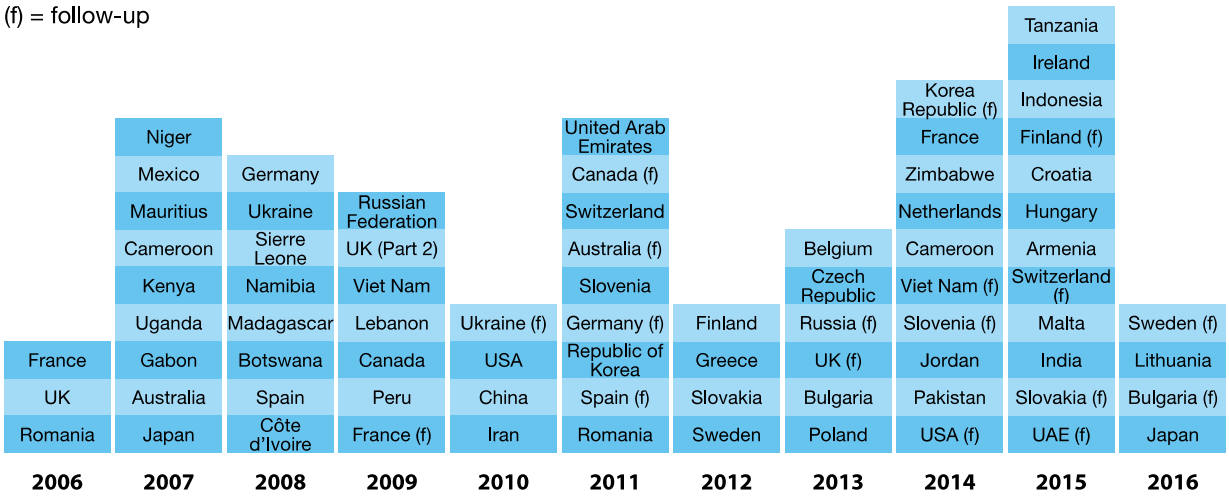


FIG. 10. IRRS missions conducted since its inception.

The second IRRS, limited in scope to the role of the government and the regulatory body related to new NPP construction, was requested by the UK. In 2009 the UK requested a more complete IRRS mission. A third mission was conducted in 2013. The UK is so far the only Member State where three IRRS missions have been conducted.

Most other Member States with large nuclear power programs, including Belgium, Canada, China, Czech Republic, France, Germany, Japan, Republic of Korea, Netherlands, Pakistan, Russian Federation, Spain, Sweden and USA have requested IRRS missions. In addition, follow-up missions have taken place in Canada, France, Germany, Republic of Korea, Russian Federation, Slovenia, Spain, Vietnam and USA.

Initial full-scope IRRS missions last two weeks and require more than 20 experts, while the follow-up missions are limited to one week and around 10 experts. In addition, the Spanish regulatory body reported that the preparation of the ARM started two years before it was submitted to the IAEA.

In all cases the IRRS mission identified recommendations, suggestions and good practices for the Member State. In general, the follow-up missions declared most recommendations closed or in an advanced stage to be closed, many suggestions implemented and good practices were maintained.

The nature of the IRRS makes it difficult to use IRRS mission results to make comparisons between Member States. The situation in each Member State is unique and the purpose of the IRRS is to determine the extent to which a Member State is meeting the requirements of the IAEA Safety Standards. Comparisons between IRRS reports should not be attempted and the number of recommendations or good practices is not an appropriate measure of the status of a regulatory body.

An international workshop was held from 22 to 23 March 2007 in France to share experiences from the 2006 missions, especially the mission to France, and to provide information to Member States interested in hosting an IRRS Mission. The workshop had 83 attendees from 35 Member States. Several areas for improvements were identified concerning the preparation and development of IRRS missions, including the importance of the agenda, the self-assessment, the need to create a net of experts and the openness and transparency of the regulatory body.

Another international workshop, held in Spain from 3 to 5 November 2008, was attended by 150 participants from 14 Member States. The first day was devoted to senior officials from regulatory bodies explaining the experience and results of the IRRS mission conducted in their countries. On the second day, IAEA staff and Member State representatives described their preparation activities. The presentations were followed by open debates on how to improve the efficiency of IRRS missions. The third day was dedicated to the analysis of the IRRS mission conducted in Spain early in 2008. The workshop concluded that the IRRS mission was useful in helping to achieve the harmonization of nuclear safety and security requirements and practices.

2.3.2 Operational Safety Review Team

The OSART service started in 1982 to conduct in-depth reviews of operational safety performance at a NPP and since then, more than 175 OSART missions have been completed. In an OSART Mission, a team of experts reviews the factors affecting the management of safety and the performance of personnel at the NPP.

In 2005, the IAEA published OSART Guidelines [41], which include the methodology for the OSART missions, practical hints for reviewers concerning observations, ten specific guidelines covering the areas to be reviewed and a list of references.

OSART covers the following ten operational subjects as standard review areas:

- Management;
- Organization and administration;
- Training and qualification;
- Operations;
- Maintenance;
- Technical support;
- Operating experience;
- Radiation protection;
- Chemistry;
- Emergency planning and preparedness;
- Severe accident management.

Optional review areas include:

- Long term operation;
- Probabilistic safety analysis (PSA) applications;
- Transition from operation to decommissioning;
- Safety culture.

The OSART mission can be full scope or limited to a given set of areas.

As shown in Figure 11, an OSART includes three steps: a preparatory meeting and seminar; the mission; and the follow-up visit. The OSART process starts with a formal request from the Member State, generally with the approval or at the request of the NPP owner/operator, to conduct a mission at a specific NPP. The IAEA will then assign senior IAEA officers as Team Leader and Deputy Team Leader, while the NPP assigns a contact person.

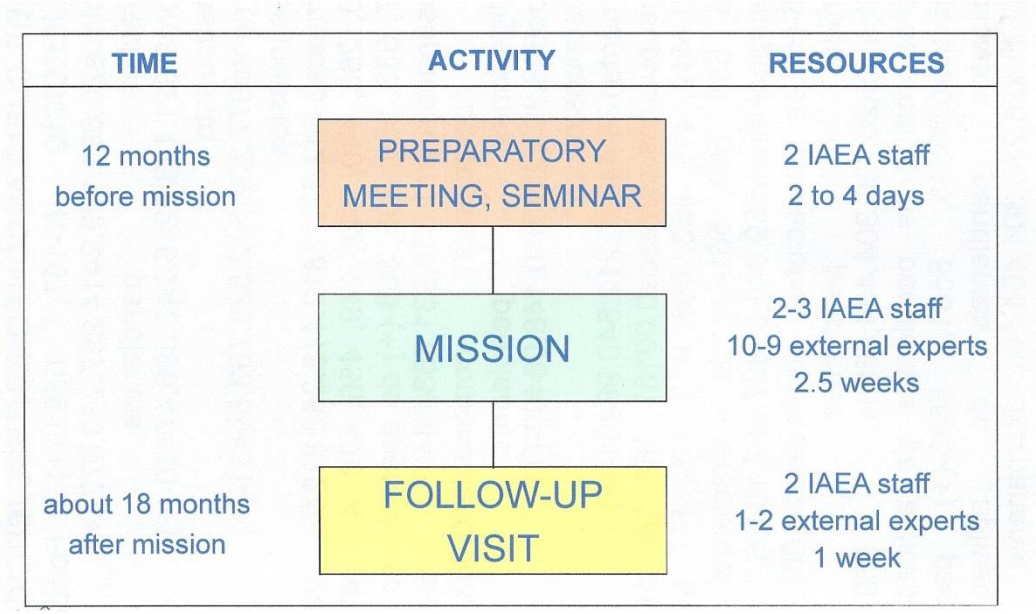


FIG. 11. The timing, activity and resources of a typical OSART mission.

2.3.2.1 Preparation

A preparatory meeting is held at the NPP about one year prior to the mission to discuss:

— Features of the OSART programme;
— Preparation by the NPP for the review;
— Preparation of a self-assessment advance information package (AIP);
— Designation of a host NPP peer (HPP) and NPP counterparts;
— Logistical support;
— Arrangements for reporting mission results;
— Any intended involvement of the media.

A seminar for applying the OSART methodology and field inspection techniques for the NPP self-assessment is also conducted at this time.

An OSART team usually consists of one experienced NPP expert for each area under review, except for the operations area, where two experts are employed. Experts are recruited on the basis of their technical skills in the area they will review. Typically, more than two thirds of the team consists of senior managers from NPPs; the remaining team members are IAEA staff. The review team includes up to three observers from Member States whose nuclear programmes are developing or where future OSART missions are planned.

To enable the review team to perform effectively and efficiently while on-site, the NPP prepares an Advance Information Package, which is similar to the ARM required for an IRRS. Team members will review this package prior to the mission so that they can familiarize themselves with the NPP organization, administration, layout, performance and general design.

The NPP will designate a counterpart—a senior NPP member responsible for assisting the OSART corresponding team expert and providing coordination with specialist staff—for each review area. In addition, the NPP will assign a HPP, also a senior NPP member with

knowledge of the NPP programmes, practices and staff. The HPP fully participates in review team meetings and activities during the mission and advises the review team as necessary.

2.3.2.2 Review mission

Since OSART mission team members will require access to the NPP, the first day of the mission is uses for access formalities. Following this, the process is similar to the IRRS process, with an entrance meeting, followed by experts reviewing written information, interviewing key staff, observing activities and discussions with other experts.

The review team meets each day from two to three hours to review and share the results of their activities and, through discussion, to develop a team consensus on emerging issues. Ultimately, the review team's recommendations, suggestions and good practices are approved by consensus. The last days of the mission are reserved for rechecking any open topics, and for completing the technical notes and discussing them in their entirety with the NPP counterparts. Additionally, each team member drafts a summary of their own technical notes which are part of the preliminary report and are also used for the oral presentation at the exit meeting.

The evaluation criteria for findings are based on the relevant IAEA Safety Standards and INSAG reports. The evaluations are also based on the knowledge and expertise of each team member. Apart from their particular area of expertise, team members are familiar with other national approaches and other relevant areas. Coupling this knowledge with the IAEA Safety Standards allows the best international standards to be identified and applied. Table 26 shows how OSART findings are categorized.

TABLE 26. CATEGORIES OF FINDINGS FOR OSART MISSIONS [41]

Recommendation	A recommendation is advice on what improvements in operational safety should be made in that activity or programme that has been evaluated. It is based on IAEA Safety Standards or proven, good international practices and addresses the root causes rather than the symptoms of the identified concern. It very often illustrates a proven method of striving for excellence, which reaches beyond minimum requirements. Recommendations are specific, realistic and designed to result in tangible improvements. Absence of recommendations can be interpreted as performance corresponding with proven international practices.
Suggestion	A suggestion is either an additional proposal in conjunction with a recommendation or may stand on its own following a discussion of the pertinent background. It may indirectly contribute to improvements in operational safety but is primarily intended to make a good performance more effective, to indicate useful expansions to existing programmes and to point out possible superior alternatives to ongoing work. In general, it is designed to stimulate the NPP management and supporting staff to continue to consider ways and means for enhancing performance.
Good practice	A good practice is an outstanding and proven performance, programme, activity or equipment in use that contributes directly or indirectly to operational safety and sustained good performance. A good practice is markedly superior to that observed elsewhere, not just the fulfilment of current requirements or expectations. It should be superior enough and have broad application to be brought to the attention of other NPPs and be worthy of their consideration in the general drive for excellence. A good practice has the following characteristics: novel; has a proven benefit; replicable (it can be used at other NPPs); and, does not contradict an issue.

While on site, the OSART members write technical notes on their observations and conclusions. These notes are the preliminary report of mission results to the host NPP and are discussed in detail with the NPP counterparts; they are also the basis for the team members' oral presentations at the exit meeting. The technical notes are presented to the NPP management and form the basis of the official report prepared by the Team Leader and Deputy Team Leader.

The final OSART report is an official IAEA publication which summarizes the review team's main observations and conclusions including recommendations, suggestions and good practices. Before the text is finalized, the NPP and regulatory bodies concerned are given the opportunity to offer comments. This report is then submitted through official channels to the Member State. The IAEA restricts initial distribution to itself, members of the review team, the NPP and regulatory body involved. The report is automatically derestricted after 90 days unless the Member State indicates otherwise.

2.3.2.3 Follow-up visit

Approximately 18 months after the OSART mission, a follow-up visit takes place. The NPP informs the IAEA on the actions taken to address the recommendations and suggestions of the OSART report. During follow-up visits, a team of about four persons including the Team Leader ranks the actions taken by the NPP and measure the effectiveness of its implementation. Recommendations and suggestions are ranked in four categories in accordance with specific criteria found in the OSART Guidelines: (1) issue resolved; (2) satisfactory progress to date; (3) insufficient progress to date; or (4) withdrawn. In the past ten years, almost all of the issues found in OSART missions had been resolved or had shown satisfactory progress at the time of the follow-up visit.

The results of follow-up visits are reported in a similar manner to those of the first mission, with technical notes being presented to the NPP management before the team leaves the site. An official detailed report is then prepared, using the findings of the original mission augmented with the results of the follow-up visit. The Member State is invited to comment. The final report undergoes an initial restricted distribution and automatic derestriction after 90 days, unless the Member State requests otherwise.

2.3.2.4 Feedback and continuous improvement

Since 1986, most OSART reports have been derestricted and are available to interested individuals and organizations.

Since 1991 summaries of OSART missions and their follow-up visits have been uploaded to the OSMIR[41] database. OSMIR is a compilation of recommendations, suggestions and good practices from OSART mission reports, and covers all missions since January 1991 for which an official report has been published. OSMIR is available on request to NPPs, utilities, regulators, research institutes and organizations directly involved in the fuel cycle, as a source of information that can help strengthen nuclear safety performance.

The IAEA closely monitors the OSART programme to increase its usefulness and effectiveness, incorporating new features and eliminating outdated ones. The feedback of experience takes place in various ways. At the end of each mission, OSART team members

[41] **OS**ART **MI**ssion **R**esults

complete questionnaires that provide feedback on the OSART process, including proposals for improvement. Similarly, the NPPs and utilities are asked to provide feedback on each OSART mission.

IAEA technical meetings and meetings with industry experts have been held to collect suggestions and opinions on the OSART programme. The OSART guidelines have been revised to reflect industry-wide progress in nuclear safety and feedback from various sources. The information acquired through the OSART programme is also used to update the IAEA Safety Standards.

2.3.3 Safety of Long Term Operation

Experience has shown that the safe and reliable operation of current NPPs can be longer than the conservative 30 to 40 years expected in the original design. The SALTO peer review addresses the strategy and key elements of long term operation and ageing management programmes. Ageing management helps ensure that SSCs important to safety remain capable of performing their required safety functions.

Other IAEA safety review services, such as Ageing Management Assessment Team and OSART services, indirectly address some aspects of long term operation. However, it was recognized that a comprehensive review service on long term operation would be very useful to Member States and the IAEA introduced its SALTO safety review service. SALTO assists Member States in ensuring the safe long term operation of NPPs and promotes the exchange of experience and information on good practices. SALTO started in 2005 and uses a peer review service similar to IRRS and OSART.

Requirement 16 of SSR-2/2 (Rev. 1) states:

> "where applicable, the operating organization shall establish and implement a comprehensive programme for ensuring the long term safe operation of the NPP beyond a time-frame established in the licence conditions, design limits, safety standards and/or regulations" [36].

It also states that long term operation needs a comprehensive programme that addresses:

- Preconditions (including the current licensing basis, safety upgrading and verification, and operational programmes);
- Setting the scope for all SSCs important to safety;
- Categorization of SSCs with regard to degradation and ageing processes;
- Revalidation of safety analyses made on the basis of time limited assumptions;
- Review of ageing management programmes in accordance with national regulations;
- The implementation programme for long term operation.

This requirement is further developed in *NS-G-2.12: Safety Guide for Ageing Management in Nuclear Power Plants* [42].

The *SALTO Guidelines* [43] describe the peer review process of long term operation and ageing management of NPPs. The key objectives of the peer review are to:

- Assess the current and ageing management;

— Identify existing status of the NPP's programmes for long term operation or potential issues in respect of safe long term operation;
— Propose measures to address issues identified;
— Facilitate exchange of experience.

The administrative part of the review process is similar to other review services.

The team is composed of a Team Leader, who is an IAEA staff member, and up to six experts. A Deputy Team Leader is assigned if necessary. The typical team composition includes a majority of external experts (usually senior experts from peer organizations) and one or two IAEA staff members. Team members are selected to ensure that a variety of national approaches to ageing management and safe long term operation are represented. The expert background and knowledge of some other national approaches coupled with the IAEA Safety Standards allows good international practices to be identified. A SALTO mission is normally one or two weeks.

As with OSART, the NPP must prepare and submit an Advance Information Package, which includes information on the following:

— Design basis documentation (if it exists);
— Final Safety Analysis Report (FSAR);
— Original safety analyses involving time limited ageing assumptions;
— NPP programmes related to long term operation;
— Plant Lifetime Management (PLiM) program if it exists;
— Programme for modifications and replacements;
— Implementation programme for long term operation, if it exists;
— Periodic Safety Review report;
— Licence renewal documentations (if relevant).

As with other peer reviews, a SALTO mission will result in findings as defined in Table 27.

TABLE 27. CATEGORIES OF FINDINGS FOR SALTO MISSIONS [43]

Recommendation	A recommendation is advice from the IAEA review team on what improvements with respect to the reviewed subject should be made in the activity or programme that has been evaluated, in order to resolve a deviation from good practices contained in IAEA Safety Standards, Safety Reports, Technical Reports and/or proven, good international practices. Recommendations are specific, realistic and designed, if implemented, to result in substantial improvements.
Suggestion	A suggestion either is an additional proposal in conjunction with a recommendation or may stand on its own following a discussion of the pertinent background. It may indirectly contribute to improvements in the reviewed subject but is primarily intended to make useful expansions to existing programmes (e.g. based on state of the art information published in IAEA TECDOCs) and to point out possible superior alternatives to ongoing work.
Good practices	A good practice is an outstanding and proven performance, programme, activity or item of equipment in use that contributes directly or indirectly to operational safety and sustained good performance. A good practice is markedly superior to other practices observed elsewhere, not just in its fulfilment of current requirements or expectations. It should be sufficiently superior and have broad enough application to be brought to the attention of

other NPPs and be worthy of their consideration in the general drive for excellence.

2.3.4 Independent safety culture assessment (ISCA)

As reported in INSAG-1 [44] and INSAG-7 [45], the lack of safety culture contributed to the Chernobyl accident. Likewise, the report of the Investigation Committee on Fukushima Daiichi Accident [46] identified shortcomings in the safety culture of practically every involved organization in Japan, including regulatory and advisory bodies.

The IAEA has long recognized that the efforts put in practice to reinforce and improve safety culture in NPPs have not yet been sufficient. The Director General in the Nuclear Safety Review for the Year 2013 notes:

> "…the IAEA has observed, based upon support missions and technical meetings, that regulators and licensees often lack a systematic, long term and committed approach to continuously improving safety culture and that nuclear organizations tend to take an inadequate, ad hoc approach to safety culture in their nuclear operations" [47].

He also noted:

> "…improvement activities have often ended up addressing only visible behaviours of people, and leaving out major underlying psychological and socio cultural drivers. As a result, changes in safety culture have been insufficient and unsustainable" [47].

2.3.4.1 Regulatory bases

Fundamental Safety Principle 3 includes a statement that managing safety in a NPP must ensure the promotion of a safety culture, which includes:

- Individual and collective commitment to safety on the part of the leadership, the management and personnel at all levels;
- Accountability of organizations and of individuals at all levels for safety;
- Measures to encourage a questioning and learning attitude and to discourage complacency with regard to safety.

This is further developed into specific requirements in *GSR Part 2 on Leadership and Management for Safety* [29], which identifies the means to promote and support a strong safety culture by:

- Ensuring a common understanding of the key aspects of safety culture within the organization;
- Providing the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, taking into account the interaction between individuals, technology and the organization;
- Reinforcing learning and questioning attitude at all levels of the organization;
- Providing the means by which the organization continually seeks to develop and improve its safety culture.

The requirements have been further developed in Safety Guides GS-G-3.1 [48] and GS-G-3.5 [49]. GS-G-3.5 includes an appendix on achieving the attributes of a strong safety culture.

GS-G-3.5 adds that an independent self-assessment should include all the attributes of safety culture. The IAEA offers its ISCA as an independent assessment. The ISCA can also be included as part of an OSART mission to take advantage of the synergy between technical and behaviour science/safety culture experts.

Member States can request an ISCA in any stage of development (design, construction, commissioning, operation and decommissioning). It is based on the IAEA Safety Standards and uses surveys, interviews, observations, focused groups and document reviews.

2.3.5 Education and Training Review Service (ETRES)

The IAEA has developed and offers a variety of education and training activities. These include a wide range of training courses, tools and workshops in topics relevant to the safety of nuclear installations.

In response to various General Conference resolutions, the IAEA has consolidated its strategy to strengthen nuclear safety education and training systems in Members States. IAEA activities include the development of curriculums and trainers, knowledge networks and steering committees in the area of competence building and education and training.

Following the Fukushima Daiichi accident, the IAEA prepared an Action Plan on Nuclear Safety [50] and the ETRES supports the capacity building and self-assessment methodologies in the Action Plan.

ETRES assists Member States in developing and maintaining a sustainable and adequate education and training programme in nuclear safety that is consistent with IAEA Safety Standards and international good practices, with due recognition to national conditions. ETRES, like other IAEA safety review services, must be formally requested by a Member State and can be applied to the entire national education and training infrastructure for nuclear safety or to specific components of the infrastructure. ETRES addresses three key areas of the infrastructure:

- *The basis and framework for nuclear safety education and training:* The legal, policy, strategy, planning and organizational matters that impact the education and training needs, the system for meeting the needs, availability of resources for education and training, and qualification and utilization of these resources;
- *Competences and training in nuclear safety:* Capabilities and competences required and training necessary to develop these competences, the available education and training, the gaps and additional education and training needed to fill the gaps;
- *Maintenance (sustainability) and improvement of competences and training:* The need for continuous maintenance and improvement of the competences needed for nuclear safety.

ETRES follows a similar approach to other IAEA safety review services, with a preparatory phase that includes a self-assessment, the mission itself and the follow-up mission.

2.3.6 IAEA peer review in emergency preparedness and response

The IAEA offers an Emergency Preparedness Review (EPREV) service as a peer review of the level of preparedness in Member States to effectively respond to nuclear or radiological emergencies. In EPREV, the Member State’s emergency arrangements are appraised against

the IAEA Safety Standards in the area of emergency preparedness and response (primarily, Ref. [40]).

The EPREV process (see Figure 12) is similar to the IRRS and OSART processes, starting with a formal request from the Member State. The IAEA works with the Member State to define the scope, content and schedule of the mission, develops its terms of reference and assembles the review team. The requesting Member State prepares advance reference material and completes a self-assessment. The actual EPREV mission takes place in the requesting Member State and a report is prepared. This report provides a basis for development of a national action plan for strengthening arrangements in place to effectively cope with nuclear or radiological emergencies through addressing the EPREV's findings. Follow-up EPREV mission is carried out to appraise the status of implementation of the recommendations and suggestions of the EPREV mission.

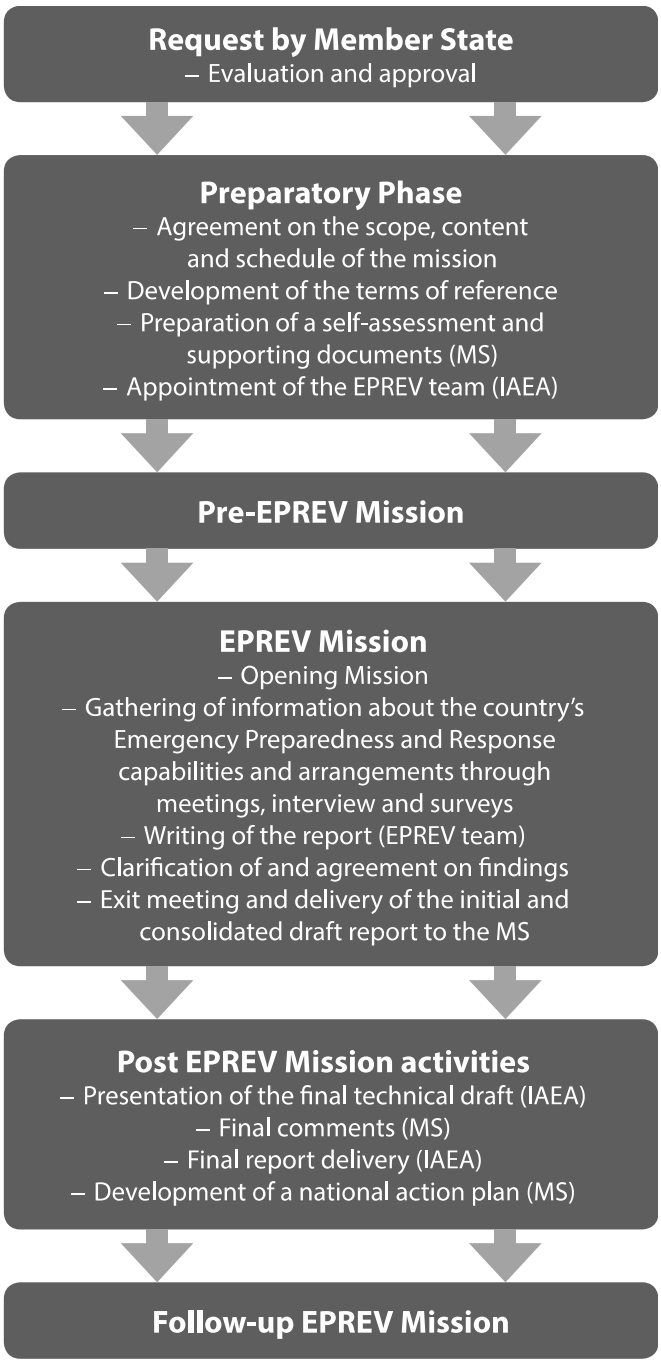


FIG. 12. EPREV process.

EPREV allows for the scope and depth of the peer review to be streamlined to the Member State's needs from peer review of emergency arrangements at a specific facility (e.g. a nuclear power plant) to a full appraisal of all emergency arrangements in place (including on-site, off-site and national).

2.3.7 Reporting operating experience and implementing feedback

Reporting operating experience and implementing operating experience feedback are essential practices for the worldwide improvement and harmonization of nuclear safety. The IAEA Safety Standards include principles, requirements and guidance on how to take advantage of operating experience.

Other international organizations, such as INSAG, OECD/NEA, EURATOM and regional associations of nuclear regulators, and industry organizations such as the WANO and the Institute of Nuclear Power Operations (INPO) also consider the use of operating experience as essential for the safe and reliable operation of nuclear installations.

The IAEA Safety Standards and the IAEA safety review services are specialized products of operating experience. Both allow others to take advantage of the experiences of others in a proactive manner.

A common example of using operating experience is when a NPP has an event and the subsequent analysis of that event is used to prevent recurrence. By sharing this analysis with others, a similar event can be avoided at another NPP. Processes must be put in place for the feedback and analysis of operating experience, including initiating events, accident precursors, near misses, accidents and unauthorized acts, so that lessons may be learned, shared and acted upon.

SSR-2/2 (Rev. 1) [36] details the steps needed to take full advantage of operating experience:

- Operating experience from the NPP has to be evaluated in a systematic way to establish the root causes and corrective actions taken. It also shall obtain and evaluate operating experience from other nuclear installations to derive lessons for its own operations;
- Events with safety implications have to be investigated in accordance with their actual or potential significance. The results of such analyses have to be included in relevant training programmes and have to be used in reviewing procedures and instructions;
- Operating experience has to be carefully examined so that corrective action can be taken before serious conditions arise;
- The operator is required to encourage the reporting of all events, including low level events and near misses, equipment failures, human errors, procedural deficiencies or inconsistencies in documentation;
- Management are required to maintain liaison with organizations involved in the design and procurement of the NPP equipment to feedback information on operating experience and obtaining advice, if necessary, in the event of equipment failures or abnormal events;
- Operating experience has to be collected and retained for the management of NPP ageing, the evaluation of residual NPP life, and for probabilistic safety assessment and periodic safety review.

NS-G-2.11, A System for the Feedback of Experience from Events in Nuclear Installations [51] provides advice on the main components of systems for the feedback of operating experience.

2.3.7.1 The Joint IAEA-OECD/NEA International Reporting System for Operating Experience (IRS)

In 1980, the OECD/NEA launched the IRS for a trial period. By the end of 1981, OECD/NEA Member States had formally approved the operation of IRS and in 1983 the IAEA extended the IRS to all its Member States with NPPs. In 1995, a comprehensive database was created and responsibility for the IRS was transferred to the IAEA. Since then, IRS members have produced a number of topical and other studies. In 2006, the IAEA created a web based IRS to facilitate efficient data input and report availability. This secure application is available to

registered users only and has been expanded to allow NPP operating organizations to access the information. The name has been revised to the *International Reporting System for Operating Experience*, although it retains the IRS acronym.

The objective of the IRS is to ensure that feedback of operating experience gained from NPPs worldwide on safety related events is widely shared amongst the international nuclear community to help prevent occurrence or recurrence of serious events. The IRS relies on the commitment of the participating Member States. The IRS is based on the principle that each participating Member State will provide timely information on its NPPs operating experience.

All participating Member States have designated an IRS National Coordinator, usually from the regulatory body, to be responsible for the exchange of information on operating experience under the IRS. National coordinators meet annually each to review the information received and to exchange information on recent unusual events.

The IRS is for use, within each Member State, by organizations professionally involved in the nuclear industry, such as:

— Safety regulators;
— Utilities with nuclear power programmes;
— NPP staff;
— TSO staff;
— Vendor companies in the nuclear field (design firms, engineering contractors, manufacturers, etc.);
— Research establishments and technical universities working in the nuclear field.

2.4 BUILDING A NATIONAL NUCLEAR SAFETY INFRASTRUCTURE

Learning Objective 1: To understand the elements of a national nuclear safety infrastructure for Member States using or considering the use of nuclear power, as well as the IAEA assistance available to Member States.

Learning Objective 2: To understand the importance and composition of a modern and comprehensive nuclear law and supporting regulations for the safe use of nuclear power.

Learning Objective 3: To understand the technical and industrial infrastructure required for a Member State to be able to site, design and construct, operate and decommission a NPP and safely manage spent fuel and radioactive waste.

Learning Objective 4: To understand the scientific and economic framework required for a Member State to be able to site, design and construct, operate and decommission a NPP and safely manage spent fuel and radioactive waste.

Learning Objective 5: To understand the education and training infrastructure required for a Member State to be able to site, design and construct, operate and decommission a NPP and safely manage spent fuel and radioactive waste.

The safe deployment of a nuclear power programme requires the development and maintenance of a nuclear safety infrastructure to address all phases in the life of the NPP and the long term management of the spent nuclear fuel and long lived radioactive waste.

SF-1 [21] includes three fundamental safety principles directly related to the national nuclear safety infrastructure. Principle 2 states that an effective legal and governmental framework for safety, including an independent regulatory body, must be established and sustained. Principle 7 addresses the protection of the present and future generations against radiation risks. Principle 9 refers to the government responsibility for providing emergency preparedness and response for nuclear and radiation accidents.

GSR Part 1 (Rev. 1) [5] Requirement 2 expands on Principle 2 by including expectations regarding the promulgation of laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. GSR Part 1 (Rev. 1) [5] Requirements 3 and 4 provide details on establishing the regulatory body and its independence. This book includes a discussion of the independence of the regulatory body in Section 3.4.

GSR Part 1 (Rev. 1) [5] Requirement 10 addresses Principle 7 and outlines provisions for the decommissioning of installations and the management of radioactive waste and of spent fuel. Present generations are those which benefit from the installation, while future generations refers to those people that may be exposed to the radiation coming from the radioactive waste generated from the installation once it has ended its active life. The decommissioning of NPPs and management of radioactive waste and spent fuel are costly operations and the funds need to be set aside now. Although NPPs provide the funds for these activities, government oversight is essential to ensure the funds are available when needed.

GSR Part 1 (Rev. 1) [5] Requirement 8 addresses Principle 9, noting that the government is responsible for establishing, maintaining and rehearsing a system to cope with emergencies affecting the population. The emergency preparedness and response system must include a well-defined line of command and technical means to protect the population, including dealing with the aftermath of an accident.

2.4.1 National nuclear legal framework

The legal and governmental framework for a nuclear power programme goes well beyond nuclear safety. Governments are obliged to regulate all aspects of nuclear applications and that will include developing nuclear industry through research, training and education; promoting its varied applications; regulating trade and commerce; and protecting people and property from the hazards associated to radiation and the wrong use of nuclear materials.

Laws related to technological applications have two main aims: allowing the development of the technology, while at the same time protecting workers, the public and the environment against undue harmful effects of the technology. In the case of nuclear technology, the legal framework must address: potential applications of nuclear material or energy; non-proliferation of nuclear weapons; safety; security; and liability. This can be done in a single law or in multiple connected laws. In any case, the law or set of laws is then expanded upon in lower level documents.

Some Member States began promulgating laws on nuclear energy and materials in the late 1940s, and now most Member States have developed or are in the process of developing nuclear laws to address the increasing uses of nuclear applications. The IAEA and OECD/NEA have established processes to help Member States develop the governmental legal framework for nuclear activities.

2.4.1.1 IAEA assistance on nuclear regulation

To assist Member States, the IAEA has established a legal assistance programme to:

- Create awareness in Member States of the international instruments in the nuclear field;
- Assist Member States in complying with their international obligations and commitments;
- Assist Member States in establishing national legal frameworks governing the safe and peaceful uses of nuclear energy;
- Transfer relevant knowledge to Member States.

In recognition of the increasing number and complexity of international instruments and in to better meet the demand from Member States, in 2011 the IAEA established a Nuclear Law Institute. Every year, the Institute offers intensive training for up to 60 lawyers in all areas of nuclear law and in drafting corresponding national legislation.

The IAEA has also published the *2003 Handbook on Nuclear Law* [52] and the *2010 Handbook on Nuclear Law: Implementing Legislation* [53]. The 2003 Handbook sets out the basic principles for developing a legal framework, while the 2010 Handbook focuses on the practical side of drafting national laws. The two Handbooks and their numerous references provide complete advice on how to develop a nuclear law. Both documents concentrate on the protection aspects and do not consider the promotion side of nuclear technology.

The 2003 IAEA Handbook on Nuclear Law

Member States can use the 2003 Handbook [52] to perform self-assessments to ensure that their already existing or developing nuclear legislative frameworks comply with the new relevant international undertakings and best practices. The 2003 Handbook is divided into five parts:

- Elements of nuclear law;
- Radiation protection;
- Nuclear and radiation safety;
- Nuclear liability and coverage;
- Non-proliferation and physical protection.

In Chapter 1, the following definition of nuclear law is included:

> "The body of special legal norms created to regulate the conduct of legal or natural persons engaged in activities related to fissionable materials, ionizing radiation and exposure to natural sources of radiation" [52].

The concepts in the 2003 Handbook are based on the principles shown in Table 28.

TABLE 28. PRINCIPLES OF NUCLEAR LAW [52]

Safety principle	Safety is considered as the primary requisite for the use of nuclear energy and ionizing radiation. It is based on subsidiary and complementary principles such as the prevention principle, the protection principle and the precautionary principle, all of them condensed in the justification principle, as defined in the IAEA Fundamental safety principles.
Security principle	Nuclear materials and technologies may be used to non-peaceful ends; terrorist or criminal groups could produce radiation dispersion devices and sabotage nuclear installations. Security is needed to protect nuclear material and facilities against such activities.
Responsibility principle	Any use of nuclear energy involves numerous parties, including research and development organizations, processors and manufacturers of nuclear devices, architect–engineering firms and construction companies, operators of nuclear installations, financial institutions and regulatory bodies. Although all involved entities bear at least part of the responsibility, the licensee has been consistently identified as the primarily responsible, as defined in Principle 1 of the IAEA Fundamental Safety Principles.
Permission principle	Prior permission for facilities and activities involving radiation risks are required. That permission should be graded and it may take names such 'authorization', 'licence', 'permit', 'certificate' 'approval' or exemption when risks are so low as to be below regulatory concern.
Continuous control principle	The authorized facilities and activities need to be conducted safely and securely, in accordance with the terms of the authorization. Nuclear legislation must provide for free access by regulatory inspectors to all premises where nuclear material is being used and stored.
Compensation principle	As safety measures cannot completely exclude the potential for nuclear damage, the nuclear law must require that States adopt measures to provide adequate compensation in the event of a nuclear accident.
Sustainable development	Economic and social development can be 'sustainable' only if the world's environment is protected from degradation. Fissile material and sources of ionizing radiation can pose

principle	health, safety and environmental risks for very long periods of time. Principle 7 of the IAEA Fundamental Safety Principles addresses the protection of present and future generations by requiring that current generation does whatever is possible for assuring the long term safety of radioactive waste repositories.
Compliance principle	Nuclear energy has been deemed to involve particular risks of radiological contamination transcending national boundaries. Both regionally and globally, bilateral and multilateral instruments are building an international law of nuclear energy. To the extent that a State has adhered to the international legal regimes in question, national nuclear law must reflect the obligations that they contain.
Independence principle	Nuclear law places particular emphasis on the establishment of a regulatory authority, whose decisions on safety issues are not subject to interference from entities involved in the development or promotion of nuclear energy
Transparency principle	The transparency principle requires that bodies involved in the development, use and regulation of nuclear energy make available all relevant information concerning how nuclear energy is being used, particularly concerning incidents and abnormal occurrences that could have an impact on public health, safety and the environment
The international cooperation principle	The potential trans boundary impacts, the worldwide security risks, the large number of international legal instruments and the increasingly multinational character of the nuclear industry forces national nuclear energy legislation to make adequate provision for encouraging public bodies and private users of nuclear energy to co-operate in relevant international nuclear activities.

The 2010 IAEA Handbook on Nuclear Law: Implementing Legislation

The 2010 Handbook [53] supplements the 2003 Handbook [52] by providing practical advice on drafting legislation and introduces the '3S' concept—safeguards, safety and security—defined in the IAEA Safety Glossary [31] as:

- Safeguards (agreement). An agreement between the IAEA and one or more Member States which contains an undertaking by one or more of those States not to use certain items in such a way as to further any military purpose and which gives the IAEA the right to observe compliance with such undertaking;
- Safety (nuclear). The achievement of proper operating conditions, prevention of accidents or mitigation of accident consequences, resulting in protection of workers, the public and the environment from undue radiation hazards;
- Security (nuclear). The prevention and detection of, and response to, theft, sabotage, unauthorized access, illegal transfer or other malicious acts involving nuclear material, other radioactive substances or their associated facilities.

The 3S concept reflects the areas an adequate legislative and regulatory framework must cover to ensure the peaceful uses and prevent the non-peaceful uses of nuclear energy. Measures taken to address one of these areas can contribute to addressing the others as well, although not without some inconveniences and contradictions. The relations among the three concepts are shown in Figure 13. Good nuclear safety arrangements in a NPP also serve to improve safeguards and security functions but, for example, security may restrict accessibility to critical components, which may hinder safety operations when needed. A well-developed regulatory safety infrastructure in a State can help ensure the security of radioactive material. Similarly, an effective safeguards system can enhance security measures, such as the prevention of illicit trafficking or the deterrence and detection of unauthorized acts involving nuclear or other radioactive material.

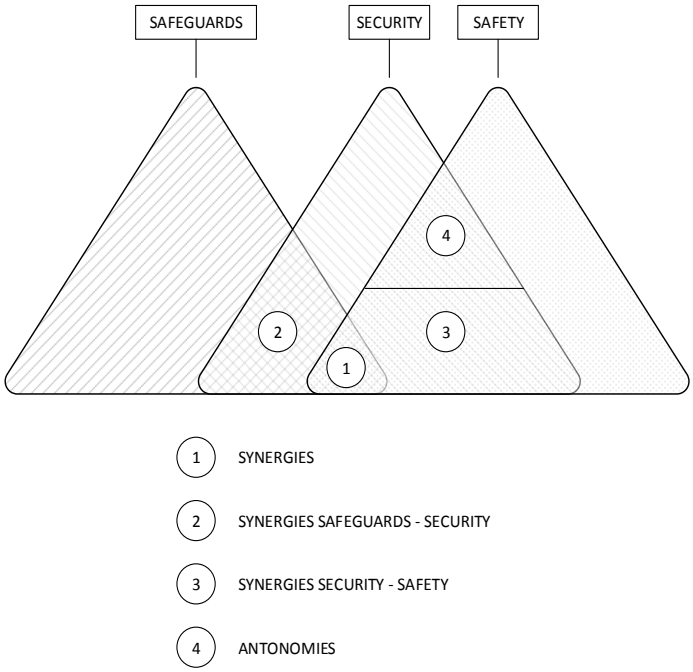


FIG. 13. Interfaces and relationships between safeguards, safety and security.

The 2010 Handbook proposes that the nuclear law be structured as shown in Table 29. Each chapter of the 2010 Handbook includes three parts:

- Narrative summary. A brief narrative summary of key issues and approaches in the area of nuclear legislation being considered;
- Model provisions. Possible model provisions covering the subject area presented and offering the language developed by persons experienced in nuclear law and technology;
- References. A list of relevant documents available at the time of publication.

TABLE 29. STRUCTURE OF A NUCLEAR LAW AS PROPOSED IN THE 2010 IAEA HANDBOOK OF NUCLEAR LAW [53]

I.	Objectives of the law
II.	Scope of the law
III.	Definitions of key terms
IV.	The regulatory body
V.	Authorizations (licences, permits, etc.)
VI.	Inspection
VII.	Enforcement
VIII.	Responsibilities of licensees, operators, users
IX.	Specific chapters or sections for relevant subject areas, such as: Radiation protection; Radioactive sources and radioactive material; Safety of nuclear facilities and decommissioning; Emergency preparedness and response;

Mining and processing of radioactive material;
Transport of radioactive material;
Radioactive waste and spent fuel;
Nuclear liability and coverage;
Safeguards;
Export and import control;
Nuclear security and physical protection;
Final clauses (entry into force, amendments, repeals).

The 2010 Handbook refers extensively to the IAEA Safety Standards and some of the concepts discussed include:

— Effective independence of the regulatory body;
— Major responsibilities of the regulatory body: (1) enacting requirements; (2) verifying compliance with requirements; and (3) enforcing regulation in case of non-compliance;
— International legal instruments, such as the CNS and Joint Convention;
— The radiation protection principles of justification, optimization and limitation as defined in SF-1 [21];
— The IAEA Code of Conduct on the Safety and Security of Radioactive Sources [63] and its associated Guidance for the Import and Export of Radioactive Sources [64];
— Major phases in the life of nuclear installations as shown in Table 30;
— Unique nature of nuclear and radiological emergencies;
— Requirements associated with civil nuclear liability.

TABLE 30. MAIN PHASES IN THE LIFE OF A NPP AND REGULATORY REQUIREMENTS

Phase	**Duration (years)**	**Needed safety infrastructure**	**Basic references**
Decision to build	1-3	Conduct formal public consultation. Establish State and industry management organizations	INSAG-22 SSG-16
Preparatory work for NPP selection	3-7	Draft and enact nuclear law. Create and nominate regulatory body. Consider international obligations.	SF-1 GSR Part 1 (Rev. 1) GSR Part 4 (Rev. 1)
Site selection	2-3	Safety requirements for site selection and verification. Consider natural phenomena and human made hazards.	SSG-18 SSG-9 NS-G-3.1
Design and construction	5-7+	Safety requirements for design, construction, verification and quality assurance. Integrate safety and security requirements	SSR-2/1 (Rev. 1) NSS No. 19
Testing and commissioning	1-2	Safety requirements for commissioning. Licensing NPP operators. Put into practice the emergency plan.	NS-G-2.9 TRS-380 GS-R-2
Commercial operation	40-60+	Safety requirements for operation, design changes, long term operation and periodic reviews.	SSR-2/2 (Rev. 1) NS-G-2.15 SRS-81

		Continuous regulatory oversight and inspection.	INSAG-19
Decommissioning	5-10	Safety requirements for decommissioning. Regulatory inspection and oversight during decommissioning.	SRS-77 SSG-15 SSR-6
Long term management of nuclear fuel	15-100+	Governmental decision of spent fuel management: recycling, immediate geological disposal and temporary storage.	GSR Part 5 SSR-5

2.4.1.2 OECD/NEA activities in nuclear regulation

The OECD/NEA has established a Legal Affairs Section, which:

- Assists its member countries in the development, strengthening and harmonization of nuclear legislation based on internationally accepted principles for the safe and peaceful use of nuclear energy;
- Supports the modernization of the international nuclear liability conventions and broad adherence to their regimes;
- Collects, analyzes and disseminates information on nuclear law developments from around the world through an extensive publications programme and regularly conducted intensive, high level educational programmes in nuclear law;
- Provides legal support to the OECD/NEA programmes and projects.

OECD/NEA activities related to international nuclear liability were discussed in Section 2.1.5.

The OECD/NEA has established a Nuclear Law Committee; a group of lawyers, policy makers, academics and from time to time technical experts. Although the Committee's terms of reference focus on the international nuclear liability regime, it also provides a forum for discussions concerning the development and harmonization of legislation on other aspects of nuclear activity.

The OECD/NEA provides current online information on national legislation, regulatory and institutional frameworks and international protocols and conventions on nuclear activity and liability issues. Table 31 shows the information provides for each member country. The OECD/NEA also publishes the Nuclear Law Bulletin twice per year and includes expert contributions on contemporary nuclear law issues, developments in State legislation and international agreements, updates on intergovernmental activities and texts of significant new laws and other legal documents.

TABLE 31. CONTENTS OF THE OECD/NEA MEMBER COUNTRY NUCLEAR LEGISLATION PROFILES

General regulatory framework	**Institutional framework**
1. Introduction	1. Regulatory and Supervising Authorities
2. Mining regime	2. Advisory Bodies
3. Radioactive Substances	3. Public and Semi-public Agencies
4. Nuclear Installations	
5.Trade in Nuclear Materials and equipment	
6. Radiation Protection	
7. Radioactive Waste Management	
8.Non-proliferation and Physical Protection	
9. Transport	
10. Nuclear Third Party Liability	

The OECD/NEA, in cooperation with the University of Montpellier 1, established the International School of Nuclear Law in 2001. Supported by the IAEA and the International Nuclear Law Association, the School has provided high quality, intensive education in international nuclear law to hundreds of graduate students and young professionals from around the world. The programme has evolved over the last decade to address developments in an increased body of laws and legal regimes. The OECD/NEA also offers the International Nuclear Law Essentials, a one-week programme for experienced professionals on contemporary issues in international nuclear law.

A comprehensive presentation of the history, current and future activities on nuclear law is found in *International Nuclear Law: History, Evaluation and Outlook*[42] published by OECD/NEA in 2010 to commemorate the 10th anniversary of the International School of Nuclear Law.

2.4.2 National nuclear technical and industrial framework

A Member State's nuclear infrastructure is not limited to government institutions; it also includes semi-public and public institutions. All Member States have an organization responsible for environmental protection. Many Member States have an organization responsible for the coordination of national standards and working with international bodies such as the International Standards Organization. Many Member States also have a national organization for producing radiation protection recommendations and working with international organizations such as the International Commission on Radiation Protection (ICRP) and the United Nations Scientific Committee on the Effects of Atomic Radiation

[42] OECD/NEA No. 6934.

(UNSCEAR). Some Member States have created a national organization for radioactive waste management.

Many Member States have or had a specific organization for the development of nuclear applications. These organizations performed basic and applied research as well as training and education on nuclear science and technology. Although some remain today, many have been disbanded or transformed.

2.4.2.1 Early development of national nuclear industry infrastructure

The USA was the first major user and exporter of pressurized water reactors (PWRs) and boiling water reactors (BWRs), imported by west European and Asian countries. The former Soviet Union developed the VVER, a pressurized water reactor exported to east European countries and the RBMK, a boiling water reactor with graphite moderator built in what is now the Russian Federation and Ukraine. Canada developed the CANDU reactor, with heavy water cooling and moderator (PHWR), which was exported to a number of countries. France and the UK developed a gas cooled, graphite moderated reactor mainly used domestically, although single units were exported to Italy, Japan and Spain, and the gas cooled advanced type (AGR) limited to the UK. Some of the early importers, including China, France, Germany, Japan, Republic of Korea and Sweden, have developed their own systems, based on the initially imported technology and on their own research and development, which have since been exported.

All of these exporting countries created scientific, technical and commercial infrastructures, which have served as models for importing countries. Many of these importing countries have also created robust scientific, technical and commercial infrastructures, allowing them to contribute increasingly to the design and construction of NPPs and be fully responsible for the operation and dismantling of its NPPs.

2.4.2.2 IAEA assistance to the creation of a national industrial infrastructure

Launching a nuclear power programme is a major undertaking that requires careful planning, preparation and investment. The infrastructure to support the successful introduction of nuclear power covers a wide range of complex and interrelated issues and a commitment of at least 100 years. Planning for nuclear power can take 10 to 15 years before commissioning of the first NPP.

To assist Member States in creating a systematic process for considering and implementing a nuclear power programme, in 2007 the IAEA published *NG-G-3.1: Milestones in the Development of a National Infrastructure for Nuclear Power* [1]. NG-G-3.1 identifies three milestones as shown in Figure 14.

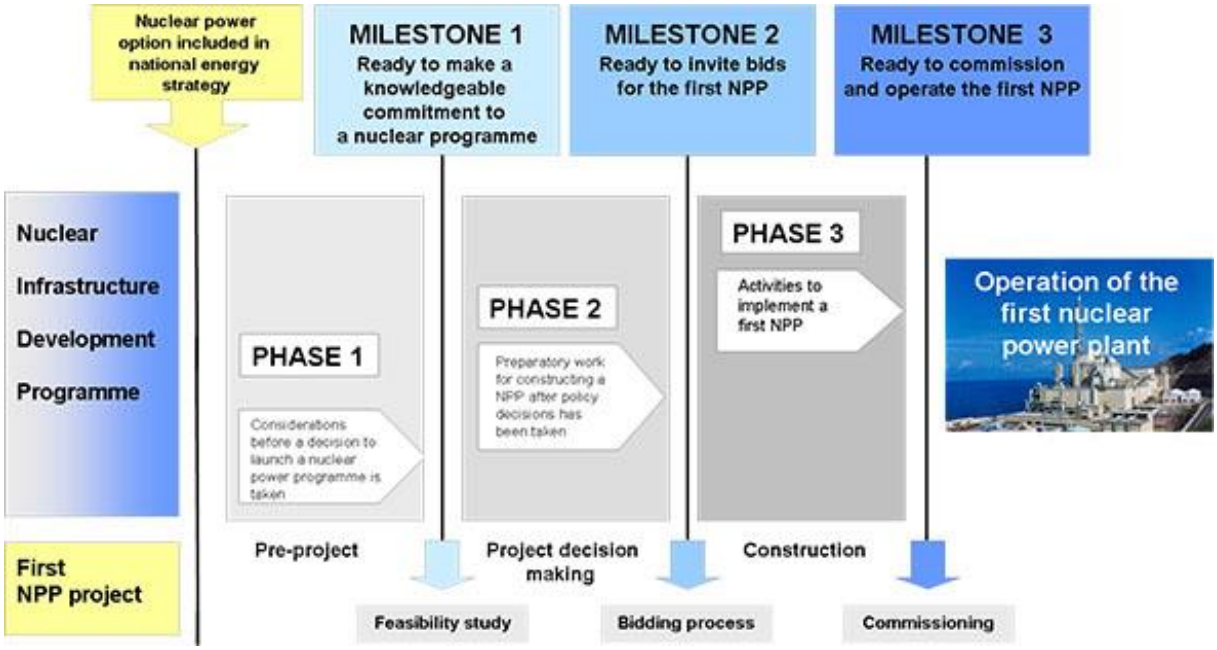


FIG. 14. Phases and milestones in the development of a nuclear power infrastructure.

At Milestone 1, the Member State will be ready to make a knowledgeable commitment to a nuclear power programme. In support of this, the regulatory body must be established, the NPP owner/operator designated and needed technical support in place.

At Milestone 2, the Member State will have the necessary infrastructure to invite formal bids for the first NPP and to supervise its construction. The necessary legal framework will be in place and the national infrastructure will have the necessary technical competence in place. The independent nuclear regulatory body will be established and staffed. Likewise, the NPP owner/operator (or utility) will have developed the competence to manage a NPP project and to achieve the level of organizational and operational culture necessary to meet regulatory requirements.

At Milestone 3, the Member State will be in a position to commission and operate the first NPP. This will require significant recruitment, development and training for all levels of staff and the demonstration that the NPP owner/operator can manage the project throughout its life. The national technical infrastructure should be developed to the point where engineering work, equipment and services can be supplied, at least for following NPPs.

By following the process outlined in NG-G-3.1 [1], the Member State will demonstrate its commitment to nuclear safety and control of nuclear materials to both national and international interested parties.

Many organizations, including government ministries, nuclear and other regulatory bodies, utilities, grid operators, research institutes and universities and the public, will have a role in supporting decision making and implementation of a national nuclear programme. NG-G-3.1 recommends the Member State establish a coordinating body, the Nuclear Energy Programme Implementing Organization (NEPIO), to bring together the wide range of views and technical expertise.

The public is a key interested party in the decision to implement a nuclear power programme and must be involved at the very early stages. In addition, since nuclear power has the

potential for causing concern across national boundaries, the Member State will also need to involve neighbouring Member States.

The process involves the government, the regulatory body and the NPP owner/operator. As Figure 15 shows, involvement changes as the programme advances.

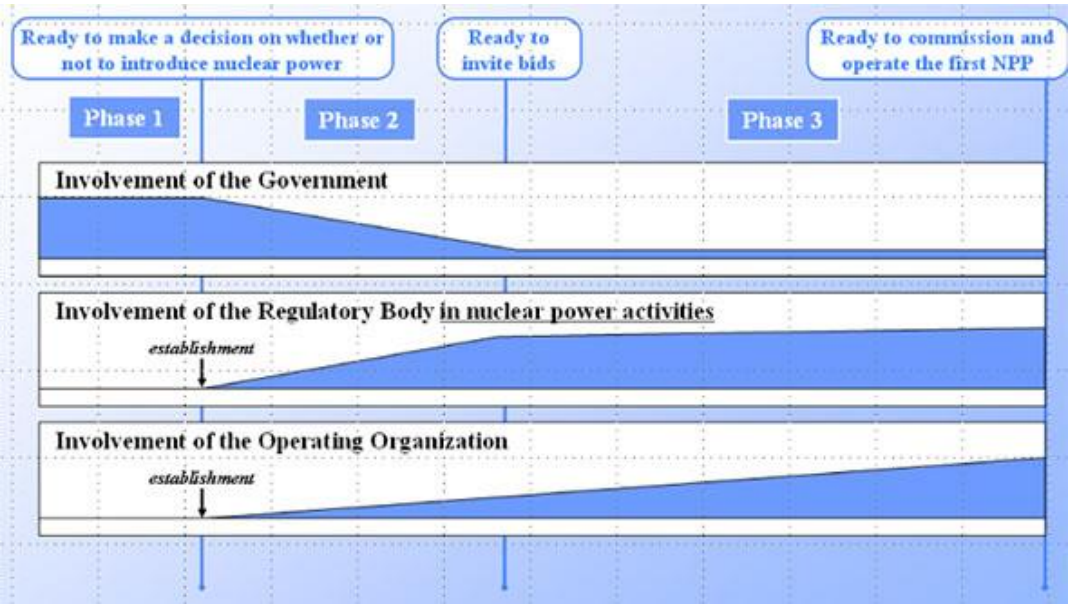


FIG. 15. Time evolution of the effort required by the government organization, the regulatory body and the NPP owner/operator in the development of a nuclear power infrastructure.

NG-G-3.1 relates issues to the national infrastructure as shown in Table 32.

TABLE 32. ISSUES AND THEIR ASSOCIATION TO THE NATIONAL INFRASTRUCTURE FOR NUCLEAR POWER

Issues covered by the legal infrastructure	Legislative framework. Regulatory framework. Nuclear safety. Radiation protection. Safeguards. Security and physical protection.
Issues for government departments	National position (take the decision to start or enlarge the national nuclear power programme). Management (manage the first two phases from decision to invitation to bid). Funding and financing. Human resource development. Interested party involvement. Environmental protection. Emergency planning. Nuclear fuel cycle (decide the management of spent fuel: recycling or final disposal). Radioactive waste management organization.
Issues for the owner/operator	Management (manage NPP, bid invitation, technology selection, design and construction, quality assurance, commissioning and operation). Funding and financing. Human resource development. Emergency planning and response. Electrical grid.
Issues for the industry and commercial organizations	Industrial involvement. Procurement.

For every issue and for every phase, the IAEA provides assistance services to Member States in the form of workshops/training; expert missions/advisory services; review missions/peer reviews; and tools/networks for the NEPIO, the regulatory body and the NPP owner/operator.

IAEA has also created the Integrated Nuclear Infrastructure Review (INIR) [54] covering the comprehensive infrastructure required for building a nuclear power programme.

2.4.3 National nuclear scientific and economic framework

Every Member State operating or intending to operate a NPP must have some nuclear science capability. That capability should include a network of universities and other high level institutions where nuclear science is cultivated and taught. Many Member States with NPPs have established national research and development centres that include research reactors, hot cells for managing highly radioactive materials, loops for thermalhydraulics studies and laboratories for radioactivity characterization and measures. The Member State should also establish a national nuclear data registry to provide researchers, designers and operators with nuclear, physical and chemical data and consolidated computational tools.

The economics of nuclear power are complex and require specialized expertise. The long life of an NPP and the costs associated with decommissioning and disposal of radioactive waste are only some of the factors that must be taken into account when considering the economics of nuclear power. The OECD/NEA has devoted significant attention to nuclear power economics.

2.4.3.1 National research and development infrastructure

Every Member State with or intending to have a nuclear power programme must have the research and development infrastructure to support safe and reliable NPP operation. Issues of interest to the regulatory body and owner/operators in every Member State with a nuclear programme are listed in Table 33.

TABLE 33. REQUIRED RESEARCH CAPABILITIES FOR ALL MEMBER STATES WITH A NUCLEAR POWER PROGRAMME

Nuclear safety evaluation methods	Defence in depth approach and probabilistic safety method and their interactions; computational models; component reliability; computational analysis of design basis accidents and severe accidents; new developments on nuclear safety and I&C systems.
NPP operation	Reactor physics; thermal hydraulics; transients and reactor stability and computational tools; corrosion, erosion and ageing of materials including embrittlement; analysis and feedback of operating experience and root cause analysis of events; decontamination technologies.
Management of nuclear fuel	Computational tools for reactor core design; behaviour of nuclear fuel in the reactor; root cause analysis of fuel failures; development of new cladding materials and new fuel compositions; behaviour of spent fuel.
Management of radioactive waste	Treatment of radioactive of operational waste in solid, liquid and gas forms: separation, solidification and storage; management of tritium; management of high activity waste.

While many Member States have established extensive research and development programmes and facilities, international research and development programmes provide a cost effective alternative. The OECD/NEA Halden Project, the OECD-LOFT experiments and the international French PHEBUS series on thermal hydraulics and severe accidents are examples in which Member States collaborate in research and development.

The IAEA has established programmes to help Member States build up a nuclear research and development infrastructure. As an example, the SKALTO[43] programme is a database that integrates the knowledge that has been acquired on ageing and long term operation of NPPs. It includes standards, TECDOCs, and minutes of IAEA meetings and seminars.

There are other international and national institutions performing relevant research activities. The EURATOM research programme, while focused on its Member States, is open to foreign participation and its research reports are readily available. The Electric Power Research Institute activities are open to foreign participation.

2.4.3.2 OECD/NEA contribution to national nuclear scientific framework

The OECD/NEA has established the Nuclear Science Committee to help its member countries develop the needed scientific infrastructure. The Nuclear Science Committee programme identifies, develops and disseminates scientific knowledge through six groups:

- Working Party on Scientific Issues of Reactor Systems (WPRS);
- Working Party on Scientific Issues of the Fuel Cycle (WPFC);
- Working Party on Nuclear Criticality Safety (WPNCS);
- Working Party on Multi-scale Modelling of Fuels and Structural Materials for Nuclear Systems (WPMM);
- Working Party on International Nuclear Data Evaluation Co-operation (WPEC);
- Expert Group on Integral Experiments for Minor Actinide Management.

WPRS addresses reactor physics, thermal hydraulics, fuel performance, radiation transport and shielding in current and future NPPs. It also considers uncertainties associated with modelling physical processes, specifically the modelling of transients.

WPFC addresses technical and scientific issues in various existing and advanced nuclear fuel cycles, including fuel cycle scenarios, recycling technologies, fuels and materials and technology and components of accelerator driven systems. It provides advice to the nuclear community on the developments needed to meet advanced long term sustainable nuclear fuel cycles, including partitioning and transmutation.

WPNCS addresses technical and scientific issues relevant to criticality safety encountered in the nuclear fuel cycle, fuel fabrication, transport and storage.

WPMM addresses the scientific and engineering aspects of fuels and structural materials, aiming at establishing multi-scale models and simulations as validated predictive tools for the design of nuclear systems, fuel fabrication and performance.

WPEC promotes the exchange of information on nuclear data evaluations, measurements, nuclear model calculations, validation and related topics.

The Expert Group on Integral Experiments for Minor Actinide Management addresses the need to manage minor actinides, such as neptunium, americium and curium, in spent fuel.

[43] Safety Knowledge for Ageing and Long Term Operation

The OECD/NEA also operates the OECD/NEA Data Bank, which provides reliable nuclear data and computer programs for use in various nuclear applications.

2.4.4 Nuclear education and training

Any Member State with currently operating NPPs or planning to operate NPPs must have a national infrastructure for nuclear education and training to ensure the necessary knowledge, skills and attitudes[44] for making appropriate decisions. A Member State with even one single NPP must have the same education, training and skills building activities that a Member State with a large nuclear power programme has; only the number of participants changes.

The nuclear education and training programme must cover the knowledge needs for each of the functions of the various actors: government, regulatory body, licensee, engineering and service companies, main suppliers and equipment vendors, construction companies, NPP operators, fuel suppliers and dismantling companies, for all phases in the life of an NPP. Table 34 shows the main subjects of required knowledge and expertise.

[44] Please note that the definition of KSA as knowledge, skills and attitudes is taken from Safety Reports Series No. 79 on Managing Regulatory Body Competence.

TABLE 34. SUBJECTS OF LEARNING INTEREST FOR ORGANIZATIONS INVOLVED IN THE DEVELOPMENT OF A NUCLEAR POWER PROGRAMME

	Government	Regulator	Licensee	Engineering & Services	Main Suppliers	Constructors.	Operators	Fuel Suppliers	Decommissioning Organization
Decision to build	Legislation Planning Economics	Legislation							
Preparatory work for NPP selection	Legislation Planning Economics	Safety Standards Security guidance	Legislation Standards Codes	Bidding Selecting Contracting					
Site selection	Social sciences	Earth sciences Security Threats	Electricity market Social science	Siting requirements Earth sciences		Siting requirements Earth sciences			
Design and construction		Safety Security Quality assurance	Nuclear engineering Quality assurance	Nuclear design Construction techniques	All types of engineering Nuclear codes	Construction techniques Nuclear codes	Initial training in NPP operation		
Testing and commissioning		Reactor physics Systems engineering	Nuclear codes and standards	Nuclear physics Systems engineering	Reactor physics Systems engineering		Reactor physics Safety culture	Reactor physics Fuel technology	
Commercial operation		Operating experience Inspection techniques	NPP reliability NPP economics	Operating experience	Operating experience		Continuous training in NPP operation	Fuel behaviour and reliability	
Decommissioning	Electricity policies	Safety Radiation protection							Decommissioning Technologies Waste management
Long term management of nuclear fuel	Spent fuel policy	Spent fuel safety and security							

To assist Member States in creating the necessary infrastructure, the IAEA has published *NG-T-3.10: Workforce Planning for New Nuclear Power Programmes* [1].

The estimations for the NEPIO, the regulatory body (REG Body) and the operating organization (OP ORG) are reproduced in Figure 16. As Figure 16 shows, the NEPIO will require from 10 to 50 experts, the regulatory body will require from 50 to 150 experts plus technical support, while the operating organization must reach and maintain to about 800 persons, of whom at least 20% should be engineers, with the remainder craftsmen and technicians.

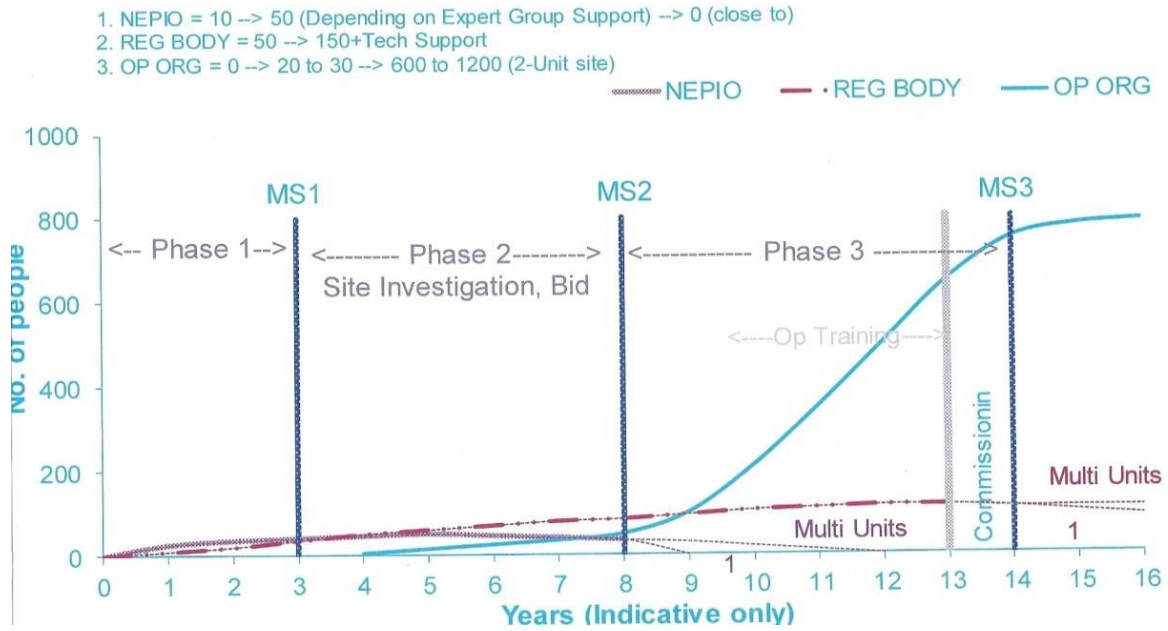


FIG. 16. Human resources requirements for a new NPP [1].

NG-T-3.10 includes much more information on staffing needs [1].

2.4.4.1 IAEA training and education services on nuclear safety

Capacity building is one of the actions within the IAEA Action Plan on Nuclear Safety [50], and in 2012, the IAEA created its Strategic Approach to Nuclear Education and Training in Nuclear Safety 2012-2020 [55].

The objectives of the Strategic Approach are:

- Maintenance and continual improvement of Member States' capacity building in nuclear safety, consistent with the IAEA Safety Standards and best practices;
- Development of an education and training support programme by the IAEA in cooperation with Member States and, as appropriate, other international organizations to support Member States' implementation of their education and training programmes at a national and regional level;
- Development by the IAEA of a process for the effective and efficient implementation of the education and training support programme and ensuring the continuous improvement of its implementation.

The approach is based on the capacity building mechanisms that the IAEA has been developing, as shown in Figure 17. The IAEA offers an extensive list of training courses,

including ‘train the trainer’, supplemented by its review services, steering committees and networks.

The IAEA offers a Basic Professional Training Course on Nuclear Safety for nuclear professionals. The course covers all areas of safety, including defence in depth, management of safety, safety assessment, site evaluation, design, operation, regulatory control and communication with the public. The IAEA offers another basic course on regulatory control, which gives an overview of regulatory frameworks, practices and approaches in line with the IAEA Safety Standards. The IAEA has also developed a number of safety training packages for Member States embarking on a nuclear power programme.

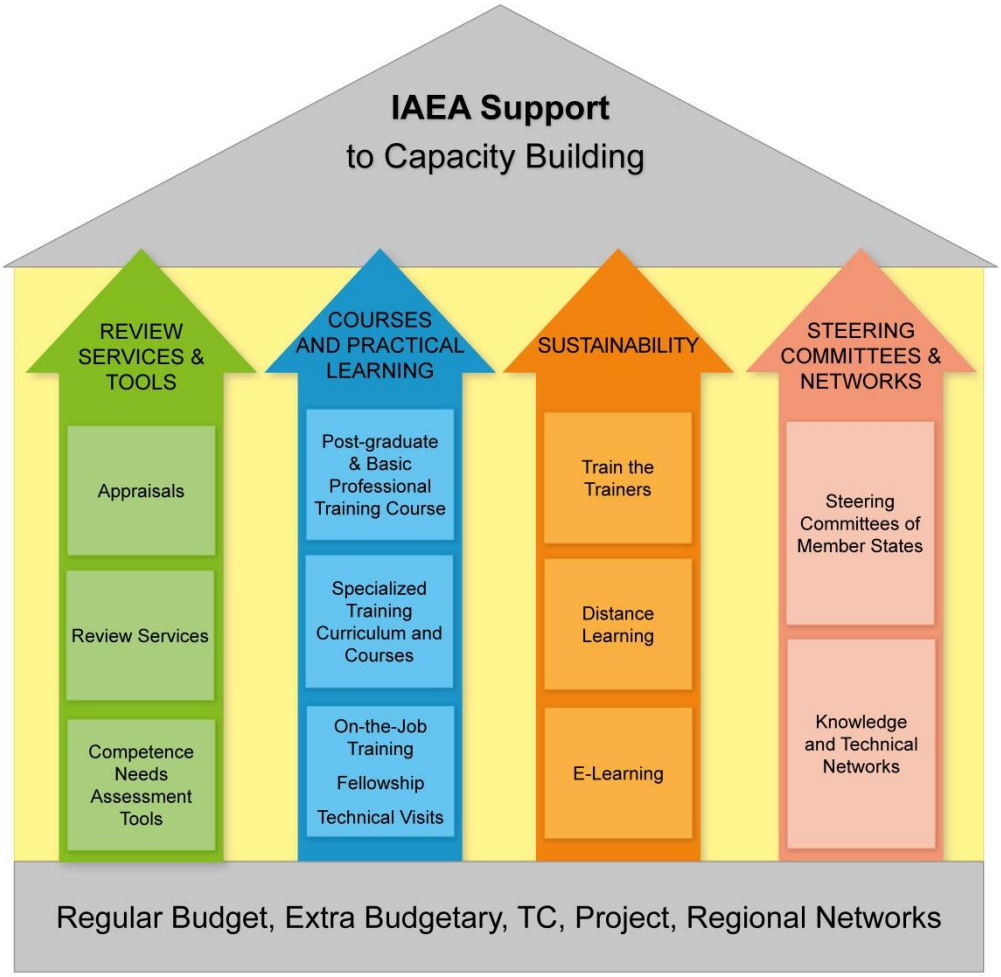


FIG. 17. IAEA mechanisms to support capacity building in nuclear safety.

At the specialized level of knowledge, the IAEA offers a long list of training courses on subjects such as safety assessment, regulatory control and regulatory functions, operational safety of NPPs, accident analysis, safety culture and management of safety. These courses can be complemented with practical on-the-job training provided by scientific visits and fellowships.

Sustainability of education and training is achieved by the train the trainers programme. Over the years the IAEA has produced a comprehensive portfolio of training materials available to requesting Member States. IAEA courses are also conducted to train trainers in using the IAEA material. This material is also available for self-study purposes.

The IAEA has also created a cyber-learning platform (CLP4NET) that has been created to exploit the advantages of this modern way of learning. The CLP4NET integrates existing IAEA and other educational establishment education and training materials in the key areas of nuclear science and technology.

The IAEA ETRES peer review service and the Systematic Assessment of Regulatory Competence Needs (SARCoN) are available to Member States. SARCoN provides a methodology and includes a software tool for its application [56]. SARCoN has been used in more than 22 Member States and is recognized by other international organizations, such as the European Commission. The IAEA has also produced specific competence profiles to assist Member States in conducting systematic and harmonized assessments of competence and training needs.

2.4.4.2 Training and education for NPP operators

The relevance of education and training of NPP operators became clear in the Three Mile Island NPP accident. At that time the Kemeny Report concluded:

> "In conclusion, while the major factor that turned this incident [the failure to close of a safety valve] into a serious accident was inappropriate operator action, many factors contributed to the action of the operators, such as **deficiencies in their training**[45], lack of clarity in their operating procedures, failure of organizations to learn the proper lessons from previous incidents, and deficiencies in the design of the control room. These shortcomings are attributable to the utility, the suppliers of equipment, and to the federal commission that regulates nuclear power" [57].

One response to the Kemeny Report was the creation of INPO in the USA, which implemented a new approach to training

In 1988, INSAG published *INSAG-3: Basic Safety Principles for Nuclear Power Plants* [58], which included a principle on training of operating personnel. INSAG-3 was updated as INSAG-12 in 1999 and includes the following principle:

> "Programmes are established for training and retraining operations and maintenance, technical support, chemistry and radiation protection personnel to enable them to perform their duties safely and efficiently. Training is particularly intensive for control room staff, and includes the use of NPP simulators" [34].

INSAG-12 goes on to state:

> "Formal training of operators, maintenance, technical support, chemistry and radiation protection personnel covers such key areas of technology as neutronics, thermal hydraulics and radiation protection, to the level necessary for the task to be performed" [34].

It adds that operating personnel need to know the layout of the NPP, the locations of important components and systems and their functions and effects of their controls, and the normal line-up of NPP systems. The operator training programme includes desk studies, use

[45] Emphasis added.

of simulators, on-the-job training and NPP familiarization. There should also be continuous training with emphasis on operating experience.

In 1994, the IAEA created a Technical Working Group on Training and Qualification of NPP Personnel[46], which produced TECDOCs on training and used the systematic approach to training (SAT) concept. Those TECDOCs led to *NS-G-2.8: Recruitment, Qualification and Training of Personnel for Nuclear Power Plants* [59] in 2002.

Although training may be contracted to specialized training organizations, the licensee is responsible for training its staff and for ensuring that contractors' staffs are suitably trained. The training must follow the SAT concept, and include considerations on training settings and methods, initial and continuous training and training for emergencies. Figure 18 shows the SAT concept, which is recognized as a best practice for training.

For initial training, the SAT concept starts with the analysis of the training needs and the competence level to be achieved by each operating position, which will serve to start recruitment of candidates. The analysis then leads to the design and development of the training programme. The licensee must implement the training using qualified trainers with up-to-date training materials. For a NPP, the training facilities must include a full-scope control room simulator, as shown in Figure 19. In all cases, candidates must be assessed using appropriate evaluation methods. The regulatory body should review and in some cases accept the training programmes for key positions in the NPP. Once initial training is completed, personnel must receive refresher and update training as required.

In the USA, INPO has added another element to the SAT process: the formal accreditation of the training programmes by an independent Training Standards Accreditation Board. The Board is composed of five independent experts who review the training programme for each NPP and decides whether to accredit the programme. This formal process is conducted in accordance with the requirements established by the U.S. National Academy for Nuclear Training [60].

[46] In 2008, the Group was reorganized to focus on the management of human resources under the name Technical Working Group on Managing Human Resources in the Field of Nuclear Energy (TWG-MHR).

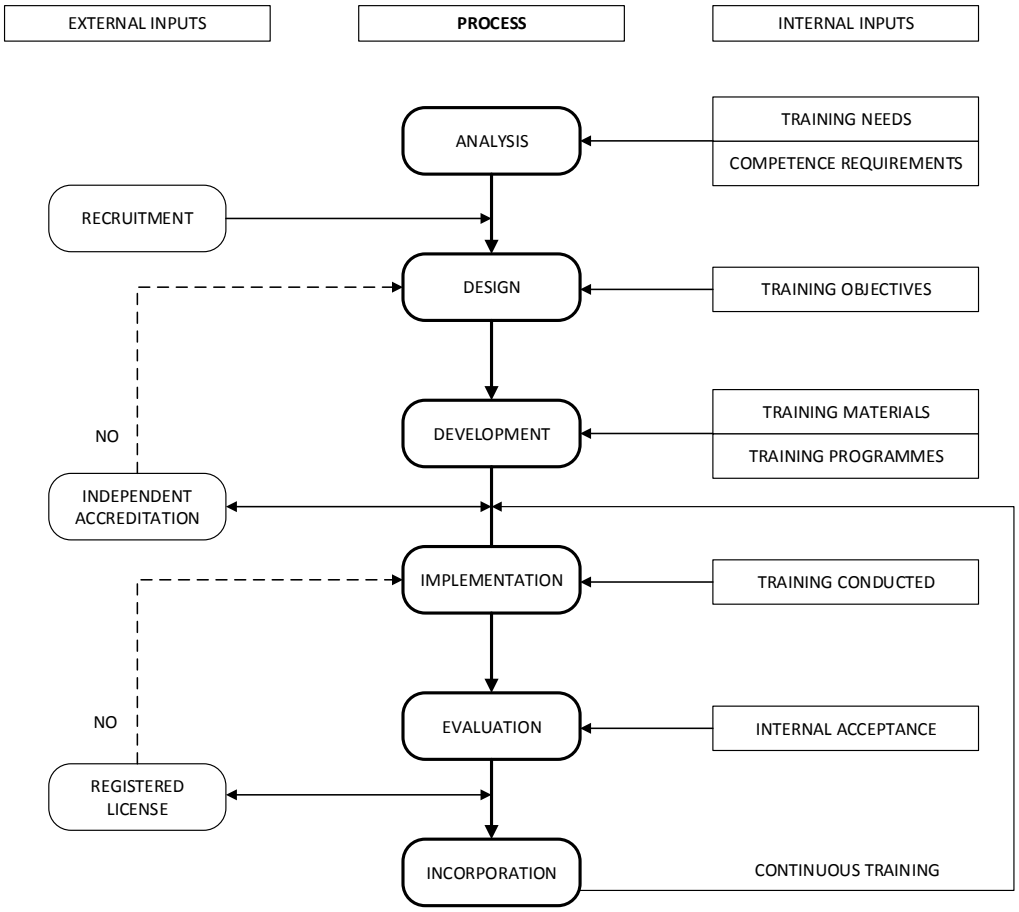


FIG. 18. Schematic representation of the SAT concept.

Various methods are available for training, including:

- **Classroom learning**: Training can be enhanced by the use of appropriate training methods, training aids and adequate training materials;
- **On-the-job training (OJT):** It should be conducted in accordance with prescribed guidelines. Progress should be monitored and assessments should be carried out by an independent assessor;
- **Training in a full scope simulator**: Initial and continuing simulator based training for the control room shift team should be conducted on a simulator that fully represents the control room. Other personnel may also benefit from simulator based training;
- **Training using mock-ups and models**: Training in mock-ups and models is very useful in maintenance and design modification activities where hazardous conditions require the work to be conducted quickly and skilfully and which cannot be practiced with actual equipment. Training mock-ups should be full scale;
- **Laboratory and workshop training:** This training will foster skills and human factor development;
- **Self-study:** The trainees should have support from a designated tutor.

The performance of each trainee should be assessed and documented. The means of assessing a trainee's ability include written examinations, oral questioning and performance demonstrations. A combination of written and oral examinations is the most appropriate form of demonstrating knowledge, while performance demonstrations are most appropriate for

evaluating skills. Simulator training sessions should include an evaluation of trainees through a debrief session.

There should be initial and continuing training. Initial training covers all of the required job competences for persons new to a position. Continuing training maintains and improves the competences of the incumbents. Operating experience and theoretical concepts in reactor physics, principles of operation of NPP systems and equipment, thermalhydraulics, NPP chemistry, reactor safety, industrial safety and radiation protection should be reviewed periodically. For control room operators, continuing training in the full scope simulator should be provided at appropriate intervals to ensure that the knowledge and understanding essential to safe and efficient NPP operation are retained and refreshed. Simulator training exercises should be planned systematically and reflect operating experience with emphasis on those situations that do not occur frequently, such as start-up, shutdown, special transients and accident conditions. Teamwork should be emphasized in dealing with incidents and accidents.



FIG. 19. Training simulator (right) must fully replicate the NPP control room (left).

A training programme for emergencies should be established to train and evaluate NPP staff and staff from external emergency response organizations in confronting and coping with accident conditions and maintaining and improving the effectiveness of the response. Regular emergency drills and exercises should be conducted to ensure that NPP staff and staff from other participating organizations possess the essential knowledge, skills and attitudes required for the accomplishment of non-routine tasks under stressful emergency conditions.

3 LEVEL B – ORGANIZATION AND MANAGEMENT OF THE REGULATORY BODY

Level A provided an overview of the international consensus that has developed regarding nuclear safety and the expectations of any national framework set up within this consensus. One of the main objectives to be accomplished under the national framework is the establishment of the regulatory body. The IAEA Safety Glossary defines regulatory body as:

> "An authority or a system of authorities designated by the government of a State as having legal authority for conducting the regulatory process, including issuing authorizations, and thereby regulating nuclear, radiation, radioactive waste and transport safety" [31].

The number of authorities which comprise the regulatory body and the relationships between them depends on the overall organization and traditions of the Member State.

GSR Part 1 (Rev. 1) Requirements 3 and 16 state respectively:

> "The government, through the legal system, shall establish and maintain a regulatory body, and shall confer on it the legal authority and provide it with the competence and the resources necessary to fulfil its statutory obligation for the regulatory control of facilities and activities" [5].

> "The regulatory body shall structure its organization and manage its resources so as to discharge its responsibilities and perform its functions effectively; this shall be accomplished in a manner commensurate with the radiation risks associated with facilities and activities" [5].

This chapter provides a consolidated view of relevant IAEA requirements and guidance pertaining to the organization and management of a regulatory body. The information provided here is applicable to the regulatory body of any Member State. However, it is recognized that influences such as culture and local practices may affect the way in which a regulatory body meets the IAEA requirements. Notwithstanding, it should remain the objective of each regulatory body to achieve a level of performance consistent with recognized international best practices.

This chapter discusses in detail:

- Constitution of the regulatory body;
- Regulatory philosophy and relationships;
- Organization of the regulatory body;
- Independence of the regulatory body;
- Documentation of the management system;
- Continuous improvement processes, benchmarking and management systems;
- Support to national processes.

3.1 CONSTITUTION OF THE REGULATORY BODY

Learning Objective 1: To understand the authorities, responsibilities and duties of the regulatory body.

Learning Objective 2: To understand issues surrounding the funding of the regulatory body.

The Oxford Dictionary defines "constitution" as a body of fundamental principles or established precedents according to which a state or other organization is acknowledged to be governed. The fundamental principles of a regulatory body come from the legislation creating the regulatory body.

At this point, a brief discussion regarding authority, right, responsibility, accountability and duty is necessary. Authority is generally defined as the power to take action. This goes beyond simple permission to include having the capability necessary to take the action. In the case of a regulatory body, this means having the needed financial, human, technical and other resources. Rights are regarded as a moral or legal entitlement to have or do something. Responsibility is the obligation to successfully complete an assigned task and being answerable for the result. The responsibilities of a regulatory body arise largely from the nuclear legislation. Accountability is being prepared to justify why actions were or were not taken, usually to whoever provided the authority and assigned the responsibility. Duty, in its simplest form, includes both responsibilities and expectations.

As an example, the nuclear legislation will assign the **responsibility** for issuing authorizations to the regulatory body. At the same time, the government will give the regulatory body the **authority** to issue authorizations by providing the regulatory body with the legal means and other resources (financial, human, technical, etc.). The regulatory body, in turn, is **accountable** to the government for the authorizations it issues (or doesn't issue). At the same, time the government may expect that the authorizations issued (or not issued) be placed in the public domain, so the regulatory body has a **duty** to do this.

3.1.1 Authorities, responsibilities and duties of the regulatory body

Typically, the regulatory body is established by the government under a legal instrument such as a law, which also confers on it the legal authority and rights necessary for the regulatory body to carry out its statutory obligations. It is not uncommon for several agencies to have responsibilities within the regulatory framework for safety. It is important that the responsibilities and functions of each agency be clearly specified in the relevant legislation and that there is appropriate coordination of and liaison between the involved agencies, in particular in areas of potential overlap.

The following authorities, responsibilities and duties should be regarded as a baseline for a regulatory body. They are based largely on GSR Part 1 (Rev. 1) [5] Requirements 3 and 4, but also reflect other IAEA Safety Standards and international good practices. Additional authorities such as the authority to charge fees for regulatory services, administrative authorities and authorities that are specific to the practices or unique to individual Member States are not covered here.

3.1.1.1 Establish and maintain a regulatory framework

The regulatory framework varies somewhat between Member States but typically consists of the enabling legislation such as the nuclear law, which is the responsibility of the government, and the regulations, guidance documents and licences, which are the responsibility of the regulatory body.

Regulations and guides provide the framework for the regulatory requirements and conditions to be incorporated into individual authorizations. They also establish the criteria to be used in assessing compliance. It is important that consistency be maintained between the regulations and the guidance documents, and that they provide attention to radiation risks in accordance with a graded approach. Typically, the law establishing the regulatory body that will specify the activities and areas for which the regulatory body is authorized to make regulations.

Regulations have the force of law and may be viewed as the operational part of legislation, commonly dealing with matters such as the procedures and processes that must be followed or standards that must be met in order to comply with the law. Regulations and guides should include the principles, requirements and associated criteria for safety that serve as the basis for regulatory judgments, decisions and actions.

The regulatory body must have the authority to establish regulations and guides to specify the principles, requirements and associated criteria for safety upon which the regulatory body's judgments, decisions and actions are based. This involves three aspects: development of the regulations and guides; reviewing and revising them to keep them up to date; and promoting them to interested parties and the public.

The development of regulations and guides should be an open and transparent process, involving consultation with interested parties and taking account of internationally agreed standards and feedback of relevant experience. The regulations of other Member States can also be a good source of information. The writing of sound regulations requires a good understanding of both the subject area of the regulations and how to formulate effective regulations. As a result, a team approach to the preparation of regulations involving both subject matter and legal experts is a common practice.

It is important that regulations and guides be reviewed on a regular basis and revised as necessary to keep them up to date. Regulatory body staff must keep themselves informed of developments at the international level (such as standards and recommendations and operating experience worldwide) to determine if changes are warranted to the existing regulations and guides. Many Member States have reviewed their regulatory requirements in light of lessons learned from the Fukushima Daiichi accident and are bringing forward proposed changes to strengthen their requirements.

The open and transparent process applies not only to the development of the regulations and guides, but extends to their promotion to interested parties and the public. These documents should be readily available to the public and promoted to the nuclear industry and the communities where nuclear installations are located. The principles and criteria for safety that are established through the regulations and guides should be highlighted to emphasize the regulatory body's commitment to nuclear safety.

More information on drafting regulations and guides is presented in Section 4.4 of this book.

3.1.1.2 Review and assess information

There are two aspects to this responsibility:

First, the regulatory body is responsible for reviewing and assessing information relevant to safety from any source (licensee, vendor, research organization or elsewhere) to determine whether installations and activities comply with:

— Regulatory requirements; and
— Conditions specified in the licence (once issued).

The review and assessment of information begins prior to initial licensing (during the application stage) and goes on over the lifetime of the installation. This means that the regulatory body is continuously reviewing submissions and information pertaining to the licenced installation, including the results of the regulatory body's own inspections, reviews and investigations. The objective is to have reasonable assurance at all times that the installation is complying with regulatory requirements and the conditions of its licence.

The regulatory body must apply a graded approach to the review and assessment of an installation. This means that the regulatory body's reviews and assessments are to be commensurate with the radiation risks associated with the installation. In other words, the regulatory body must give the most attention to those matters that have the greatest safety significance. This will maximize the effectiveness and efficiency of the regulatory review and assessment activity.

In performing its review and assessment, it is important for the regulatory body to acquire an understanding of the design of the installation and equipment, the concepts and safety philosophy on which the design is based and the operating principles proposed by the applicant. The regulatory body must be satisfied that:

— The information demonstrates the safety of the installation and the optimization of protection;
— The information confirms compliance with regulatory requirements;
— The level of safety provided by operational and technical provisions is adequate and is justified through appropriate experience, analysis and testing (or the appropriate combination thereof).

In carrying out the review and assessment, the regulatory body should take account of considerations and factors such as best practices, feedback of operating experience nationally and internationally, information from research findings, information compiled in regulatory inspections and records provided by the licensee.

Radiation risks should be assessed for all modes of NPP operation including anticipated operational occurrences, design basis accidents and severe accidents. Radiation risks should also be reassessed at regular intervals during the lifetime of the installation. The objective is to confirm that the radiation risks posed by the installation continue to be ALARA. If radiation risks can be further reduced without undue economic burden, then this should be done even if the risks are already well below regulatory limits.

The regulatory body should, where appropriate, use an integrated approach for review and assessment activities. This approach is particularly useful when the information being

reviewed covers many SSCs or areas. These reviews should include regular exchanges between reviewers to ensure that all cross boundary effects including crosslinks and common mode have been adequately taken into account. The success of an integrated review depends not only on the abilities and expertise of the reviewers, but also on effective and efficient project management of the work. This requires people with project management expertise and an experienced and knowledgeable project manager to head the project.

The results and decisions derived from reviews and assessments must be recorded and the information managed so it is easily retrievable and readily available to regulatory body staff. Subsequent regulatory actions, including any enforcement actions, should also be recorded. They should be added to or cross-referenced with the review and assessment file to facilitate easy follow-up at a later date.

More information on review and assessment is included in Section 4.2.

3.1.1.3 Issue, amend, suspend or revoke authorizations

The regulatory must have the authority to issue authorizations (licences) for the identified installations and activities, including specification of the conditions necessary for safety, subject to an adequate demonstration of safety in support of an application for a licence.

The legislation will spell out in broad terms those installations and activities that require a licence from the regulatory body, while regulations and guidance documents add detail, including criteria for safety to be met upon which regulatory decisions are based.

The regulatory body also needs to have the authority to require a licensee or an applicant to make arrangements to provide:

— All necessary safety related information, including information from suppliers, even if this information is proprietary;
— Access, solely or together with the licensee or applicant, for making inspections on the premises of any designer, supplier, manufacturer, constructor, contractor or operating organization associated with the licensee.

This will allow the regulatory body to perform a comprehensive independent assessment of the submission to obtain reasonable assurance of the safety of the installation. The regulatory body must also be able to verify the competence of individuals having responsibilities for the safety of the installation.

Normally, different licences will be used to cover the stages in the lifetime of an installation and may include site evaluation, design, construction, commissioning, operation, shutdown and decommissioning, and abandonment.

Licences are generally tailored to the installation. For example, a construction licence will focus on ensuring that the installation will be constructed in accordance with the design whereas an operating licence will focus on ensuring that the installation will be operated in accordance with the safety case.

A licence for an installation will normally include authorization of all the activities taking place at the installation. These may include the management system, human performance management (which includes training), maintenance and engineering, operations, fitness for service, radiation protection, environmental protection, emergency management and fire

protection, waste management and security. However, some regulatory bodies licence some of these activities separately (such as the management system). A licence will normally contain conditions as necessary to achieve the level of regulatory control considered appropriate for the installation.

Before a licence can be granted, the applicant is required to submit to the regulatory body sufficient information to clearly demonstrate that the safety of the installation meets all regulatory requirements. An important responsibility of the regulatory body is the issuance of guidance on the format and content of information to be submitted in support of an application for a licence. In addition, the regulatory body must provide guidance on the licensing process including a timeline with milestones for both the regulatory body and the applicant. The applicant needs to be aware that lack of adequate information in the application will result in delays.

Guidance should also be issued regarding the information required to support an application for licence renewal (such as repeated safety assessments taking into account operating experience and updated methods). The regulatory body should also make provisions for treating any proprietary information appropriately.

More information on authorization is provided in Section 4.1.

3.1.1.4 Address unregulated sources and existing situations

The regulatory body must have authority to establish regulatory requirements and criteria for protective actions to reduce undue radiation exposures and to remediate adverse conditions associated with unregulated sources (of natural or artificial origin) and contamination from past activities or events.

Radiation risks may arise in situations other than in installations that are under regulatory control. Three types of situations that may arise are:

— Radiation exposure arising from nature, such as radon gas in dwellings and workplaces;
— Radiation exposure that arises from human activities conducted in the past that were either never subject to regulatory control or that were subject to earlier, less rigorous control, such as radioactive residues from former mining operations;
— Protective actions, such as personal protective measures and remediation measures, that may need to be taken following an uncontrolled release of radionuclides to the environment.

In all of these cases, the protective actions considered have potential economic and social impact, and may entail some radiation risks (e.g. to workers carrying out such actions). As a general rule protective actions are only considered justified if they yield sufficient benefit to outweigh the radiation and other risks associated with taking them.

3.1.1.5 Conduct inspection of installations and activities

The regulatory body must have the authority to carry out inspections of any installation for which a licence is being sought, or for which a licence has been given, to verify that the licensee or applicant is in compliance with regulatory requirements and with the conditions specified in the licence. This includes access to premises, solely or together with the licensee

or applicant, for inspecting any designer, supplier, manufacturer, constructor, or operating organization associated with the licensee or applicant.

The regulatory body must develop and implement an inspection programme for installations to verify that the licensee is in compliance with the regulatory requirements and the conditions specified in the licence. The inspection programme should follow a graded approach and include both announced and unannounced inspections. The programme must be flexible to allow for reactive inspections.

Regulatory inspections do not relieve the licensee of any of its responsibilities for safety and do not substitute for the control, supervision and verification activities conducted under the responsibility of the licensee.

Results of inspections must be recorded and appropriate enforcement action taken if any non-compliance with regulatory requirements and conditions of the licence are found.

More information on inspection is provided in Section 4.3.

3.1.1.6 Enforce regulatory requirements

It is the usual practice for the nuclear law to spell out the offences under which enforcement actions may be taken and the potential penalties. These include non-compliances with regulatory requirements or with any conditions specified in a licence, and may also include offences such as:

- Knowingly making false or misleading statements to the regulatory body or an inspector of the regulatory body;
- Failure to assist or give information to an inspector when requested to do so;
- Taking disciplinary action against a person who assists or gives information to an inspector or to the regulatory body.

The regulatory body must have the authority to enforce its requirements and must establish and implement an enforcement policy, process and procedures for responding to non-compliances with regulatory requirements or any conditions specified in the licence. The policy should endorse a graded approach for responding to non-compliances.

The regulatory body must have a variety of enforcement techniques, including verbal notification, written notification, imposition of requirements and conditions, written warning, penalties and prosecution. Revocation of the licence may also be considered, but it is important that the installation remain under regulatory control, so some form of licence will always be needed.

More information on enforcement is provided in Section 4.3.

3.1.1.7 Communicate and consult

Most regulatory bodies have a responsibility to communicate and consult with interested parties. Good communications, with openness and transparency, is an important way of establishing trust.

As the regulatory body goes about conducting oversight of installations and activities, there is always a need to liaise with licensees to achieve common objectives in ensuring safety.

Meetings are often held to promote understanding of regulatory positions and decisions, and to discuss the arguments of each party on safety related issues, and inspectors often have discussions with workers in the field.

Liaison activities reach across all levels of the regulatory body and licensees. They should always be carried out in a professional and constructive manner with the objective of fostering mutual understanding and respect between the regulatory body and licensees. A good practice is for the regulatory body to clearly enunciate the ground rules for these liaison activities and to establish protocols for the different types of communications between the regulatory body and licensees. This will also ensure that liaison activities are conducted in such a manner that the independence of the regulatory body is maintained.

More information on communicating with the public is included in Section 4.6 of this book.

3.1.1.8 Disseminate information

Most regulatory bodies have the authority and responsibility for disseminating objective scientific, technical and regulatory information to the public concerning the activities of the regulatory body and the effects, on the environment and on the health and safety of persons, of the installations that the regulatory body licenses. This involves disseminating information that is objective, clear and easily understandable to the public. The timely communication of information regarding unplanned events and accidents is also crucial to the regulatory body maintaining credibility and public confidence. A good communication plan that takes into account communications with all interested parties is an essential part of today's regulatory body.

3.1.1.9 Structure and manage organization

The regulatory body will have the authority and responsibility to establish its organizational structure and regulatory management system to:

- Ensure that the responsibilities assigned to the regulatory body are properly discharged;
- Maintain and improve the performance of the regulatory body by means of planning, control and supervision of its activities;
- Foster and promote a strong safety culture.

GSR Part 1 (Rev. 1) [5] Requirements 16 to 22 refer to the organization of the regulatory body and recognize the relevant characteristics that it should have and maintain.

Section 3.3 provides more detail on the organization of the regulatory body.

3.1.1.10 Hire and retain regulatory body staff

The government must provide the regulatory body the authority and sufficient resources to hire and retain a sufficient number of competent regulatory staff. The regulatory body, in turn, is responsible for ensuring that its staff has the competence necessary to perform the work of the regulatory body. The regulatory body must be able to employ such professional, scientific, technical or administrative staff as may be necessary to carry out the statutory obligations of the regulatory body.

This includes recruitment and training of staff, as well as effective knowledge management to maintain the competence and skills necessary to discharge the regulatory body's

responsibilities effectively and efficiently. Knowledge management is the process of capturing, distributing, and effectively using knowledge and includes keeping records of activities such as the review and assessment of licence applications, deliberations pertaining to licensing decisions including the reasons for decision, inspections and their findings, enforcement actions, and the review and assessment of various licensee submissions.

3.1.1.11 Require a financial guarantee

GSR Part 1 (Rev. 1) [5] states that the government is required to set out the responsibilities and obligations for funding the management of radioactive waste and of spent fuel, and for decommissioning of installations. In some Member States this responsibility is passed to the regulatory body. In this case the regulatory body is responsible for ensuring that the licensee has made adequate financial provision to ensure the completion of activities required to terminate activities and remediate the licensed location, including decommissioning costs and the costs associated with the disposal of any associated nuclear substances.

3.1.1.12 Conduct proceedings

The regulatory body requires the authority to call meetings as required to address issues that fall under its control.

3.1.1.13 Establish appeal process

An applicant or licensee should have the right to appeal any decision of the regulatory body relevant to the application or licensee. The appeal process should be clearly documented and readily available to all interested parties. The details of the process will depend upon the legislative arrangements and practices in the Member State.

3.1.1.14 Keep records

Licensees are responsible for establishing and maintaining retrievable records of their installations and activities. The regulatory body provides oversight to ensure that the records meet regulatory requirements and that there is adequate reporting of information to the regulatory body to support its regulatory functions and the enforcement of regulatory requirements.

A regulatory body must also keep records of its regulatory activities, both for future reference and for training of staff. This activity is part of knowledge management for the regulatory body.

3.1.1.15 Enter into contracts

This authority allows the regulatory body to enter into contracts with experts or consultants to obtain assistance on any matter pertaining to the responsibilities of the regulatory body. For example, expert advice may be sought to review an area of a safety assessment where the regulatory body does not possess detailed knowledge.

3.1.1.16 Establish committees

This authority allows the regulatory body to stipulate the terms of reference of any committee it may establish. This may include topics such as the mandate of the committee, organization and operation of the committee, membership, the bounds of operation, duration (temporary or

permanent), communications with the regulatory body, and the need to provide independent advice.

3.1.1.17 Make bilateral arrangements

The regulatory body must have the authority to institute memoranda of understanding (MoUs) and appropriate communication and regular meetings with other agencies with responsibilities for safety within the regulatory framework to spell out coordination and liaison activities.

MoUs serve to clarify the role and responsibilities of each agency where some overlap of responsibilities and functions exist. For example, both the regulatory body and the government agency responsible for worker safety may have responsibilities for worker safety at a NPP. MoUs can serve to make clear which aspects of worker safety are under each of the agencies and can assist in achieving consistency. Examples of areas where this may apply include:

- Safety of workers and the public;
- Protection of the environment;
- Emergency preparedness and response;
- Applications of radiation in medicine, industry and research;
- Management of radioactive waste;
- Nuclear security;
- Land use and planning;
- Safety in the transport of dangerous goods, including nuclear material and radioactive material;
- Mining and processing of radioactive ores;
- Controls on the import and export of nuclear material and radioactive material.

Bilateral arrangements with other governments and international agencies are encouraged as they can be very helpful to regulatory bodies for reasons such as the following:

- Provide the means for the ready exchange of information with other regulatory bodies and international agencies (for example, safety issues on similar designs, inspection programmes and detailed inspection plans);
- Provide international contacts for obtaining assistance on nuclear related matters (for example, the regulatory response to particular inspection findings);
- Promote involvement and contribution of the regulatory body at the international level (for example, participation in international working groups assessing, from a regulatory perspective, worldwide trends in NPP events).

3.1.1.18 Participate in international activities

The regulatory body must have the authority to participate, and usually represents the Member State, in the Global Nuclear Safety Framework. This includes participating in the various conventions, peer reviews, expert missions and IAEA and OECD/NEA committees and working groups.

International obligations include conventions such as the CNS. International arrangements include bilateral agreements with other Member States and participation in international

committees and working groups such as IAEA standards committees and OECD/NEA working groups. International peer reviews include activities such as IRRS and OSART missions. The promotion of international cooperation includes assisting other regulatory bodies (for example, sharing of information through bilateral agreements), participating as experts in IAEA workshops, and participating in international conventions and workshops pertaining to nuclear safety.

3.1.1.19 Perform a regular review of licensed installations and activities

The regulatory body has the responsibility for the regular review of the safety performance of licensed installations. For large installations such as an NPP, this review should be done annually to evaluate how well licensees are meeting regulatory requirements, conditions of the licence, and regulatory expectations for the performance of programs that are important to maintaining the safety of the installations. The review should be based on information gathered throughout the previous period through regulatory body oversight activities including monitoring, inspections, event reviews, general surveillance, document assessments, and performance indicators. Results are compared to previous years, and lessons learned and trends in the nuclear industry are identified. The review should be documented and made available to the public and licensees.

3.1.1.20 Obtain advice

Most regulatory bodies have the authority to, and many have, established advisory bodies or technical committees to obtain independent expert advice. It is important to remember that obtaining advice or assistance from outside the regulatory body does not relieve the regulatory body of its responsibility for regulating the nuclear industry.

When advice or services are sought from outside organizations or experts external to the regulatory body, the regulatory body must be sure that no conflict of interests. For example, the regulatory body should avoid using an organization that also advises a licensee, unless clear rules are established. Should the regulatory body decide to establish a dedicated support organization, the regulatory body must set clear limits on the degree of control and direction by the regulatory body over the work of the support organization. This will ensure that the support organization has sufficient latitude to pursue investigations to the point where it can give definitive and independent advice.

3.1.1.21 Ensure that regulatory control is stable and consistent

The regulatory body must conduct its business in such a manner that regulatory requirements are stable and that regulatory decisions are consistent. All licence applications must be treated in a fair, equitable and consistent manner and all decisions must be objective, made in an open and transparent decision making process, and include the reasons for the decision.

To achieve this, the regulatory body should establish:

- A formal regulatory process that is based on policies, principles and associated criteria, and that follows specified procedures as established in the management system;
- A decision making process that is open and transparent;
- A process for changing regulatory requirements which is open and transparent and includes consultation with interested parties.

Documented regulatory requirements and guidance and a sound decision making process will help in ensuring a stable and consistent regulatory control. Regulatory stability and consistency also depend, to a large extent, on competent regulatory staff.

3.1.1.22 Advise government

The regulatory body has a duty to advise the government on the nuclear safety implications of any proposed or actual changes in government policy or direction. The regulatory body must also advise the government and competent authorities regarding the preparation of an emergency response plan, and in the event of an emergency, to provide expert services in accordance with the responsibilities assigned to the regulatory body. The expert services may include services for radiation monitoring and risk assessment for actual and expected future radiation risks.

During an emergency the regulatory body is expected to assemble its own emergency response team that will monitor the situation and be available to issue any authorizations that may be needed in accordance with the emergency procedures of the installation. The regulatory body undertakes communications with the public or provides information to the agency responsible for communicating with the public.

3.1.1.23 Report to public and government

The regulatory body is accountable to the government and the public for discharging its responsibilities in an effective and efficient manner. The regulatory body has a duty to report annually to the government and the public on its performance the previous year. This should include its activities and achievements, the state of the safety of licensed installations and activities, future plans and its financial position and operating results.

3.1.1.24 Promote compliance

The regulatory body has a duty to promote compliance with its requirements. In this way, applicants and licensees will have a good understanding of the regulatory requirements that apply to the licenced installation, the regulatory expectations for achieving compliance, and the consequences of non-compliance.

3.1.1.25 Share experience

The regulatory body must exchange information with other regulatory bodies and relevant international bodies on operating experience and regulatory experience, and on events and good practices and any corrective actions taken, and keep informed on other relevant international developments. Exchange channels such as the IRS, discussed in Section 2.3.7, can be used to facilitate such exchange of information.

The feedback of relevant information to licensees, in particular regarding events, lessons learned, and corrective actions taken, is also a part of this duty.

3.1.2 Regulatory body funding

Funding should permit the regulatory body to fully and effectively comply with its regulatory responsibilities. Funding must cover the necessary expenses for offices and office equipment, the staff salaries, communication, transport, inspection equipment and training. Funding is also necessary to cover the cost of participating in national and international safety and

security related research and development programmes, consultancy services and participation in lateral and bilateral agreements with regulatory bodies in other Member States.

The regulatory body may be funded entirely from government resources or from recovering costs from applicants and licensees, or a combination of both. In any case, the regulatory body must be held accountable by the government for its expenditures.

Any funds coming from enforcement actions should be directed to the government and not the regulatory body.

3.2 REGULATORY PHILOSOPHY AND RELATIONSHIPS

Learning Objective 1: To understand the typical characteristics of a competent regulatory body.

Learning Objective 2: To understand why a regulatory body must use a graded approach

Learning Objective 3: To understand the prescriptive and performance based regulatory approaches.

Learning Objective 4: To understand the term "licensing basis".

Learning Objective 5: To understand the need for and basic elements of the regulatory body's inspection philosophy.

Learning Objective 6: To understand the need for and basic elements of the regulatory body's assessment philosophy.

Learning Objective 7: To understand the need for and basic features of the regulatory body's decision making process.

Learning Objective 8: To understand the relationships that a regulatory body should establish with licensees and with other related companies or organizations.

Regulatory philosophy can be regarded as a general expression of the way the regulator intends to apply the nuclear law and regulations in the oversight and regulation of nuclear installations. The legal framework addresses the process for decision making, whereas the regulatory philosophy indicates the direction the regulatory body will take in its decision making.

It is important for the regulatory body to clearly articulate its regulatory philosophy so that its staff, applicants, licensees and the public have a clear understanding of how the regulator intends to regulate the nuclear industry. Regulatory bodies around the world have used policy statements, regulatory publications and public papers and presentations to present their regulatory philosophies and a standard approach does not exist.

The regulator needs to show that it is serious about safety but not unreasonable in its demands. It needs to listen to interested parties, but clearly show its independence in its regulatory decision making. The regulator needs to be transparent so that the public can see how the regulatory body is addressing its responsibility, yet recognize the proprietary nature of some of the information it receives in support of applications and compliance activities.

3.2.1 Need and benefit

The regulatory body exists to ensure that those using nuclear energy or material do so without undue risk to the health and safety of persons or the environment throughout the entire lifetime of the installation. The regulatory body defines the requirements necessary to ensure an adequate level of safety, then licenses those applicants that have demonstrated that they can meet those requirements. The regulatory body then ensures compliance with the requirements and takes action in case of non-compliance. The regulatory body provides

society with the assurance that installations do not pose an unreasonable risk to people and the environment.

3.2.2 Characteristics

The characteristics of a competent regulatory body are similar to those of any successful organization. The following is not a comprehensive list, but rather an overview of some of the characteristics of any competent regulatory body. Many of these characteristics are discussed in other sections.

3.2.2.1 Clear mandate, purpose and goals

For a regulatory body, the mandate and purpose will come from the nuclear law. To fulfil that mandate, the regulatory body must then establish goals and a vision and share these with staff. To the extent possible, staff should be involved in the development of the goals and vision.

The regulatory body must also be structured in a way that every part of the organization is assigned specific aspects of the mandate, purpose and goals so there is complete coverage with no overlap. In a strong regulatory body, grouping of functions and jobs allows consultation and coordination without delay or difficulty.

3.2.2.2 Strong safety culture

It may be obvious, but a competent regulatory body must have a strong safety culture so that nuclear safety issues receive, as an overriding priority, the attention they deserve. Safety culture is not a separate management entity or feature of the regulatory body, but rather the attitudes and behaviour of all individuals in relation to safety. It is integrated into the regulatory body's management system and permeates all of its activities with a "safety first" approach. Figure 20 illustrates the presentation of safety culture.

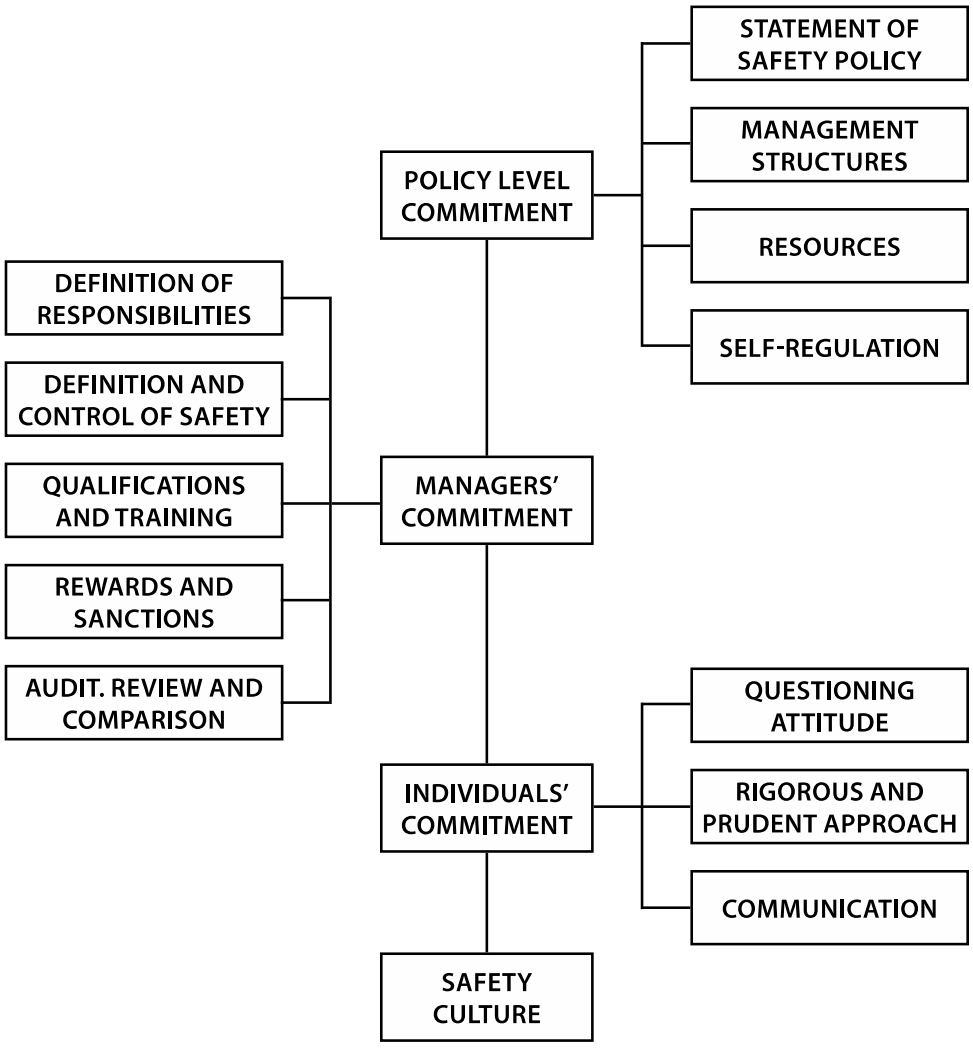


FIG. 20. Illustration of the presentation of safety culture [37].

A strong safety culture includes:

— Individual commitment to safety through personal accountability and communication;
— Management commitment to safety through leadership accountability, decision making and a respectful work environment;
— Measures to encourage a questioning and learning attitude at all levels of the organization, and to discourage complacency with regard to safety;
— A management system that provides continuous training, problem identification and resolution, an environment for raising concerns and effective work processes.

3.2.2.3 Alignment of responsibility, authority and accountability

A good regulatory body is structured in such a way that everyone in the regulatory body understands their responsibilities. Closely associated with this is that everyone also has the authority to do what is necessary to fulfil their responsibilities. To complete the alignment, everyone in the regulatory body is then held accountable for achieving their responsibilities. When there is alignment in the organization, there is a high probability that all goals of the regulatory body will be achieved.

3.2.2.4 Competent staff with high morale

A regulatory body is only as good as its staff. Regulatory body staff must not only have strong technical skills, they must understand the nuclear law and regulatory requirements and the techniques that the regulatory body uses. Many of the knowledge and skills staff need are unique to the regulatory body, which means that the regulatory body must establish a staff development programme. This includes training in not just the specific functions of the regulatory body and the needed scientific and technical knowledge, skills and abilities, but also the regulatory philosophy.

Each staff member should have a personal development program that provides a continuous program of training and development. Staff members must be given development opportunities to acquire new knowledge, skills and abilities, including job assignments to other parts of the regulatory body and participation in external meetings, conferences and workshops.

The regulatory body must also provide training and development opportunities for managers and future managers. The knowledge, skills and abilities required to lead are different from those required of staff members.

3.2.2.5 Forward looking—while understanding its past

The regulatory body should strive to be on the forefront of new ways of doing business to improve its effectiveness and efficiency. In addition, the regulatory body should always be analyzing emerging trends that may impact the organization: the trends in the nuclear industry; in the thinking of the government and the public; and in global events. Some regulatory bodies carry out annual reviews to consider potential improvements to business models in view of changing interested party views and new technologies, and the implications for the regulatory body of regional, national and global events and views.

At the same time, the regulatory body must remember how it got where it is. As the regulatory body implements new techniques, it must understand what impact, if any, these changes will have on previous decisions and activities.

3.2.2.6 Flexible and adaptable

Many of the demands on the regulatory body are driven by industry. For example, the regulatory body's staffing depends on the plans of the industry. If new projects are started, the regulatory body will first need expertise in siting and environmental assessments, followed by design and construction, and then operation and decommissioning. As the industry goes through the siting, design, construction, operation and decommissioning of installations, the regulatory body must be flexible and adapt by acquiring new skills and changing its organization as necessary.

3.2.2.7 A learning organization

A strong regulatory body is constantly learning from its own experiences as well as the experiences of others, including licensees and other regulatory bodies. It will also look beyond the nuclear industry to other industries that require high reliability to ensure safety, such as the aviation industry. The learning goes beyond just analyzing the experiences to include making changes as necessary.

The regulatory body must have a programme for independent research in support of its regulatory program. The regulatory body may manage the research programme itself, or it may participate in joint research projects with other regulatory bodies. The regulatory body should also participate in bilateral, regional and international activities with its counterparts in other Member States.

3.2.2.8 Independent

The regulatory body must, and must be seen to be, independent of proponents of the nuclear industry. The regulatory body cannot be completely independent of government, but it must be able to take decisions under its statutory mandate without undue pressure or constraint.

3.2.2.9 Consistent

A strong regulatory body establishes clear requirements that apply equally to all interested parties and it enforces these requirements consistently. Closely associated with this is the concept of being firm but reasonable. The requirements that the regulatory body establishes must be line with the graded approach and not be unduly harsh or restrictive. Once established, however, the regulatory must be firm that all licensees meet them.

3.2.2.10 Open and transparent

A strong regulatory body operates in an open and transparent manner. Openness is providing information to interested parties while transparency can be described as operating in a way that allows interested parties to understand how decisions are made.

Effective internal and external communications are essential for a successful regulatory body. Communications must be clear and unambiguous and take account of the needs and expectations of all parties.

3.2.3 The graded approach

Regulatory body activities must be carried out commensurate with the radiation risks associated with the installation; using a graded approach. Application of a graded approach by the regulatory body focuses the way that an installation and its activities are assessed, licenced and inspected on the basis of risks, without unduly limiting the licensee. The regulatory body should use a graded approach in all its activities.

The regulatory body must consider the magnitude of the risks associated with the installation, including occupational doses, radioactive discharges and the generation of radioactive waste during operation, as well as the probabilities and potential consequences of anticipated operational occurrences and accidents. The graded approach should also take account of other relevant factors such as the maturity of the licensee organization and complexity and ageing related issues pertaining to the installation.

The application of the graded approach should be reassessed periodically, to ensure that new knowledge is properly taken into account. This reassessment may result in changes to the scope, extent and level of detail of, and the effort devoted to, regulatory body activities.

3.2.4 Prescriptive and performance based approaches

A prescriptive regulatory approach places a great deal of importance on the adequacy of the regulations for safety and requires detailed development. Detailed regulations establish exactly what the applicant or licensee must do, either by setting deterministic requirements or by identifying issues that the licensee must address and present for assessment. Specific technical requirements are then taken from relevant international or national industrial standards, or industrial standards of other Member States, as agreed by the regulatory body. Issuing detailed regulations requires extensive regulatory body resources for their development and updating.

A performance based (non-prescriptive) regulatory approach allows the licensee more flexibility in determining how to meet the established safety objectives. Fewer and less detailed regulations are required, but this approach requires the establishment of specific safety goals and targets. The regulatory body's main task is to verify that the licensee has identified and implemented appropriate measures to ensure safety. Two licensees may develop two different, yet equally effective, ways of meeting the safety objective. As a result, regulatory body staff must have the knowledge and skills to assess these different approaches.

In most cases, a regulatory body uses a combination of both prescriptive and performance based approaches. No regulatory body wants to be so prescriptive that it takes away the primary responsibility for safety from the licensee. On the other hand, no regulatory body can rely entirely on performance based requirements for nuclear safety. Some regulatory bodies may be more prescriptive, while others may be more performance based.

In the past the regulatory body of the importing Member State tended to adopt the regulatory philosophy of the regulatory body of the exporting Member State. This led to the concept of "reference NPP design" where the new NPP was twinned with an existing licensed NPP in the exporting Member State to ensure the same safety features and safety assessments would apply to the imported NPP. Recently, many Member States have begun adopting technology neutral requirements that can be applied to any NPP design (mainly based on IAEA safety standards). This gives Member States more flexibility in the selection of its regulatory philosophy. As a result, there are situations where a NPP vendor is facing a different set of licensing requirements and different regulatory approach in different Member States. In 2006, the OECD/NEA established the Multinational Design Evaluation Programme (MDEP) to attempt to reach consensus among regulators on regulatory requirements for specific new designs.

3.2.5 Licensing basis definition

The licensing basis consists of various elements. One element consists of the regulatory requirements that are set out in the applicable laws, regulations and regulatory documents. Another element is the demonstration by the applicant that all the regulatory requirements are satisfactorily met for the installation under consideration. Once the regulatory body agrees, it will issue a licence, which will include a number of conditions. This licence, with any conditions, then also forms part of the licensing basis. Any changes to the design, safety analysis or operation of the installation that could render invalid claims made or conclusions given in the licensing basis will require the approval of the regulatory body prior to implementation.

The licensing basis is maintained by ensuring that the demonstration of safety is updated in response to changes in regulatory requirements and changes to the design, safety analysis or operation of the installation.

3.2.6 Inspection philosophy

The regulatory body must carry out inspections of installations to verify that the licensee is in compliance with the regulatory requirements and with the conditions specified in the licence. The inspection philosophy indicates the way the regulatory body will carry out inspections and conduct various activities associated with the inspection function. The inspection philosophy must align with the nuclear legislation to ensure inspections are legally supported and that regulatory actions in the event of non-compliance findings are enforceable.

Suggestions for inclusion in the inspection philosophy are given below. This list should not be regarded as complete, but serves as a reference to assist a regulatory body in drafting or updating its inspection philosophy. The inspection philosophy must suit the needs of the Member State and the regulatory body.

3.2.6.1 Inspection programme

The inspection philosophy should state that inspections of installations will be carried out to verify that the licensee is in compliance with the regulatory requirements and the conditions specified in the licence. The philosophy should also state that inspections will cover all areas of responsibility of the regulatory body including the activities of suppliers of services and products to the licensee. The inspection programme should take a proactive approach to the identification and correction of issues that could lead to future accidents. This will make it clear that the regulatory body will carry out inspections as part of its regulatory oversight activities. In addition to inspecting current performance, inspections should also examine trends and other parameters which may give an indication of future performance.

3.2.6.2 Responsibility for safety

The inspection philosophy must clearly state that inspection by the regulatory body does not relieve the licensee of its prime responsibility for ensuring nuclear safety.

The licensee retains the prime responsibility for safety, no matter what activities are undertaken by the regulatory body or any other organization. As a general rule, the licensee cannot take credit for regulatory inspections toward fulfilling the requirements of its own inspection programme.

3.2.6.3 Graded approach

The inspection philosophy should state that inspections will be commensurate with the radiation risks associated with the installation, in accordance with a graded approach.

This means that the regulatory body will inspect an installation in proportion to the radiation risk posed to the public or environment. Even within an installation, the inspection program activity must be commensurate with the importance to nuclear safety associated with the activity or SSC. SSCs with high safety significance will receive considerably more attention than less safety significant SSCs.

There can be significant variation between Member States as to the scope and depth of inspections necessary to verify compliance. There are many factors that can contribute to this such as the maturity of the nuclear industry and cultural norms in the Member State. The regulatory body may wish to highlight these factors in the inspection philosophy.

3.2.6.4 High level of assurance

The scope and depth of regulatory inspections has to be to the extent necessary to provide a high level of assurance that licensed installations are in compliance with the regulatory requirements and the conditions of the licence. The inspection philosophy should expand on this statement by describing what the regulatory body understands to be a "high level of assurance".

3.2.6.5 Enforcement approach

The inspection philosophy should outline the regulatory approach to enforcement in response to non-compliance with regulatory requirements or any conditions specified in the licence. The approach should be objective and evidence based, according to the safety significance of the non-compliance. The safety significance of a non-compliance can increase if, for example, there is a recurrence of the non-compliance or if there are many of the same non-compliances occurring in different areas of the installation at the same time.

Enforcement actions by the regulatory body may include recorded verbal notification, written notification, imposition of additional regulatory requirements and conditions, written warnings, penalties and ultimately revocation of the licence. Regulatory enforcement may also entail prosecution, especially in cases where the licensee does not cooperate satisfactorily in the remediation or resolution of the non-compliance. The inspection philosophy should clearly explain the regulatory body's graduated response to non-compliances.

3.2.6.6 Inspection types

The inspection philosophy should include programmed (planned) inspections and reactive inspections; both announced and unannounced.

Section 4.3 of this book provides a complete discussion on the types of inspections that a regulatory body can use.

3.2.6.7 Inspection programme

The inspection philosophy should require the development and implementation of a programme of inspection activities that includes the inspections that will be carried out (areas and programmes to be inspected), the types of inspections, and the frequency of inspections. The frequency of inspections should take account of the licensee's own processes to the extent that they have been demonstrated to be effective in monitoring compliance and correcting non-compliances with regulatory requirements and the conditions of the licence.

The objective of the inspection programme is to determine those inspections and frequencies necessary to gain a high level of assurance that licensed installations are in compliance with their licence and licensing basis.

3.2.6.8 Sharing of information

The inspection philosophy, programme, and procedures should be shared with licensees and the public. It is important that the licensee understand how the regulatory body will assess its performance. Making this information available to the public will promotes public confidence in the regulatory process and the safety of nuclear installations and will add to the credibility of the regulatory body.

3.2.6.9 Coordination of inspections activities

The inspection philosophy should require that inspections with significant overlap be coordinated to reduce or eliminate the overlap and improve efficiency. Inspections of the same area but for somewhat different purposes may benefit from being conducted simultaneously. This allows two expert groups to work together and produce an overall more effective inspection.

3.2.6.10 Inspection and enforcement results

The inspection philosophy should require that the results of inspections and any resulting regulatory actions (such as enforcement) will be recorded and made available to the licensee and the public.

This promotes public confidence in the regulatory process and the safety of nuclear installations. It also adds to the credibility of the regulatory body.

3.2.6.11 Interested party engagement

The inspection philosophy should encourage interested party engagement to promote understanding of the regulatory approach and methods, and to provide a forum for dialogue to further enhance the effectiveness and efficiency of the regulatory inspection programme. Engagement keeps the interested parties informed of the regulatory body's approach and methods and gives interested parties the opportunity to feedback their perspectives.

3.2.6.12 Use of contractors

The inspection philosophy should discuss how contractors will be used when the inspection demands cannot be met by regulatory staff or when regulatory staff does not possess the expertise required for a particular inspection. Contractor inspection activities should be under the supervision of regulatory staff.

3.2.6.13 Inspections by others

The inspection philosophy should allow the regulatory body to credit the inspections conducted by other regulatory agencies provided that the inspections meet or exceed the standards of the regulatory body.

3.2.6.14 Resident and non-resident inspectors

The inspection philosophy should address whether the regulatory body will use resident inspectors.

Resident inspectors may provide benefits such as improving the ability of the regulatory body to engage in on-site surveillance of SSCs, tests, processes and other licensee activities at any

time. The full time presence of inspectors may also help to discourage complacency or non-compliance on the part of the licensee and can improve the ability of the regulatory body to identify and respond promptly to problems. With resident inspectors, the frequency and intensity of inspections can be more readily optimized, and the regulatory body will be better able to coordinate its inspection activities with key licensee activities.

An important factor to consider when establishing a resident inspection office is maintaining regulatory independence from the licensee. There are two considerations here:

The first consideration is the physical separation of the resident inspector office from the licensee staff. Generally, the licensee will provide the space, physically separated from the licensee's staff, while the regulatory body will provide the necessary administrative assistance and equipment. The second consideration is ensuring that resident inspectors maintain their objectivity and avoid regulatory capture. This is best achieved by staffing the resident inspection office with at least two and preferably three (for a single reactor unit) resident inspectors and by considering limiting the term of a resident inspector at any one installation.

Another factor to be considered is the physical distance between the non-resident inspectors and the installation. This has implications for resources in terms of costs, inspectors' time and the time for response to unforeseen circumstances. The use of resident inspectors may also be dependent on the extent to which outside consultants or dedicated support organizations are contracted by the regulatory body to perform inspections. The responsibilities and practices of both resident and non-resident inspectors should be defined in a manner that does not diminish the licensee's responsibility for safety.

Non-resident inspectors, in general, are attached to the regulatory body head or regional office. Typically, their major job is to prepare and conduct planned inspections, and to conduct reactive inspections or assist resident inspectors when needed. In some cases they may be involved in review, assessment and licensing when not performing inspections. Non-resident inspectors may be assigned to inspect more than one installation, which may be a more efficient use of limited resources. Alternatively, a non-resident inspector may be assigned to a particular installation and may coordinate inspection activities at that installation. A non-resident inspector is less likely to feel isolated from the activities and decision making of the regulatory body.

3.2.7 Assessment philosophy

GSR Part 1 (Rev. 1) Requirement 25 states:

> "The regulatory body shall review and assess relevant information—whether submitted by the authorized party or the vendor, compiled by the regulatory body, or obtained from elsewhere—to determine whether facilities and activities comply with regulatory requirements and the conditions specified in the authorization. This review and assessment of information shall be performed prior to authorization and again over the lifetime of the facility or the duration of the activity, as specified in regulations promulgated by the regulatory body or in the authorization" [5].

Requirement 26 states:

> "Review and assessment of a facility or an activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach" [5].

The regulatory body will make decisions regarding the safety of installations on the basis of assessments of information submitted by licensees or applicants. The assessment philosophy indicates how the regulatory body will carry out these assessments. The assessment philosophy must align with the regulatory requirements and conditions of the authorization to ensure assessments are valid and well founded, and that corrective actions in the event of non-compliance are enforceable.

The following should be considered for inclusion in an assessment philosophy. They are based largely on IAEA requirements and guidance. The suggestions provided should not be regarded as complete, but rather to serve as a reference to assist a regulatory body in drafting or revising its assessment philosophy. The regulatory body must create an assessment philosophy that meets its needs.

3.2.7.1 Relevant information

Relevant information—whether submitted by the licensee or the vendor, compiled by the regulatory body, or obtained from elsewhere—should be assessed to determine whether installations comply with regulatory requirements and the conditions specified in the licence, and with relevant objectives, principles and associated criteria for safety.

This assessment of information should be performed prior to licensing and again over the lifetime of the installation, as specified in the regulations or the licence.

3.2.7.2 Decisions relating to safety

Decisions relating to safety should be made on the basis of the assessment of the licensee's submissions, the studies and evaluations performed independently by the regulatory body itself, and the safety objectives and specific requirements established by the regulatory body.

Regulatory body decisions may include judgment by technically competent persons on the basis of regulatory requirements and operational experience.

3.2.7.3 Graded approach

The assessment should be appropriate to the stage in the regulatory process under consideration and will follow a graded approach, commensurate with the radiation risks associated with the installation.

The regulatory body should assess licence applications and other documents submitted by the licensee or applicant to determine if the proposed safety measures are technically and scientifically sound, and to determine if the installation complies with the relevant objectives, principles and associated criteria for safety.

3.2.7.4 Assessment of radiation risks

All radiation risks associated with normal operation, anticipated operational occurrences and accident conditions of the installation should be assessed prior to operation and periodically during the lifetime of the installation to determine whether radiation risks are ALARA.

3.2.7.5 Review of proposed modifications

Any proposed modifications that might significantly affect the safety of the installation should be subject to review and assessment.

3.2.7.6 Guidance for submissions

The regulatory body should make available to applicants, licensees and the public guidance for submissions pertaining to the stages of the regulatory process.

The regulatory body should provide documented guidance to applicants and licensees for the information to be submitted for each of the stages of the regulatory process. This guidance is very helpful in ensuring that all the information the regulatory body needs is included in the initial submission, reducing the possibility of delays in the assessment.

3.2.7.7 Documented acceptance criteria

The acceptance criteria including safety objectives and regulatory requirements used for assessments should be documented and available to applicants, licensees and the public.

3.2.7.8 Safety targets

Safety objectives and regulatory requirements will specify safety targets for levels of safety performance in the protection to be achieved at the installation.

3.2.7.9 Safety objectives and requirements

The regulatory body should develop safety objectives and requirements itself or it may adopt objectives and requirements that have been developed and issued by international organizations or by regulatory bodies in other Member States.

If safety objectives and requirements are taken from another Member State, the regulatory body must have a good understanding of their basis, use and effectiveness, and may need to adjust them for the specific situation.

3.2.7.10 Expert advice

The regulatory body may obtain technical or other expert professional advice or services as necessary in support of its regulatory functions, but this does not relieve the regulatory body of its assigned responsibilities.

Depending upon the organization and resourcing of the regulatory body, the assessment may be conducted entirely by regulatory staff, or by some combination of regulatory staff and other expert professional advice or services.

3.2.7.11 Needed expertise and conflicts of interest

When external support is contracted, arrangements should be made to ensure that there is no conflict of interest for those organizations and contractors that provide the regulatory body with advice and services.

If this is not possible domestically, then the regulatory body should consider obtaining advice or assistance from organizations in other Member States or from international organizations.

The regulatory body must always have the necessary expertise to assess advice provided by advisory bodies, information submitted by licensees and applicants and results of assessments performed by outside organizations.

Information contained in submissions and safety analysis should be verified to the extent necessary for the regulatory body to gain reasonable assurance that the information submitted by the applicant or licensee is sufficiently complete, detailed and accurate to demonstrate the safety of the installation, the optimization of protection, and that all regulatory requirements and all relevant objectives, principles and associated safety criteria have been met.

Much of the effort that the regulatory body will need to expend in the assessment process will be concentrated on the performance of a step by step procedure to determine whether the applicable safety objectives and requirements for each topic have been met. This stage of the process consists of examining the submissions from the licensee on its managerial arrangements, engineered systems, operational procedures and the safety analysis. This safety analysis should assess normal operation, anticipated operational occurrences and postulated accidents to demonstrate the safety of the installation meets the safety objectives and regulatory requirements. The regulatory body must determine whether these submissions have provided a sufficiently complete, detailed and accurate demonstration. In carrying out the assessment, the regulatory body may find it useful to perform its own analyses or research. This in no way compromises or diminishes the applicant or licensee's responsibility for the safety.

The regulatory body should also verify claims made in the documentation by the appropriate inspections of the installation. These inspections also allow the regulatory body to supplement the information and data needed for the assessment, as well as gain a better understanding of the installation and its management and operation. The staff of the regulatory body who carry out assessment should be able to visit the licensee's site and if necessary contractors' establishments.

The regulatory body may find that there are instances where the current safety knowledge for existing or proposed installations is insufficient. In these cases, the regulatory body should encourage the applicant or licensee to carry out the necessary research and development work to extend the understanding of safety related issues. The regulatory body should only accept a safety submission that is supported by sufficient technical arguments and should always require the applicant or licensee to justify the assumptions made and data used.

The regulatory body may decide to initiate research and development work where it considers that there is a need for additional studies beyond those already undertaken. There may also be situations where the regulatory body requires independent research and development work. In such cases, the regulatory body should ensure that the organizations conducting this work have no conflict of interest.

3.2.7.12 Process availability

The process for the assessment of installations, including review and assessment procedures and the decision making process, should be documented and made available to applicants, licensees and the public.

3.2.7.13 Review and assessment process

The assessment process should consist of examining the applicant's submissions on all aspects relating to the safety of the installation. It should include consideration of normal operation, anticipated operational occurrences and accident conditions including human errors that have the potential for causing the release of radioactive material to the environment, and the exposure of workers or the public.

The submissions should be as complete as possible, and one of the initial tasks of the assessment is to confirm their completeness. The assessment process should include checks on the site and elsewhere to validate claims made in the submissions. Licensees often have external peer reviews conducted at their installations by national or international organizations. The results of such reviews could provide the regulatory body with additional insights into the activities of the licensee.

3.2.7.14 Internal guidance

The regulatory body should provide internal guidance on the procedures to be followed in the assessment process and guidance on the safety objectives to be met.

Detailed guidance on specific topics for assessment should be provided, as necessary. Consideration should be given to the extent to which the regulatory body's internal guidance may be made available to licensees and the public.

3.2.7.15 Regulatory efficiency

For regulatory efficiency, the findings of the preliminary review should be prioritized on the basis of their potential implication for the overall safety assessment of the installation and associated hold points in the licensing process.

For regulatory effectiveness, assessment efforts should usually be focused more on those aspects of site evaluation, design or operation which involve untested or innovative features.

3.2.7.16 Acceptance review

For more important submissions by the licensee (such as the safety analysis report) the regulatory body should perform an acceptance review of the documentation. As a result of this acceptance review, an application or submission that is grossly deficient in certain areas may be returned to the licensee for correction and resubmittal.

3.2.7.17 Systematic review

In carrying out an assessment of a licensee's submission, the regulatory body should employ a systematic plan to provide assurance that all topics significant to safety will be covered and that licensees of similar installations are treated equally.

This plan should include a series of procedures that the regulatory body will follow for all aspects and topics covered by the submission to identify those items for which applicable safety objectives and requirements have been met and those for which they have not.

3.2.7.18 Review and assessment plan

The regulatory body should prepare an assessment plan annually and share it with licensees. The plan will take account of information received from licensees regarding their intentions for regulatory submissions in the coming year.

Sharing the plan with licensees will help them with their forward planning as they will have a better understanding of the time that will be required by the regulatory body to carry out upcoming reviews and assessments.

3.2.7.19 Conventional hazards

Risks not related to radiation (conventional hazards) may arise during operation. These should also be taken into account in the regulatory decision making process.

3.2.7.20 Review and assessment results

The results and decisions arising from assessments should be recorded and made available to licensees and the public. The results should be used as feedback for the regulatory process.

3.2.8 Regulatory decision making

The core functions of the regulatory body require it to make regulatory decisions, such as the issuing of regulations and licences, the approval of design changes and enforcement actions. The regulatory body must establish, implement and follow a clear and well documented process for making its regulatory decisions.

Some elements of the regulatory decision making process will be prescribed by the government in the legal framework. However, in accordance with the principle of regulatory independence, most of the regulatory decision processes should be created by the regulatory body and outlined in its rules of procedure and integrated management system. These decision making processes will vary depending on the regulatory body and the type of decision, but should have the following features:

- **Clear fundamental objectives, principles and criteria**: The regulatory body must specify fundamental objectives, principles and criteria governing each type of regulatory decision that are clear and understandable to all interested parties. These objectives, principles and criteria must include provisions for interested party input to the decision;
- **Completeness of information**: The information on which a decision is based must be relevant and sufficiently complete. This usually requires some judgment on the part of the regulatory body and may require consultations with external experts, advisory bodies and interested parties. Incomplete information will have a negative impact on the applicant or licensee's schedule;
- **Documentation**: Records must be kept of all relevant information—from the applicants and licensees, regulatory body review and assessment, external scientific and technical experts and advisory bodies, other interested parties—whether provided in oral or in written form. The decision itself and the reasons for the decision must be properly documented;
- **Open and transparent**: Openness and transparency promote and demonstrate independence in regulatory decision making. The regulatory body needs to have the authority and the obligation not only to communicate its regulatory decisions and the reasons for the decisions to the licensee(s) concerned, but also to make this information available to the extent possible to other interested parties, including the public.

3.2.9 Relationships with licensees

GSR Part 1 (Rev. 1) Requirement 21 states:

> "The regulatory body shall establish formal and informal mechanisms of communication with licensees on all safety related items, conducting a professional and constructive liaison" [5].

Regular communications, both formal and informal, with licensees serves many purposes such as: the promotion of compliance with regulatory requirements and conditions of the licence; explanation of regulatory philosophy; discussion of design changes proposed by the licensee; the safety performance of the NPP; and the contents of applications to the regulatory body. Formal and informal discussions can help to eliminate or minimize misunderstandings regarding regulatory requirements and expectations and enhance the credibility of the regulatory body staff.

The objective is for the regulatory body to foster mutual understanding and respect through frank, open and yet formal relationships, providing constructive liaison on safety related issues. All communications must be conducted in a professional, constructive and respectful manner. A formal programme of meetings at different levels of management should be established between the regulatory body and the licensee, to promote good relations and facilitate future planning. Written records, especially of any decisions or agreements reached, should be kept of these meetings.

The regulatory body should establish clear rules for communications through a formal communications protocol. This establishes the communication process between the regulatory body and licensees and helps to ensure a common understanding between all parties. It will also assist in ensuring that liaison activities are conducted in a manner that maintains the independence of the regulatory body.

3.2.10 Relationships with other companies and organizations

Much of the information needed by the regulatory body may be prepared by contractors for the applicant or licensee. These contractors may be involved in design, manufacture, construction, installation, maintenance or safety analysis, and may themselves have subcontractors. The applicant or licensee must make arrangements with its contractors to ensure that all relevant information is made available to the regulatory body. The regulatory body must have the authority to request any information that it considers necessary to assess an application and to verify compliance.

The regulatory body may seek or may permit the participation of contractors in meetings between the regulatory body and the licensee to clarify issues concerning safety and to facilitate the exchange of information. It may be necessary for the regulatory body—with the knowledge of the licensee—to have direct contact with a contractor. Even with these contacts, the applicant or licensee remains responsible for the safety of the installation.

Often the regulatory body obtains technical or other expert professional advice or services in support of its regulatory functions. However, the regulatory body must always retain an adequate core competence to:

- Make informed decisions;
- Assess information submitted by applicants and licensees;
- Assess advice provided by advisory bodies and support organizations;
- Be a knowledgeable customer regarding contracts for advice or services.

Some regulatory bodies have established advisory bodies, either on a temporary or a permanent basis, to provide independent advice. The regulatory body must carefully select the members of these advisory bodies in a way that minimizes any biases and avoids conflicts of interest. A good practice is to institute a formal process for the operation of the advisory body including its mandate, roles and responsibilities and interactions with the regulatory body.

Technical and other expert professional advice or services may be provided in several ways by experts external to the regulatory body. The regulatory body may decide to establish a dedicated support organization, in which case clear limits need to be set for the degree of control and direction by the regulatory body over the work of the support organization. This is to ensure that the support organization has sufficient latitude to pursue investigations to the point where definitive independent advice can be given. Other forms of external support would require a formal contract between the regulatory body and the provider of advice or services.

Arrangements should be made to ensure that there is no conflict of interest for those organizations that provide the regulatory body with advice or services. If this is not possible domestically, then the regulatory body should seek the necessary advice or assistance from organizations in other Member States or, where appropriate, from international organizations.

In addition to the regulatory body, other governmental agencies may participate in the regulatory process in accordance with national legislation, regulations and practices. The regulatory body should establish and maintain liaison throughout the lifetime of the installation with these governmental agencies and where necessary, develop formal working procedures. Areas of the review and assessment in which such agencies might participate should be identified. These agencies may include:

- Environmental protection authorities;
- Authorities responsible for public liability issues;
- Authorities for security and/or safeguards;
- Authorities for planning the use of water resources and land;
- Authorities responsible for public and occupational health and safety;
- Fire protection authorities;
- Transport authorities;
- Law enforcement agencies;
- Agencies with responsibilities for civil engineering structures and buildings, and electrical and mechanical equipment;
- Emergency preparedness and response agencies;
- Other agencies with responsibilities for limits on releases of radioactive effluents;
- Other regulatory agencies, particularly those performing similar functions.

There may be specific technical areas in which the regulatory body can obtain information for use in the review and assessment process from other regulatory bodies. Exchange of information will be particularly useful whenever regulatory bodies of other Member States have experience in licensing similar installations. Arrangements such as bilateral agreements between Member States may be used to establish exchange of information protocols. Another possibility is to set up a group of regulatory bodies with similar interests. Sources of information and expertise include international bodies such as the IAEA and the OECD/NEA.

Note that none of these activities in any way relieve the Member State regulatory body of its responsibilities for making decisions and recommendations.

3.3 ORGANIZATION OF THE REGULATORY BODY

Learning Objective 1: To be aware of the IAEA Safety Standards relating to the regulatory body's management system.

Learning Objective 2: To understand the role of leadership and management in nuclear safety.

Learning Objective 3: To understand the core values required of a regulatory body.

Learning Objective 4: To understand the importance of knowledge management in the regulatory body

Learning Objective 5: To understand the importance of management of competence in the regulatory body.

Learning Objective 6: To understand the importance of staffing and succession planning in the regulatory body.

Learning Objective 7: To understand the importance of engaging with interested parties.

3.3.1 IAEA safety standards for management systems

The IAEA Safety Standards that should be taken into account by a regulatory body when establishing its management system include:

- Fundamental Safety Principles (IAEA Safety Standards Series No. SF-1) [21];
- Governmental, Legal and Regulatory Framework for Safety (IAEA Safety Standards Series No. GSR Part 1 (Rev. 1)) [5];
- Leadership and Management for Safety (IAEA Safety Standards Series No. GSR Part 2) [29];
- Application of the Management System for Facilities and Activities (IAEA Safety Standards Series No.GS-G-3.1) [48];
- The Management System for Nuclear Installations (IAEA Safety Standards Series No. GS-G-3.5) [49];
- Licensing Process for Nuclear Installations (IAEA Safety Standards Series No. SSG-12) [26];
- Use of External Experts by the Regulatory Body (IAEA Safety Standards Series No. GSG-4) [28].

3.3.1.1 Fundamental Safety Principles (SF-1)

The management system requirement is established through Fundamental Safety Principle 3, which states:

> "Effective leadership and management for safety must be established and sustained in organizations concerned with, and facilities and activities that give rise to, radiation risks" [21].

And through paragraph 3.12:

> "[…] Safety has to be achieved and maintained by means of an effective management system. This system has to integrate all elements of management so that requirements for safety are established and applied coherently with other requirements, including those for human performance, quality and security, and so that safety is not compromised by other requirements or demands. The management system also has to ensure the promotion of a safety culture, the regular assessment of safety performance and the application of lessons learned from experience" [21].

This principle applies to both the regulatory body and the licensee, although each will address the principle in a different manner.

3.3.1.2 Governmental, Legal and Regulatory Framework for Safety (GSR Part 1 (Rev. 1))

GSR Part 1 (Rev. 1) Requirement 19 states:

> "The regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement" [5].

This is followed by a number of more detailed requirements including:

- The regulatory body is required to establish and implement a management system whose processes are open and transparent;
- The management system of the regulatory body has to be continuously assessed and improved;
- The management system of the regulatory body has three purposes:
  - To ensure that the responsibilities assigned to the regulatory body are properly discharged;
  - To maintain and improve the performance of the regulatory body by means of the planning, control and supervision of its safety related activities;
  - To foster and support a safety culture in the regulatory body through the development and reinforcement of leadership, as well as good attitudes and behaviour in relation to safety on the part of individuals and teams.

In addition:

- The management system must maintain the efficiency and effectiveness of the regulatory body in discharging its responsibilities and performing its functions;
- The management system must specify, in a coherent manner, the planned and systematic actions necessary to provide confidence that the statutory obligations placed on the regulatory body are being fulfilled. Furthermore, regulatory requirements have to be considered in conjunction with the more general requirements under the management system of the regulatory body.

3.3.1.3 Leadership and Management for Safety (GSR Part 2)

GSR Part 2 [29] establishes requirements that support Principle 3 of Fundamental Safety Principles [21], in relation to establishing, sustaining and continuously improving leadership and management for safety, and an effective management system. This is essential in order to

foster and sustain a strong safety culture in an organization. Another objective is to establish requirements that apply Principle 8, which states that "All practical efforts must be made to prevent and mitigate nuclear or radiation accidents."

GSR Part 2 consists of six sections:

- Section 1: Introduction;
- Section 2: Responsibility for safety;
- Section 3: Leadership for safety;
- Section 4: Management for safety;
- Section 5: Culture for safety; and
- Section 6: Measurement, assessment and improvement.

GSR Part 2, which supersedes GS-R-3, was revised to take into account suggestions for improvement from Member States and experience from the Fukushima Daiichi accident. GSR Part 2 is generic for many organizations including regulatory bodies.

3.3.1.4 Application of the Management System for Facilities and Activities (GS-G-3.1)

GS-G-3.1 [48] provides generic guidance for establishing, implementing, assessing and continually improving a management system to meet the requirements, initially established in GS-R-3, of GSR Part 2 [29]. GS-G-3.1 also provides illustrative examples of the application of the management system requirements.

3.3.1.5 The Management System for Nuclear Installations (GS-G-3.5)

GS-G-3.5 [49] also provides recommendations and guidance for establishing, implementing, assessing and continually improving a management system.

3.3.1.6 Licensing Process for Nuclear Installations (SSG-12)

SSG-12 [26] describes how the licensing process should be applied at the various stages of the lifetime of an installation, with discussion of the topics and required documents to be considered at each stage (siting and site evaluation, design, construction, commissioning, operation, decommissioning and release from regulatory control). Some of these stages may be grouped together, depending on national regulations. SSG-12 also provides guidance on how a regulatory body can apply the graded approach to the licensing process. In addition, SSG-12 describes the processes that should be undertaken to meet the legal and regulatory requirements in a Member State to licence a nuclear installation.

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

GSG-4 [28] provides recommendations and guidance on the process the regulatory body should use to determine the need for external expert advice and the processes and procedures it should use for identifying a suitable support provider and making contractual arrangements for the work. GSG-4 also provides recommendations on how the regulatory body should take the advice of external experts into account while still retaining responsibility in making its decisions.

3.3.2 Some considerations about leadership and management of safety

Successful leadership and management of safety may be looked upon as consisting of two aspects: good overall leadership abilities and skills; and the establishment of those attributes which are essential for the proper management of nuclear safety.

3.3.2.1 Attributes of good leaders

Although it is beyond the scope of this book to provide details on leadership, all good leaders have the following skills and attributes:

- **Clear goals and objectives:** Good leaders establish clear goals and objectives and then focus all of their actions on achieving these goals and objectives. To the extent possible, good leaders involve others in the establishment of the goals and objectives.
- **Integrity**: Leaders must have integrity. They should be honest, fair, candid and forthright, and treat everyone with respect;
- **Decisiveness**: One of the most basic duties of any leader is to make decisions. Highly effective leaders make decisions based on the information available and will make tough calls when circumstances require it;
- **Delegation of responsibility**: Good leaders cannot accomplish everything by themselves, nor should they micro manage. Leaders set objectives and goals for others, provide the necessary support and then let staff get on with it;
- **Good communication**: Leaders understand that good communication is two-way; they must be able to clearly express their messages, views and opinions clearly and must be active listeners, taking the time and effort to understand the messages of others.

3.3.2.2 Leadership in safety matters

SF-1 states that:

> "Effective leadership and management for safety must be established and sustained in organizations concerned with, and facilities and activities that give rise to, radiation risks" [21].

SF-1 goes on to state that leadership in safety matters must be demonstrated at the highest levels in an organization. This applies equally to regulatory bodies. The head of the regulatory body and the senior management must be role models and lead by example. It is not sufficient to just talk of the importance of safety; it must also be demonstrated through everyday actions and decision making to send a clear message to all staff that they are serious about safety.

The senior management is responsible and accountable for the planning and implementation of a management system that is appropriate to the regulatory body. It is the role of senior management to establish and cultivate principles that integrate all requirements into daily work. Senior managers should provide the individuals performing the work with the necessary information, tools, support and encouragement to perform their assigned work properly. Visible and active support, strong leadership and the commitment of senior management are fundamental to the success of the management system. Senior managers should communicate the beliefs that underlie the organization's policies through their own behaviour and management practices.

In assigning responsibilities and accountabilities, managers should ensure that the individuals concerned have the capabilities and the appropriate resources to discharge these responsibilities effectively. They should also ensure that individuals are aware of and accept their responsibilities, and that they know how their responsibilities relate to those of others in the organization.

The role of senior management is pivotal when it comes to establishing a strong safety culture within an organization. If the leaders do not exhibit the attitudes and behaviour appropriate to a strong safety culture in their own activities, it becomes difficult to convince the staff to undertake such attitudes and behaviour. "Do as I say but not as I do" will not establish a strong safety culture. Senior management needs to develop individual values, institutional values and behavioural expectations for the organization and needs to act as role models in the promulgation of these values and expectations. Management at all levels needs to communicate to individuals the need to adopt these individual values, institutional values and behavioural expectations as well as to comply with the requirements of the management system.

3.3.2.3 Safety assessment capability

A very important aspect in the management of safety for a regulatory body is the assessment of safety. Safety assessment involves the systematic analysis of normal operation and its effects, of the ways in which failures might occur and of the consequences of such failures. Safety assessments cover the safety measures necessary to control the hazard and the design and engineered safety features are assessed to demonstrate that they fulfil the safety functions required of them. Where control measures or operator actions are called on to maintain safety, an initial safety assessment has to be carried out to demonstrate that the arrangements made are robust and that they can be relied on. An installation may only be constructed and commissioned once it has been demonstrated to the satisfaction of the regulatory body that the proposed safety measures are adequate.

The assessment of safety must continue over the life of the installation as necessary to demonstrate to the satisfaction of the regulatory body that safety measures remain adequate and that regulatory requirements continue to be met. Such assessment should take account of changed circumstances (such as the application of new standards or scientific and technological developments), the feedback of operating experience, modifications and the effects of ageing. PSR, which is recommended by the IAEA and practiced in many Member States, is one approach to the continuation of the assessment of safety. It should be noted that this also requires both the licensee (to perform the assessments) and the regulatory body (to review the assessments) to maintain a safety assessment capability.

3.3.3 Values

The values of an organization define what it considers important. In an effective organization, all staff members are committed to the organization's values. Some common regulatory body values are described below.

3.3.3.1 Safety

Safety means recognizing the importance of safety as an overriding consideration in daily work. Safety is demonstrated through a strong safety culture with:

— Individual commitment to safety through personal accountability;

— Management commitment to safety through accountability, decision making and a respectful work environment;
— Measures that encourage a questioning and learning attitude at all levels of the regulatory body and that discourage complacency with regard to safety;
— A management system that supports a strong safety culture through continuous training, problem identification and resolution, providing an environment for raising concerns and effective work processes.

3.3.3.2 Respect

Respect is valuing the rights, responsibilities and contribution of all interested parties. Respect is demonstrated by:

— Treating colleagues and external interested parties with dignity and fairness;
— Listening to others and respecting different points of view;
— Maintaining a safe and healthy workplace that is free of harassment, violence, discrimination, abuse of power and threats.

3.3.3.3 Integrity

Integrity means acting with honesty. Integrity is achieved by:

— Acting in a manner that will bear the closest scrutiny;
— Making decisions that respect and give priority to rightful regulatory body and public interests;
— Avoiding real, apparent or potential conflicts of interest between official duties and personal interests;
— Speaking out when aware of wrongdoing.

3.3.3.4 Service

Service means acting in the best interests of the Member State's citizens and is accomplished by:

— Respecting the rule of law and carrying out duties in accordance with legislation, policies and directives, in a non-partisan and objective manner;
— Providing decision makers with all information, analysis and advice needed to make fully informed decisions in an honest, respectful and impartial manner;
— Maintaining an arms-length relationship with licensees;
— Collaborating with other national and provincial/state regulators.

3.3.3.5 Excellence

Excellence means being dedicated, competent and professional. Excellence is demonstrated by:

— Striving to fulfil roles and responsibilities effectively and efficiently, and continually seeking to improve the quality of policies, programmes and services;

— Striving for ongoing development of technical skills;
— Sharing knowledge and contributing to the professional growth of others;
— Nurturing pride in the work and protecting the reputation and values of the regulatory body.

3.3.3.6 Responsibility

Responsibility means using public resources in a manner that maintains public trust and confidence. Responsibility is exercised by:

— Judiciously managing public money, property and other resources entrusted to the regulatory body;
— Respecting and protecting private and confidential information and interested parties' intellectual property, in accordance with the regulatory body's policies and government requirements;
— Being accountable for the decisions made, actions taken and advice given;
— Embracing social, environmental and economic sustainability.

3.3.3.7 Professionalism

Professionalism means understanding your roles, responsibilities and authorities and acting in a competent manner that brings credit to the regulatory body. Professionalism is demonstrated through embracing continuous improvement and learning, treating others with respect, effective time management, effective communication skills, respecting the priorities of the regulatory body and remaining objective.

3.3.4 Knowledge management

The nuclear industry is knowledge based, similar to other highly technical industries, and relies heavily on skilled employees and their know-how. Recent trends such as workforce ageing, declining student enrolment numbers and the risk of losing accumulated knowledge and experience have drawn attention to the need for knowledge management.

Regulatory bodies have long understood the vital link between knowledge management and safety. Specific and advanced levels of knowledge are typically needed to achieve and maintain the high levels of safety required. Appropriate technical expertise and experience must be developed and be available throughout the lifetime of nuclear installations. If the regulatory body does not have the required technical knowledge, a full understanding of the potential consequences of its decisions and actions may not be possible and safety may be compromised.

Effective decision making during design, licensing, procurement, construction, commissioning, operation, maintenance, refurbishment, and decommissioning of nuclear installations needs to be risk informed and knowledge driven. Nuclear technology is complex and brings with it inherent and unique risks that must be managed to acceptably low levels. Nuclear installations typically have very long lifetimes with changing operational conditions. The regulatory body's ability to take safe decisions and actions is continually being threatened by the risk of knowledge loss. To ensure safety, the regulatory body has a responsibility not only to establish adequate technical knowledge and experience, but also to maintain it. This is why knowledge management is so important.

The IAEA Safety Glossary defines knowledge management as:

> "An integrated, systematic approach to identifying, managing and sharing an organization's knowledge and enabling groups of people to create new knowledge collectively to help in achieving the organization's objectives" [31].

Knowledge management consists of the three fundamental components shown in Figure 21: people, processes and technology. Knowledge management focuses on: people and organizational culture to stimulate and nurture the sharing and use of knowledge; on processes or methods to find, create, capture and share knowledge; and on technology to store and make knowledge accessible which will allow people to work together without being located together. People are the most important component. Knowledge management depends upon people's willingness to share and reuse knowledge.

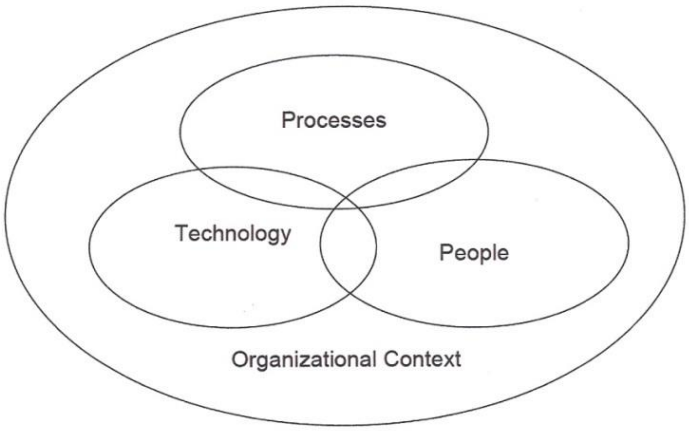


FIG. 21. The organizational context for knowledge management [78].

Many people see knowledge as power and some fear that if they share their knowledge they will lose their importance or their marketability. Regulatory bodies must overcome this concern by providing incentives to staff to share their knowledge. However, incentives are not enough to overcome cultures that reward and promote staff who hoard knowledge or that foster competition among employees or groups that should be complementary.

Trust plays an important role in the sharing and use of knowledge. If people believe they will benefit from sharing their knowledge—either directly or indirectly—they are more likely to share. The use to which people put the knowledge of others often depends on whether they know and trust the source of the knowledge.

IAEA activities associated with knowledge management are primarily targeted at licensees. However, the vast majority of the work is also applicable and relevant to regulatory bodies.

3.3.5 Management of competence of the regulatory body

The regulatory body needs to educate and train its staff on the general regulatory functions and on the particular technology the person is going to be responsible for. Regulatory bodies may recruit university graduates with degrees in nuclear science and engineering, but these studies do not include details on regulatory functions. After entering the regulatory body, all newly hired staff should receive initial training programme on the nature, functions and organization of the regulatory body, the legal and regulatory framework for the nuclear industry, the legal authorities, responsibilities, accountabilities and duties of the regulatory

body, as well as the various regulatory body processes and procedures. The new hire must then receive position specific training.

Once this initial training is complete, all regulatory staff should receive update and refresher training as required. Many regulatory bodies have established a lecture and seminar series to keep staff informed of new developments. In some cases, staff members are sent on assignment to other regulatory bodies for training and experience.

The IAEA has developed IAEA-TECDOC-1757 on Methodology for the Systematic Assessment of the Regulatory Competence Needs (SARCoN) for Regulatory Bodies of Nuclear Installations [56], which includes guidelines for training regulatory staff. It includes over 100 questions for self-assessment and competence needs under the four quadrant framework shown in Table 35.

TABLE 35. FOUR QUADRANT MODEL ON REGULATORY COMPETENCE

1. Competences related to the legal, regulatory and organizational basis 1.1 Legal basis 1.2 Regulatory policies and approaches 1.3 Regulations and regulatory guides 1.4 Management system	**2. Technical disciplines competences** 2.1 Basic science and technology 2.2 Applied science and technology 2.3 Specialized science and technology
3. Competences related to regulatory body's practices 3.1 Review and assessment 3.2 Authorization 3.3 Inspection 3.4 Enforcement 3.5 Development of regulations and guides	**4. Personal and behavioural competences** 4.1 Analytical thinking and problem solving 4.2 Personal effectiveness and self-management 4.3 Communication 4.4 Team work 4.5 Managerial and leadership competences 4.6 Safety Culture

The competence required in a regulatory body depends on a range of factors, including the regulatory approach adopted, the legal framework, and the types of installations and activities. Each regulatory body needs to establish its own sets of competences, levels of competences and evaluation standards. Competences comprise different sets of knowledge, skills and attitudes (KSAs) that need to be formally defined within the regulatory body. Further information on the quadrant model is available in *Safety Reports Series No. 79: Managing the Competence of the Regulatory Body* [2]. Each regulatory body will need to tailor the specific KSAs associated with the competence areas to meet its needs.

Maintaining competence is a key part of the regulatory body management system. Senior management must be committed to ensuring that the regulatory body has and maintains competence appropriate to its needs. Since learning is a lifelong process, the regulatory body must be committed to the ongoing development of a professional, competent, versatile and motivated workforce.

The regulatory body must review all of the functions it requires to fulfil its mandate, taking into account both internal and external factors. The regulatory body must recognize that organizational design is an important feature when considering its overall competence. The organizational design needs to be established before regulatory body can determine the required KSAs of individual staff members. Since it takes time to develop competent staff, the planning must take into account both short and long term needs. Figures 22 and 23 provide a process for developing the learning plan for the regulatory body.

The plan for developing and maintaining competence must cover training and development, staffing plans, use of external support and other methods of meeting competence needs—particularly to narrow competence gaps. The plan must give special attention to circumstances where the gap analysis indicates the potential for the gap to widen, for example due to a planned increase of installations and activities.

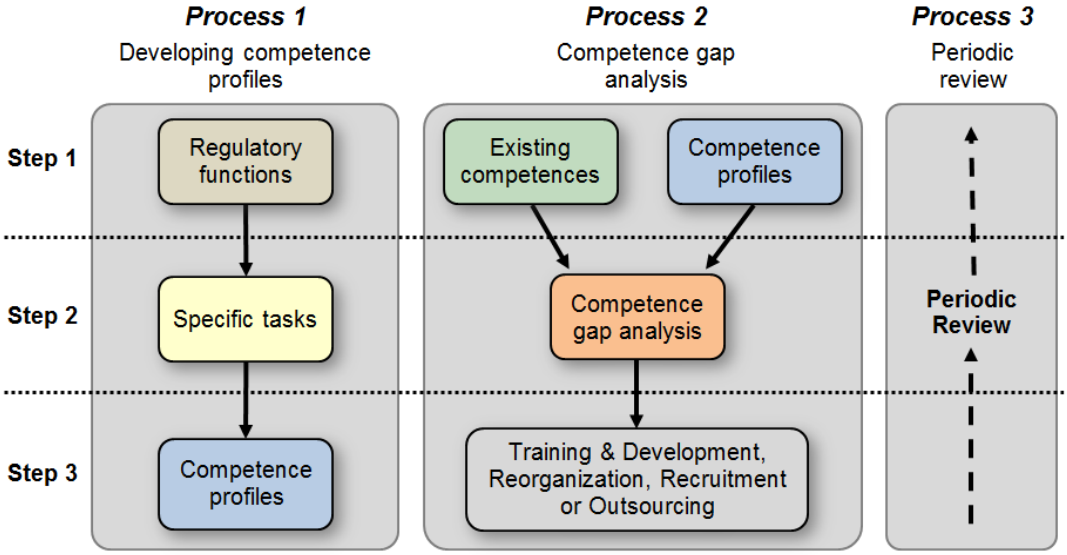


FIG. 22. Process for developing a learning plan.

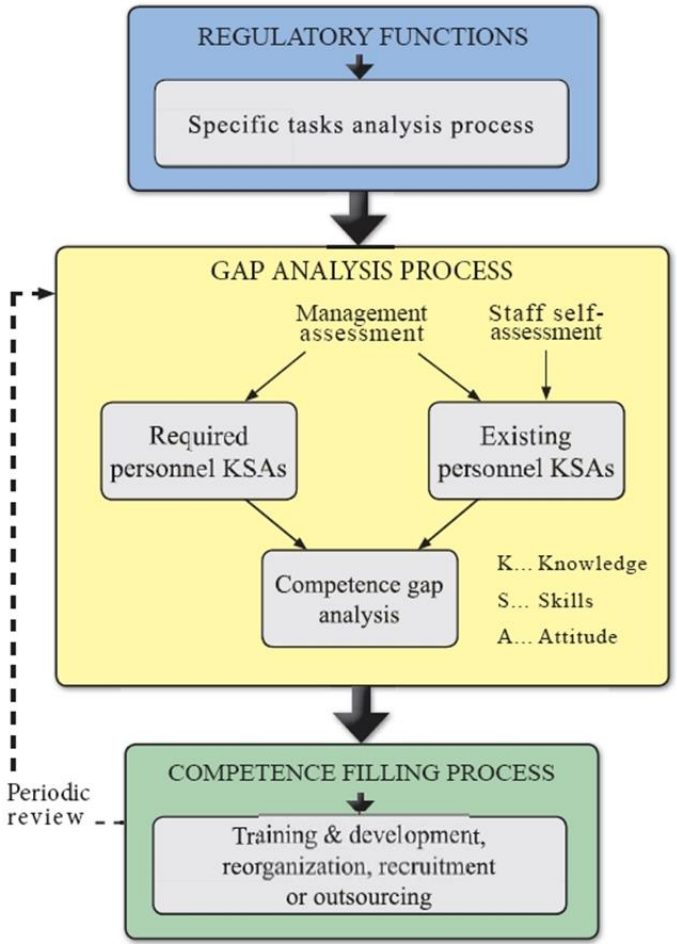


FIG. 23. A competence analysis flowchart.

3.3.6 Staffing and succession planning

Regulatory effectiveness is dependent on the staff of the regulatory body. The nature of the work performed by the staff is multifaceted and complex. Effective and efficient staffing is vital to ensure the regulatory body's ability to quickly adapt to new challenges and rapidly changing situations while enabling the regulatory body to respond proactively to succession issues.

The regulatory body must employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of installations and activities to be regulated, to perform its functions and to discharge its responsibilities. To achieve this, the regulatory body must first develop a human resources plan that states the number of staff necessary and the essential KSAs so that the regulatory body can perform all necessary regulatory functions. The human resources plan should also cover recruitment and, where relevant, rotation of staff (such as to a vendor design office and back) to obtain staff with appropriate competence and skills. Succession planning should be included as a part of the human resources plan.

A process should be established to develop and maintain the necessary KSAs for regulatory body staff. Not only will this serve as an element of knowledge management, it allows the development of appropriate training programmes. The training programme should cover principles, concepts and technological aspects, as well as the procedures followed by the regulatory body for licensing, review and assessment, inspection and enforcement and preparing regulatory requirements.

Regulatory staff must have an appropriate combination of education, training and experience related to the installations that are regulated. The regulatory body should establish an initial training programme for persons new to a position and a continuing training programme for incumbents to ensure that KSAs remain up to date. The regulatory body must pay particular attention to succession planning for key managers and senior technical staff. The introduction of new types of installation, the introduction of novel technology, the ageing of installations or the passage of an installation to another phase of its lifetime will all present challenges to the regulatory body. The expertise required by the regulatory body's staff will change with time.

The regulatory body requires expertise in a wide range of technical matters and in human factors. The phase and scale of the nuclear programme will dictate how various disciplines are represented. The regulatory body must have enough experienced staff to be able to do basic regulatory work and to evaluate the quality and results of the work performed by consultants.

The staff of the regulatory body will be expected to coordinate and manage various activities of the regulatory programme, some of which may be performed by the regulatory staff and others with the assistance of consultants, TSOs and advisory committees. Therefore some staff should have project management experience.

The regulatory body should establish and maintain communication and a good working relationship with other governmental, professional and private organizations at the national and international levels. For this reason, members of the regulatory staff should have up to date knowledge of the responsibilities and structures of these organizations and should maintain contacts with their personnel.

The effectiveness of the regulatory body will also depend on the status of its staff in comparison with those of the applicant or licensee. Members of the regulatory body staff

should therefore be appointed at grades and with salaries and conditions of service that facilitate their regulatory relationships and reinforce their authority.

3.3.7 Interested party engagement

It is increasingly important for regulatory bodies to be open and transparent and to engage with interested parties if they are to be regarded as credible and fulfilling their nuclear safety mandate in an effective and efficient manner. GSR Part 1 (Rev. 1) states:

> "The regulatory body shall promote the establishment of appropriate means of informing and consulting interested parties and the public about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body" [5].

In keeping with the prime responsibility for safety, the applicant or licensee also has an obligation to inform the public about the activities being carried out and the possible radiation risks associated with an installation. Regulatory bodies must be careful not to take this responsibility from the licensees as it may affect their credibility and independence.

Section 4.6 provides in-depth information regarding public information programmes.

3.4 INDEPENDENCE OF THE REGULATORY BODY

Learning Objective 1: To understand why independence of the regulatory body is important and how this is achieved in practice.

Learning Objective 2: To understand the political aspects of regulatory independence.

Learning Objective 3: To understand the importance of openness and transparency for the regulatory body and how these relate to regulatory body independence.

3.4.1 Importance, legal basis, limitations and practicalities

GSR Part 1 (Rev. 1) [5] discusses the need for independence in Requirements 3 and 4. Article 8 of the CNS reaffirms the independence principle and states that there has to be:

> "…an effective separation between the functions of the regulatory body and those of any other body or organization concerned with the promotion or utilization of nuclear energy" [6].

This independence is also an obligation for Contracting Parties to the Joint Convention.

The regulatory body must be effectively independent of all entities—including other government organizations—that promote the development of the nuclear industry. Effective independence means that the regulatory body has the legal authority, technical competence and resources to regulate nuclear installations and activities; and its regulatory decisions are free from undue political and economic influence. This will ensure that regulatory decisions are made and enforcement actions taken only in the best interest of safety.

INSAG considered the independence issue in INSAG-17. Although INSAG fully recognizes the need for independence, it also understands that:

> "…a regulatory body cannot be absolutely independent in all respects of the rest of government: it must function within a national system of laws and under budget constraints, just as other governmental organizations do" [61].

It adds that:

> "…the necessary political guidance and oversight must be clearly defined and limited in the appropriate legal instruments in order to ensure a high degree of professional independence in the way the regulatory body operates its regulatory decision making" [61].

INSAG concludes that the activities of the regulatory body are closer to the judicial branch than the executive branch of government.

Ideally, the independent legal status and decision making powers of the regulatory body will be clearly defined in the nuclear law. The nuclear law should also provide legal barriers to protect this independence.

The general safety objectives that licensees must meet should be established in advance of any regulatory decisions and should be consistent with widely endorsed international safety principles such as those in SF-1 [21]. Any departures from such safety principles need to be discussed and justified, with relevant information made publicly available. In this way, special interest groups will be less able to unduly influence regulatory body decisions.

Independence in regulatory decision making does not remove the need for accountability. Although the regulatory body must not be subject to political influence or pressure in taking specific safety decisions, it must be accountable to government and elected officials, as well as to the general public, with regard to effectively and efficiently fulfilling its mission to protect workers, the public and the environment from radiation hazards. There are several ways to provide this accountability, for example, through regular, public reporting and through professionally recognized audit and peer review procedures.

The legal framework must clearly identify the regulatory body financing mechanism. If the costs of regulatory activities are to be recovered from the licensees, the financing mechanism needs to be designed to prevent its misuse. The budget for the regulatory body should not be decided by or be subject to the approval of those parts of the government that are responsible for exploiting or promoting nuclear technologies, nor should it depend on fines collected from licensees. Moreover, the budgetary process should be designed so that the legitimate financial needs of the regulatory body and the consequences of inadequate funding are brought to the attention of the political decision makers at the highest level.

To properly balance the independence of regulatory decision making, licensees and other interested parties need to have specific legal mechanisms to appeal regulatory decisions under predefined conditions.

The regulatory body itself must perform its functions and conduct its daily business in such a way that it does not compromise its independence. The staff of the regulatory body must always operate professionally in its relationships with licensees and remain objective, fair, equitable and consistent in its assessments and decisions. In addition, the regulatory body

must maintain a clear separation from organizations that promote the nuclear industry or are closely tied to licensees.

To assist in avoiding undue influence in its decision making, a regulatory body may issue a code of ethics for its staff to follow. Examples of measures contained in a code of ethics include:

— Regulatory staff may not have a financial interest in nuclear activities;
— Regulatory staff may not accept gifts or other gratuities such as meals from licensees or their vendors, contractors and suppliers (exceptions may be allowed for working meals and conferences).

3.4.2 Political aspects

The political system in the Member State needs to ensure clear and effective separation of responsibilities and duties of the regulatory body from organizations promoting the development of nuclear technologies. In this regard, a distinction should be made between independence and accountability. The regulatory body must not be subject to political influence or pressure in taking decisions relating to safety. However, the regulatory body must be accountable in respect of fulfilling its mission to protect workers, the public and the environment from undue radiation hazards.

The government, political groups, individual politicians, vendors, licensees, special interest groups and members of the public all have legitimate reasons to interact with the regulatory body and influence regulatory body decisions. To maintain its independence, the regulatory body must ensure that all of these interactions are open and transparent and take place in accordance with pre-established rules.

A number of measures can be taken to ensure that the regulatory body is well equipped to meet any challenges to independence in regulatory decision making in matters of nuclear safety. Some of these measures need to be taken by the relevant political decision makers (government and legislators). Others are the responsibility of the senior management of the regulatory body. These measures can be grouped into three tiers:

— The establishment of the legal framework governing regulatory activities, including the basis for adequate and stable financing of regulatory activities;
— The establishment and implementation of clearly defined processes for regulatory decision making;
— The establishment and implementation of a clearly defined competence management programme for the regulatory body, which includes an internal management programme for human resources, provides the means to secure independent scientific and technical support and includes international cooperation.

To achieve independence in regulatory decision making and to ward off any challenge to independence, the regulatory body must establish a clear, well documented and carefully implemented process for making regulatory decisions. Some elements of this process should be prescribed in the legal framework, as decided by government and legislators. The regulatory body must then take these elements and elaborate the regulatory decision making process.

3.4.3 Openness and transparency

Openness and transparency are means to promote independence in regulatory decision making and to demonstrate this independence to government, licensees, other interested parties, and the public. The regulatory body must have the authority and the obligation not only to communicate its regulatory decisions to the licensee(s) concerned, but to make this information available to the public. This will serve two purposes. First, it will demonstrate the independence of the regulatory decision making process to the public and second it will hold the regulatory body accountable to the public, whose health and safety the regulatory body is responsible for protecting.

A systematic programme for professional reviews and audits of regulatory performance will, in addition to enhancing the performance of the regulatory body, promote independence in decision making. The programme should include:

- Participation in various types of international cooperation and intercomparison exercises, providing checks that the methods, models and data used in various regulatory activities are in line with recognized international practices. Cooperation with regulatory bodies in Member States with NPPs of the same design is particularly important for sharing competence and experience;
- Systematic and prescribed use of external and independent scientific and technical advice and review, particularly for significant regulatory decisions;
- Formal internal quality audits and self-assessments at regular intervals;
- External peer reviews, such as those offered by the IAEA, either of a specific regulatory activity or issue or of the performance of the regulatory body as a whole.

Governments or legislators may also choose to set up their own review activities in line with established national procedures.

It is important that the findings, conclusions and recommendations of these reviews and audits, as well as the response of the regulatory body, are made public. For Contracting Parties to the CNS and/or the Joint Convention, these peer reviews and audits will also provide valuable input to the review process and should be duly reflected in the national reports.

3.5 DOCUMENTATION OF THE MANAGEMENT SYSTEM

Learning Objective 1: To understand the role of the management system.

Learning Objective 2: To understand regulatory processes, their development and management.

3.5.1 Role of the management system

GSR Part 1 (Rev. 1) [5] Requirement 19 states that the regulatory body is required to establish and implement a management system whose processes are open and transparent.

The management system of the regulatory body has three purposes:

- To ensure that the regulatory body properly discharges its assigned responsibilities;
- To maintain and improve the performance of the safety related activities of the regulatory body;
- To foster and support a strong safety culture in the regulatory body.

All of the activities necessary for the regulatory body to meet its statutory obligations should be combined into one integrated management system that includes:

- Identifying interdependences and their potential to impact on each other;
- Assigning priorities to the goals, strategies, plans and objectives;
- Establishing procedures to ensure that these priorities are respected.

The management system includes the policy statements of the regulatory body and a description of the processes that explain how work is to be prepared, reviewed, carried out, recorded, assessed and improved. It is important that the documentation of the management system is understandable to those who use it. By developing and documenting its processes, the regulatory body will ensure the stability and consistency of its regulatory control and prevent subjectivity in its decision making. Regulatory body processes are usually supported by detailed working level documents such as work instructions.

3.5.2 Processes

3.5.2.1 Types of Processes

Processes describe major activities of the regulatory body and are based on the regulatory body's mandate, policies and principles. The processes of a regulatory body can be divided into three categories:

- **Core processes**: These processes produce the output that is critical to the success of the regulatory body and include: production of regulations and guides; review and assessment; licensing; inspection; enforcement; emergency preparedness and response; and communication and consultation with interested parties;
- **Management processes**: These processes describe how senior management sets and communicates expectations and how it exercises control and include: managing the

regulatory body; providing human resources; providing financial resources; managing external relationships; and assessing and improving the performance of work;

— **Supporting processes**: These processes provide the infrastructural services necessary to perform the core and management processes effectively. Supporting processes include: training; information technology; procuring goods and services; and documentation and records.

3.5.2.2 Developing processes

In determining to what extent a process should be developed, the regulatory body should consider factors such as the following:

— Effects of the process on health, safety, environment and security;
— Statutory and regulatory requirements;
— Risk that the subject of the process poses to the organization;
— Effectiveness and efficiency;
— Competence levels of staff;
— Need to retain process knowledge;
— Complexity of the process.

Processes must be developed using a top-down approach and be hierarchically linked. Individual tasks or activities in the processes are usually described in work or technical instructions. To properly develop the regulatory body processes requires considerable effort and includes the following:

— Identifying the processes necessary for the management system:
  - What processes are needed?
  - Who are the internal and/or external interested parties for each process?
  - What are the statutory and mandatory requirements?
  - What are the expectations of the interested parties?
  - What are the safety, health, environmental, security, quality and economic requirements affecting each process?
  - Who is the process owner?
  - Are any of the processes outsourced?
  - What are the inputs and outputs for each process?
— Determining the sequence of and the interactions between these processes:
  - What is the overall flow of the processes?
  - How can this flow be described?
  - What are the interfaces between the processes?
  - What documentation is necessary?
— Determining the criteria and methods necessary to ensure that these processes are effective:
  - What are the characteristics of the intended and unintended results of each process?
  - What are the criteria for monitoring, measurement and analysis?
  - How can these criteria be incorporated into the process?
  - What are the economic issues (cost, time, waste, etc.)?
  - What methods are appropriate for data gathering?
— Ensuring the availability of the resources and information to support these processes:

- What are the resources necessary for each process?
- What are the communication channels?
- How can external and internal information about each process be provided?
- How is feedback of information to be obtained?
- What data needs to be collected?
- What records need to be kept?

— Measuring, monitoring and analyzing the processes:
- How can process performance be monitored?
- What measurements are necessary?
- How can the data gathered best be analyzed?
- What information do the results of this analysis provide?

— Implementing continuous improvement:
- How can each process be improved?
- What corrective and/or preventive actions are necessary?
- Have these corrective/preventive actions been implemented?
- Are they effective?

For each process, the following activities should be performed:

— Select a process team made up of the team leader (normally the process owner), the team itself (representatives from the departments that are affected) and a facilitator;
— Develop a description of the process;
— Identify the major inputs and outputs and the interested parties;
— Determine the risks and hazards of the proposed process to identify appropriate control measures necessary to ensure that risks and hazards are managed;
— Identify additional expectations from the process to control performance;
— Develop a flow chart for the process;
— Develop the process description.

3.5.2.3 Process description

The end result of this work is the process description, which should include the following topics:

— Governing documents, definitions and key requirements;
— Key process responsibilities;
— Descriptions of activities;
— Supporting documentation and requirements for records;
— How the process was validated where necessary;
— Requirements for review of the procedure;
— Procedures for the approval and distribution of the process documents.

The process description and its supporting documents must be written in a manner that the user can easily understand and should use graphical representations, checklists, flow charts, visual media, etc. where these will help the user.

3.5.2.4 Process management

Managing the processes of the regulatory body efficiently is critical to the regulatory body's success. Senior management should assign a process owner for each of its processes. The process owner is a manager in the regulatory body with a direct interest in the effectiveness of the process. The process manager must have a good understanding of the process and should have the authority to:

— Assess the impact of the process on safety and on regulatory body plans and objectives;
— Monitor the effectiveness of the process;
— Propose and initiate changes in the process;
— Monitor and control the major resources used in the process;
— Effect changes to instructions.

The process owner is responsible for tracking the performance of the process and implementing corrective measures if necessary and for conducting a review of the process when required. Process ownership should not be assigned based on someone's position in the management structure. Senior managers should not feel they have to own all the processes personally. However, they should use information from the process owners to help them direct and manage the regulatory body.

3.5.2.5 Processes contracted to other organizations

In cases where the regulatory body contracts another organization to perform one or more of its processes, the regulatory body must ensure that there is control over the process. The nature of this control will depend on the importance of the outsourced process and the risks involved in its outsourcing. In every case, the contractual agreement must be clear regarding:

— Specification and validation requirements for the process;
— Any statutory or regulatory requirements to be met;
— Management system requirements, including requirements on process monitoring and methods of measurement, performance targets for processes and the reporting of results;
— Audits to be performed by the organization and the regulatory body.

The regulatory body may impose its own management system requirements on the contractor, or may accept the contractor's management system requirements. Where a regulatory body has the competence but chooses to outsource a process, the regulatory body should define the process control criteria and include them as requirements for the contractor. Where the regulatory body chooses to outsource a process because it does not have the competence to carry out the process, the regulatory body should ensure that the controls proposed by the contractor are adequate. In cases where it is not possible to verify the output from the contractor, the regulatory body should include requirements for validation of the contractor's process.

Outsourced processes sometimes interact with other processes within the regulatory body's management system. Management of the interactions should include:

— Agreement on the outputs from the regulatory body that will serve as inputs for the contractor and the outputs from the contractor that will serve as inputs to the regulatory body;

- Arrangements for the transfer of information between the regulatory body and the contractor;
- Arrangements for monitoring of the contractor by the regulatory body;
- Possible interactions and communication channels between the contractor and the regulatory body's interested parties.

3.6 CONTINUOUS IMPROVEMENT AND BENCHMARKING

Learning Objective 1: To understand the need for continuous improvement and how this can be accomplished.

Learning Objective 2: To understand how a regulatory body can benchmark itself against others.

Learning Objective 3: To understand the means that a regulatory body can use to review and audit its performance.

3.6.1 Continuous improvement

3.6.1.1 Improvement of management system processes

A good regulatory body is always looking for opportunities to improve and will establish a continuous improvement process. A number of sources can be used to identify opportunities for improvement, including:

- Performance of the management system in meeting goals and plans;
- Feedback from users;
- Experience from outside organizations;
- Technological developments;
- Improvements identified by individuals;
- Improvements identified from reviews of products;
- Results of assessments, audits, benchmarking and management system reviews.

Continuous improvement can be achieved:

- At the working level, by introducing incremental improvement activities within existing processes;
- At the process level, by process owners;
- At the organizational level, through regulatory body wide improvement projects (at the level of the management system) which lead either to the revision and improvement of existing processes or to the implementation of new processes. These projects are usually carried out by cross-functional teams and are distinct from routine operations.

It should be noted that continuous improvement is not the same as constant change. The regulatory body must give revised or new processes the time to become established before contemplating additional change.

3.6.1.2 Continuous improvement process

The continuous improvement process includes the following elements:

— Reason for improvement: A process problem should be identified and an area for improvement selected, noting the reason for working on it;
— Current situation: The effectiveness and efficiency of the existing process is evaluated. Data should be collected and analyzed to determine what types of problem occur most often. A specific problem should be selected and an objective for the improvement process should be set;
— Analysis: The causes of the problem should be identified and verified;
— Identification of possible solutions: Alternative solutions should be explored.
— Identification of the preferred solution: The preferred solution is one that eliminates the problem, avoids the introduction of new problems and is in line with the regulatory body's other objectives;
— Implementation and standardization of the new solution: The new process should be rolled out to users. For minor changes to one group's work instructions, the rollout may consist of a brief discussion at the group meeting. For major changes to a process affecting the entire regulatory body, the rollout may include briefings by senior management, training and other activities;
— Evaluation of the effectiveness and efficiency of the new process: Following a reasonable introductory period, the regulatory body should evaluate the effectiveness and efficiency of the solution.

3.6.2 Benchmarking

Benchmarking is the process of comparing the regulatory body's performance against peers or best practices.

The IRRS, discussed in Section 2.3.1, is a comprehensive and direct assessment of a regulatory body's performance against accepted international standards.

The CNS also provides an opportunity for benchmarking. The CNS obliges Contracting Parties to submit reports on their implementation of the obligations for peer review at regular Review Meetings.

Regional groups also provide benchmarking opportunities. A good example was when the European Nuclear Safety Regulators Group organized and conducted the evaluation of the results of the stress tests required of all European reactors following the Fukushima Daiichi accident [62]. This peer review served as a limited benchmarking exercise.

3.6.3 Reviews and audits of regulatory performance

A systematic programme for reviews and audits of regulatory performance is an important element of the management system and should include:

— Participation in various types of international cooperation and intercomparison exercises, providing checks that the methods, models and data used in various regulatory activities are in line with internationally recognized practices. Cooperation with regulatory bodies in Member States with NPPs of similar design and manufacture is particularly important for sharing competence and experience;
— Appropriate use of external and independent scientific and technical advice and review, particularly in the preparation of the more important regulatory decisions. For such

purposes, use of standing scientific and technical advisory committees by the regulatory body is considered a good practice;

- Formal internal audits and self-assessments at regular intervals;
- External peer reviews—such as the IRRS—either of a specific regulatory activity or issue or of the performance of the regulatory body as a whole. Many Member States have established national auditing organizations for the review of the activities of national authorities.

It is important that the findings, conclusions and recommendations of such reviews and audits, as well as the response of the regulatory body, are made public. For Contracting Parties to the CNS, these national peer reviews and audits will also provide valuable input to the peer review process and should be included in the Contracting Party's national report.

3.7 SUPPORT TO NATIONAL PROCESSES

Learning Objective 1: To understand the role and involvement of the regulatory body in emergency preparedness and response.

Learning Objective 2: To understand the role and involvement of the regulatory body in advising government.

Learning Objective 3: To understand the role and involvement of the regulatory body in event reporting systems.

3.7.1 Emergency preparedness and response

A regulatory body has two different roles in emergency preparedness and response. Firstly, the regulatory body ensures that the licensee has appropriate emergency arrangements in place to respond to an emergency on the site. To do this, the regulatory body will review (and in some Member States approve) the licensee's emergency plan and procedures to verify that they provide for an effective response on the site and for coordination with off-site response organizations. Then the regulatory body regularly inspects the licensee's emergency arrangements, including observing and evaluating some of licensee's drills and exercises. Secondly, the regulatory body may be assigned with specific role and responsibilities in emergency preparedness and in the event of an actual emergency. Thus, the regulatory body may be responsible for contributing to development of emergency arrangements at the national level and to act as a response organization in the event of an emergency in line with its emergency plan and procedures and the Member State's emergency plan. Such role and responsibilities may include assessing the emergency situation and providing necessary expert services, providing advice to government and other response organizations, and establishing communication with international counterparts.

Response to a nuclear emergency will involve many organizations at the national, regional and local levels with authority and responsibilities to prepare for and to respond to an emergency off the site. The regulatory body may be the only relation between these organizations and the licensee and will need to make sure that the off-site response organizations will have enough information to develop and implement off-site emergency arrangements as well as that the licensee has an access to support from these off-site response organizations when needed. In this context, the regulatory body will need to act as a coordinating authority among the licensees and off-site response organizations throughout the overall preparedness process to provide for an effective on-site and off-site response should an emergency occur.

The regulatory body will usually have an important public information role during emergencies. By providing timely, coordinated, consistent, accurate and unbiased information, the public will better understand the situation and respond accordingly.

Section 4.5 of this book provides more information on emergency preparedness and response.

3.7.2 Advice to government

The regulatory body will also advise the government on nuclear and radiation safety issues relating to the nuclear power programme. The communication of nuclear safety with decision

makers, such as high level government representatives and legislators, facilitates political decisions such as those related to the approval of adequate budget and organizational infrastructure for nuclear safety, improves relationships and coordination of joint activities.

The safety of nuclear installations is an international concern. In many Member States, the regulatory body represents the Member State at the international level on nuclear and radiation safety issues. International cooperation by the regulatory body, through multilateral or bilateral agreements, may include exchange of information, mutual assistance in regulatory activities, staff training and regular staff meetings on specific subjects. The regulatory body should participate in the preparation of international standards and may also serve as the contact point for international systems for the exchange of safety related information (such as the IRS).

3.7.3 Event reporting systems

The reporting of operating experience and regulatory experience has led to significant corrective actions to improve nuclear and radiation safety, both in nuclear installations and in regulatory bodies.

The regulatory body must put in place the necessary means to make information on incidents in nuclear installations, including accidents and abnormal occurrences, and other information as appropriate, available to licensees, government, national and international organizations, and the public.

The regulatory body must also establish and maintain a means for receiving information from other Member States and from licensees, as well as a means for making available to others lessons learned from operating experience and regulatory experience. The regulatory body has to require appropriate corrective actions to be carried out to prevent the recurrence of safety significant events. To enhance safety globally, feedback is necessary on measures that have been taken in response to information received via national and international knowledge and reporting networks.

The regulatory body should be organized to provide the public with factual, objective and understandable information concerning its activities, both on a regular basis and in relation to abnormal events. The regulatory body should be as open as possible while complying with national legislation on confidentiality. The regulatory body should have specialized expertise in public information and many regulatory bodies have established a specialized public information unit.

4 LEVEL C – OPERATIONAL REGULATION

This chapter describes the operational regulatory functions a regulatory body must manage.

4.1 AUTHORIZATION

Learning Objective 1: To understand international requirements and guidance related to authorization.

Learning Objective 2: To understand licensing during the NPP life cycle.

Learning Objective 3: To understand how regulatory control is secured through the granting of a licence.

Learning Objective 4: To be aware of alternate licensing processes.

Learning Objective 5: To understand the key stages in the authorization of a new NPP.

Learning Objective 6: To understand how the regulatory control derived from the licence is exercised through the phases of a NPP life-cycle.

Learning Objective 7: To understand how the licensing basis for a NPP is secured for life extension.

Learning Objective 8: To understand considerations for the licensing of the first NPP in a Member State.

Learning Objective 9: To understand the main contents of a NPP licence.

Authorization[47] is a key activity of the regulatory body, resulting with the granting or denial of a licence. When granted, the licence is generally accompanied with a list of limits and conditions bounding the activities authorized by the licence. When denied, the reasons are stated. The licence is granted on the basis of the review and assessment of the applicant's demonstration on the safety of the proposed installation. The licensing of a new installation may, depending on national practice, involve issuing a single licence, a combined licence, or a series of licences. Once a licence is issued, the regulatory body may also require that the licensee seek specific regulatory body approval for certain activities or changes. In this way, the regulatory body retains oversight of the installation.

Member State licensing practices vary, with some regulatory bodies issuing an operating licence for the design life of the installation. Some regulatory bodies issue licences with a shorter validity period, usually with some form of reassessment of the safety case. Still other regulatory bodies issue licences with no expiry date, but requiring a periodic demonstration of continuing safety. Life extension is a specific situation where the regulatory body authorizes, based on an acceptable review and assessment, operation of the installation beyond its

[47] The terms authorization, licence, permit and approval are frequently used interchangeably. For simplicity, this book will use licence except where quoting another document.

original design life and issues the appropriate licence. All of these practices can achieve effective regulatory control of an installation throughout its lifetime.

4.1.1 International obligations for authorization: Convention on Nuclear Safety

CNS Article 6 [6] stresses the importance of upgrading NPPs during the operational phase of the lifetime. This may be as a result of a periodic review of safety or as a result of operational experience feedback. The regulatory body is responsible for control of modifications to a NPP and for operating limits and conditions resulting from upgrading.

CNS Article 7 [6] requires that the legislative and regulatory framework in the Contracting Party include a system of NPP licensing and the prohibition of the operation of a NPP without a licence.

CNS Article 19 [6] requires that the initial licence to operate a NPP is based upon an appropriate safety analysis and a commissioning programme demonstrating that the NPP, as constructed, is consistent with design and safety requirements.

4.1.2 IAEA requirements and guidance

4.1.2.1 Governmental, Legal and Regulatory Framework for Safety (GSR Part 1 (Rev. 1))

GSR Part 1 (Rev. 1) [5] Requirements 23 to 26 refer to the authorization process.

Requirement 23 establishes that regulatory body authorization, including specification of the conditions necessary for safety, is a prerequisite for a nuclear installation.

Requirement 24 establishes that the applicant must submit an adequate demonstration of safety in support of an application for the authorization of a nuclear installation.

Requirements 25 and 26 oblige the regulatory body to review and assess the application in accordance with the stage in the regulatory process. The depth and scope of the review and assessment of the nuclear installation is required to be in accordance with a graded approach.

It should be noted that authorizations are not limited to the issuing of a licence. The licence itself may require the licensee to obtain regulatory body approval for various aspects of the nuclear installation operation.

4.1.2.2 Safety of Nuclear Power Plants: Commissioning and Operation (SSR–2/2 (Rev. 1))

SSR-2/2 (Rev. 1) [36] Requirement 12 requires the completion of systematic safety assessments, such as periodic safety review, throughout the lifetime of a NPP. The relationship between these systematic safety assessments and the authorization of operations varies considerably. In some cases, the assessment is a necessary element of an application for a new licence. In other cases, they are a condition of the licence and the basis for continued authorization by the regulatory body. Some regulatory bodies require routine comprehensive safety assessment programmes that deal with specific safety issues, significant events and changes in safety standards and operating practices as they arise.

4.1.2.3 Licensing Process for Nuclear Installations (SSG-12)

In 2010, the IAEA published *SSG-12: Licensing Process for Nuclear Installations* [26] to assist regulatory bodies in meeting GSR Part 1 (Rev. 1) [5] Requirements 23 and 24 and to provide:

- Recommendations on developing the basis of a licensing process to be applied by regulatory bodies for granting licences for nuclear installations, including some aspects of regulatory control;
- Information on the topics and documents that should be considered in the licensing process throughout the lifetime of the nuclear installation.

SSG-12 recommends the regulatory body enact mandatory regulations for requesting and issuing authorizations. The regulatory body should also produce safety guides to give examples on the contents of requests for authorization. SSG-12 includes an appendix with examples of documents to be submitted to the regulatory body.

4.1.2.4 Documentation for Use in Regulating Nuclear Facilities (GS-G-1.4)

In 2002, the IAEA published *GS-G-1.4: Documentation for Use in Regulating Nuclear Facilities* [25]. GS-G-1.4 is still valid, pending revision, and includes recommendations for regulatory bodies and licensees on the documentation to be prepared for authorization of nuclear installations. An appendix provides an outline of the authorization process.

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

In 2013, the IAEA published *GSG-4: Use of External Experts by the Regulatory Body* [28] to provide recommendations and advice on how to obtain expert professional advice and services to the regulatory body to fully and satisfactorily comply with its functions. The regulatory body may need to use external expertise during the authorization process, however the regulatory body must have a minimum, adequate core competence in every core regulatory function, both to be a knowledgeable customer and to understand the advice received.

4.1.3 Licensing during the nuclear installation lifetime

4.1.3.1 Background

The licensee has the prime responsibility for safety during the lifetime of a nuclear installation and must put in place the governance arrangements and management systems to ensure that it remains fully compliant with its licensing basis at all times. These arrangements and systems will:

- Provide assurance to all interested parties that it is operating safely;
- Ensure that applications for changes to the licensing basis, or changes within the licensing basis that require regulatory body authorization, are made in a timely manner.

The regulatory body is responsible for ensuring that appropriate regulatory control is exercised throughout the lifetime of the nuclear installation. Regulatory control ensures that there are measures in place to prevent changes in the level of hazard or risk at a nuclear installation without appropriate assurance that it is safe to do so. Regulatory control does not

relieve the licensee of its prime responsibility for safety. It does however provide an additional level of assurance to a wide range of interested parties that the licensee is fulfilling its responsibility.

4.1.3.2 General

Licensing of nuclear installations is one of the principal functions of a regulatory body. This licensing process may result in the granting of one or more licences during the lifetime of a nuclear installation, depending on national laws and regulations.

A licence is a legal document issued by the regulatory body allowing a licensee to perform specified activities. The term licensing process is often used for nuclear installations; it includes all licensing and authorization processes for a nuclear installation and its activities. The terms *licence, authorization* and *permit* are considered to be synonymous; authorization may take different forms, such as certification, granting of a permit, agreement, consent, regulatory approval or granting of another similar regulatory instrument, depending on the governmental and regulatory framework of the Member State.

The holder of a current and valid licence is termed a licensee. The licensee is the person or organization having overall responsibility for a nuclear installation and its activities and possessing all necessary licences for the installation and its activities. The person or organization having overall responsibility for a nuclear installation needs to apply to the regulatory body for permission to begin or continue to carry out certain activities, as specified by the regulatory body. A licensee may lose its licence for operation, for instance, but should not be released from its prime responsibility for safety and security unless so specified by the regulatory body.

Licences may be granted:

- For a specific time period (e.g. 10 years, 40 years), or for a specific stage in the lifetime of the nuclear installation (e.g. construction, operation). In such a case, a mechanism should be put in place to ensure that the former licensee remains responsible for safety and security at the installation if the licence has expired, unless the site has been removed from regulatory control;
- For an indefinite period of time, under certain conditions and until the licence is officially terminated by the regulatory body;
- For a specific activity or a specific condition of the nuclear installation.

The licensing process involves fulfilment of a set of regulatory requirements applicable to a nuclear installation and formal submissions by an applicant. The licensing process may also include agreements and commitments made between the regulatory body and the applicant (e.g. in the form of letters exchanged or statements made in technical meetings).

The regulatory body must establish the documents the applicant must prepare and submit as part of the licensing process. The regulatory body must also have the authority to request additional relevant information as required. SSG-12 [26] includes a list of documents that should be submitted. The licence will also include specific documents that the licensee must maintain. The documents submitted to the regulatory body as part of the licensing process should be updated, as appropriate, during the lifetime of the nuclear installation.

The regulatory body should specify the required contents for a licence application. For simple licences, the regulatory body may create a licence application form, but this is not practical for nuclear installation licence applications.

4.1.3.3 Public participation

The public should be given an opportunity to present their views during certain steps of the licensing process. If a site is near a Member State's national border, there should be appropriate cooperation, including public participation, with neighbouring Member State(s) in the vicinity of the nuclear installation.

Transparency, along with public participation and involvement in the regulatory process, reinforces the credibility of the regulatory body and enhances local public confidence in the nuclear regulatory system. The process for public participation should allow individuals or societal groups to challenge the issuing of a licence or authorization if it appears to jeopardize health or safety.

Throughout the lifetime of the nuclear installation, the public participation process, including participation of local, national and international interested parties, should be open, transparent, well described and balanced, and should ensure that security sensitivities and commercial proprietary information are respected. A process for consideration and resolution of concerns should be established.

4.1.3.4 Steps of the licensing process

Figure 24 shows the main stages in the licensing process. Past experience has shown that there is some overlapping of these stages and one stage may start before the previous one is fully completed. Moreover, in a given stage, there may be one or more 'hold points' set by national legislation and regulatory requirements. These hold points give the regulatory body the power to ensure that the licensee is properly controlling the risks to the health and safety of people and to the environment from the nuclear installation.

Each step of the licensing process may be divided into several sub-steps or may be merged or combined as appropriate to facilitate the regulatory process. Conditions may be attached to licences granted at each step and may require that the licensee obtain further, more specific, authorizations or approvals before carrying out particular activities.

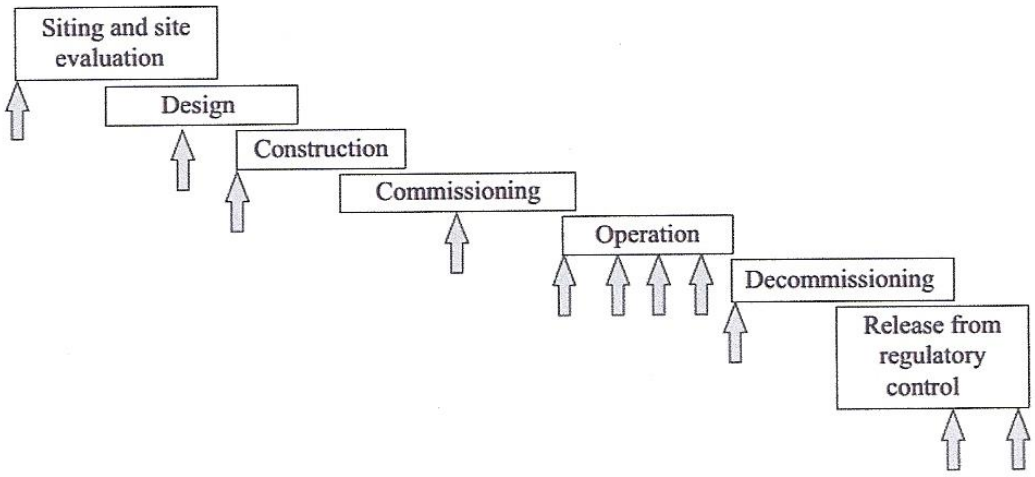


FIG. 24. Stages in the lifetime of a nuclear installation; the arrows indicate where hold points may be imposed.[48]

Government will undertake a range of facilitative activities to bring a new nuclear installation into operation. These activities may lead to decisions or regulatory judgments. Government is likely to be involved in site identification, the completion of planning activities, and the justification that establishes the benefits of a specific design outweigh the detriments. Government and related decisions are often made prior to the deliberations of the regulatory body on whether to grant a licence and in some cases a government department or agency coordinates the range of government and regulatory decisions and grants a licence. Regardless of who issues a licence, a licence must not be issued without the concurrence of the regulatory body. Depending on the range of responsibilities assigned to the regulatory body, there may be a need to coordinate the regulatory decision making on nuclear safety with those of other regulators with responsibility for environmental protection, transport safety, public health and security.

Although international licensing practices vary considerably, they all bring the nuclear installation under regulatory control and place requirements on licensees to operate within strict parameters set out in regulations or conditions attached to the licence. Licences include a range of measures including:

— Use of hold points;
— Control of key documentation;
— Control of changes to the site, the operating organization or the nuclear installation.

There are different national approaches to licensing new nuclear installation that can involve the issue of a single licence, a combined licence or separate licences for the site and for operation. Irrespective of these differences, the licensing process seeks to establish that the:

— Site is suitable for construction of a nuclear installation;
— Organization to be licensed has the capability and capacity to fulfil its responsibilities for safety;
— Nuclear installation design, located on the specific site, provides defence in depth against harmful effects to people or to the environment.

[48] Taken from SSG-12 [32]

There is also a consistency in the key stages in the authorization of a new NPP. This recognizes that regulatory control, through the granting of a licence is appropriate when there is a significant change in the level of hazard on the site. Such authorizations typically occur when nuclear fuel is first brought on to the site, at first criticality, and at commencement of full power operation.

In some Member States the regulatory body will confirm the qualifications and authorization of staff through the inspection of the licensee's arrangements. In other Member States the regulatory body will exercise more direct regulatory control by issuing licences to key operating personnel, such as control room operators.

Regulatory requirements, in the form of regulations or conditions attached to the licence, will place a duty on a licensee to apply to the regulatory body before it makes changes to the site, the organization, the nuclear installation, or its operation that affect safety. The regulatory body will normally process these requests within the existing licensing basis.

The licensing regime must be sufficiently robust and flexible to allow major changes to be completed within the licensing basis. This might include large scale organizational change, replacement of major components such as steam generators or major upgrades to protection systems.

In exceptional circumstances a licensee's proposals may necessitate a licence amendment. This may occur as a result of changes related to the site, the licensee's organization or the nuclear installation. This may be due to a proposed change to:

- Scope of activity on the site, e.g. a new fuel storage facility on the site, changes in the site boundary, reuse of part of the site for another purpose;
- Organizational changes e.g. due to corporate restructuring, or changes in ownership; or,
- Changes to the nuclear installation that are outside the conditions or limits stated in the licence, e.g. changes to the power rating, a change to load follow, or a change in fuel.

Throughout the life of the nuclear installation, the regulatory body must maintain regulatory control in several key areas. The areas which generally receive the greatest regulatory attention are operational limits and conditions, nuclear installation modifications and organizational change. The regulatory body will also exercise regulatory control through hold points during construction and commissioning and, in some cases, control of return to power after an outage.

The responsibility of the licensee for the safety of a nuclear installation continues after operation has ceased and the regulatory body must continue to exercise an appropriate level of regulatory control. The licensing arrangements for decommissioning vary considerably but focus on radiation protection and the safe management of spent fuel and radioactive waste.

4.1.4 Alternative regulatory licensing processes

An alternative regulatory process for NPP licensing exists, using early site permits, certified standard designs and a combined construction and operating licence. This process is beyond the scope of this book, but more information can be found in SSG-12 [26].

4.1.5 Life extension

When designing a nuclear installation, the designers make certain assumptions about the life of the installation. However, at the end of this assumed lifetime, a licensee may decide to invest in extending the life of the installation for commercial reasons by:

- Replacing obsolete or ageing equipment;
- Upgrading the installation to comply with current safety standards.

If a licensee concludes that the life extension of a nuclear installation is commercially viable it will prepare a safety justification.

The exact form of regulatory control to ensure compliance with the licensing basis for a period of further operation varies due to differences in regulatory frameworks. In some cases, a licence is issued for short periods and regulatory control is exercised through relicensing based on reviews of safety and the satisfactory completion of related corrective actions and upgrades. In other cases a licence is issued for a period of time consistent with the anticipated economic life of the nuclear installation and relicensing again provides the basis for regulatory control. In some cases a licence is issued for an undefined period, but the regulatory body must authorize continued operation based on the review of safety and the satisfactory completion of related corrective actions and upgrades.

In all cases, the safety of the nuclear installation must be reassessed and the authorization of a period of further operation will depend on the satisfactory completion of the most safety significant modifications. Less safety significant modifications may be scheduled for completion following the granting of a licence for further operation.

4.1.6 New entrant considerations

INSAG-22 [63] provides general advice on new entrant considerations for the operational phase of a NPP. The regulatory body will need to ensure that: the full range of regulatory controls is established; they are set out clearly in regulations or conditions attached to the licence; and they are captured in the regulatory body's management system.

Another priority for a new entrant will be to decide on the nature and duration of a licence. This will determine the additional regulatory controls that will be set out in regulations or in conditions attached to the licence.

A specific decision will be necessary on whether to licence or certify persons for specific positions in the licensee organization (control room operators, shift supervisors, etc.) or rely on other mechanisms to ensure competence.

4.1.7 Main contents of a licence

Although in some cases, the nuclear law will establish the contents of a licence, in most cases, the regulatory body decides on the contents of the licence. The licence should include:

- Unique licence identification;
- Issuing authority: the laws and regulations under which the licence is issued; the official designations of those who are empowered by those laws or regulations to issue the

licence and whose signature and stamp should appear on the licence; and the authority to which the licensee will be accountable under the terms of the licence;

- Identification of the individual or organization legally responsible for the nuclear installation;
- Sufficiently detailed description of the nuclear installation, its location and its activities, including a clear depiction and description of the site boundaries, and other drawings, as appropriate;
- Maximum allowable inventories of sources;
- Requirements for notifying the regulatory body of any safety significant modifications;
- Obligations of the licensee with respect to both safety at the nuclear installation and the safety of its equipment, radiation sources, workers, the public and the environment;
- Any limits on operation and use (e.g. dose limits, discharge limits, action levels, limits on the duration of the licence);
- Any separate additional authorizations that the licensee is required to obtain from the regulatory body;
- Requirements for reporting events and incidents at the nuclear installation;
- Requirements for providing routine reports to the regulatory body;
- Requirements for retention of records by the licensee regarding the nuclear installation and its activities, including the time periods for which records should be retained;
- Requirements for arrangements for emergency preparedness;
- Means and procedures for changing any information stated in the licence;
- Documentary basis. The documents in support of the application and those prepared and used by the regulatory body in the review and assessment process, which together form the basis for issuing the licence;
- Relationship to other licences; that is, whether the licence is contingent upon a prior authorization or is a prerequisite for a future authorization. Mechanisms should be established so that expiry of a licence is avoided;
- Procedures for, information about and identification of the legal framework for challenging the licence or part of the licence;
- Licence conditions as described below.

Licence conditions are additional specific obligations for the licensee. Licence conditions should be incorporated into the licence to supplement general requirements or make them more precise. Licence conditions should cover safety related aspects affecting the nuclear installation. Each licence condition must be consistent with all other licence conditions in that the fulfilment of one should not conflict with the fulfilment of another or with any other legal requirement. It may be useful to group the licence conditions into categories, such as:

- Conditions that set technical limits and thresholds;
- Conditions that specify procedures and modes of operation;
- Conditions pertaining to administrative matters;
- Conditions relating to inspection and enforcement;
- Conditions pertaining to the response to abnormal circumstances.

One exception to the above is if a requirement is already detailed in the nuclear law or regulatory framework. In this case, the licence should refer to the requirement, not repeat it. This will avoid confusion.

On a particular site, there may be different nuclear installations at different stages of their lifetimes with different licensees and with authorizations or licences having different licensing bases. In these cases, the regulatory body must establish a process ensuring consistency. In cases where several licensees share common safety related features, the regulatory body must ensure that individual licences do not compromise safety.

4.1.8 Examples of licensing processes

4.1.8.1 Licensing of new nuclear installations

The following extract from the report of the 2012 IRRS mission to Sweden[49] illustrates the roles of government and the regulatory body in the licensing process.

> "Applications for new NPPs, other nuclear facilities and major modifications of operating NPPs, such as power up-rates, must be examined both under the Act on Nuclear Activities and the Environmental Code. According to the application procedure, an application for a permit is submitted to SSM, which prepares the case under the Act on Nuclear Activities, and to the Land and Environment Court, which prepares the case under the Environmental Code. An application for a licence to construct, possess or operate a nuclear installation contains an Environmental Impact Assessment (EIA), an initial preliminary safety analysis report (PSAR) along with technical and other statements of the proposed NPP and its operation. SSM assesses whether the NPP is likely to be located, designed and operated in such a way that the safety and radiation protection requirements and the requirements for security and safeguards are met".
>
> "The court prepares the case in accordance with the provisions of Chapter 22 in the Environmental Code. The basis is General rules of consideration under Chapter 2, Environmental Code, the submitted EIA, drawings and technical descriptions of site conditions, production volume or other similar data and the use of raw materials, other inputs and topics like energy use. Both SSM and the Land and Environment Court give their opinions to the Government, who decides on permissibility according to Chapter 17 of the Environmental Code, and for a decision for a permit under the Act on Nuclear Activities (design, construction, commissioning and operation)".
>
> "The authorization by the Government includes the following licensing conditions to allow continued stepwise examination until the proposed NPP can be put into routine operation:
>
> —the licensee may not begin construction of the NPP without SSM approval;
> —The NPP may not be taken into commissioning phase including trial operation without being approved by SSM;
> —The NPP may not be taken into routine operation without being approved by SSM".

Many licensing decisions are a major project and in such cases a regulatory body must organize its activities in such a way as to provide a properly considered and timely regulatory

[49] https://www-ns.iaea.org/downloads/actionplan/IRRS%20Mission%20to%20Sweden_Feb_2012_1.pdf

decision. The following extract from the report of the 2008 IRRS mission to Spain[50] illustrates of how a regulatory body can organize to deliver a licensing decision.

> "Each nuclear installation has a Project Manager (PM) at the CSN[51]; one of his/her main functions is precisely to ensure performance of the established processes needed for review of compliance with all relevant regulations and guides. The PM monitors the compliance with deadlines and assesses, or asks to assess, the appropriate fulfilment of the conditions".
>
> "The applications for authorization are reviewed and assessed by the CSN in accordance with clearly defined written procedures. The reviews, inspections and assessments are done based on the compliance with the regulations of the Member State of installation design origin as applicable. The content of the application is different according to the activity. There is a Management Procedure where the criteria and systematic for the assessment of the applications from Licensees are established".
>
> "The CSN has issued guidance to the operator on the format and content of documents to be submitted in support of an application for authorization. There are guides with the detailed content of documents as: Radiation Protection Manual, On-site Emergency Plan, Organization Manual and Quality Assurance Manual. For the other required official documents, there are standard contents as practiced in the State of origin of the design. According to the CSN policy, it was considered as not necessary to develop respective standards".
>
> "The deadlines for sending additional information when the documentation is incomplete are established in the RINR. The deadlines for the applications for renewal of an operational licence and other documentation of the authorization are established in the authorization of each NPP. A minimum period of 6 months is established in internal CSN process descriptions for the official submission of an application for authorization. For complex authorization cases the preliminary assessment may start prior to the official receipt of the documentation. When, in order to issue its perceptive report, the CSN has to request additional information from the licensee, it grants the latter a period of 15 days, extendable, for the answer. As a general rule, the licensee usually asks for this period to be extended".
>
> "The overall results of the review process is documented by the Project Manager in the "Proposal for technical decision (PDT)" to be endorsed b the CSN plenary and then submitted to the Ministry. The content of the licence is specified adequately in the Law".
>
> "In an annex to the authorization for operation binding conditions and limitations are issued to the licensee regulating the operation as well future interactions with the regulator. It fixes the documentation on which the licence is based, the treatment of modifications to such documentation or to the design and operational modes as well the annual reports. These reports have to encompass design modifications; internal and external operating experience; applicability to the facility of the new

[50] https://www-ns.iaea.org/downloads/actionplan/IRRS%20Mission%20to%20Spain__Jan-Feb_2008.pdf
[51] Cosnsejo de Seguridad Nuclear (CSN) is the Spanish nuclear regulator

requirements issued by the regulatory body of the State of design origin, programme for training staff whose jobs may impact safety; results from the environmental radiation monitoring programme; staff dosimetry results; radioactive waste management plan activities; and operating life management activities".

"The CSN report for granting or refusing an authorization is published on the CSN's external Website. The criteria whereby the authorization is accepted or rejected are presented, and if accepted, the conditions under which the operation of the installation or facility is granted are specified. The CSN has in place the procedures established for subsequent amendment, renewal, suspension or revocation of an authorization".

The regulatory body exercises regulatory control to ensure that operators of nuclear installations are suitably qualified and experienced to perform their duties. The following extract from the report of the 2008 IRRS mission to Germany[52] illustrates the authorizations and regulatory approvals related to individuals.

"Each NPP is required to prepare an organization chart and submit it to the competent licensing and supervisory authority. This chart must show the assignment of major tasks and responsibilities to the NPP personnel and in particular the classification of each member of the personnel in one of the following categories to which this guideline applies. The Guideline Relating to the Proof of the Technical Qualification of NPP Personnel (Richtlinie für den Fachkundenachweis von Kernkraftwerkspersonal) provides information related to the positions requiring verification. These positions include NPP Manager, Head of Department or Section, responsible shift personnel (shift supervisor, deputy shift supervisor, shift operating engineer, reactor operators), Radiation Protection Officer, Training Manager, Head of Quality Assurance, Nuclear Safety Officer, and Physical Protection Officer. Also listed are the documents and specific requirements associated with each position that must be provided to the competent authority. Additionally, specific training, experience and examination requirements are specified for certain positions, including the subjects to be covered".

"Examination requirements are specified including a written and oral examination, with the required oral board members specified as well. For each responsible person addressed in the Guideline, the licensee or applicant requests approval for a particular individual to fill that position. UM BW reviews the provided documentation associated with the individual and either grants or rejects approval for that particular individual. The licensee/applicant is notified of the decision in writing".

4.1.8.2 Licensing during the nuclear installation lifetime

Maintaining confidence in nuclear safety during the lifetime of the nuclear installation can be achieved by demonstrating to interested parties that the licensing basis is maintained through licensee activities and oversight exercised by the regulatory body. The following extract from

[52] https://www-ns.iaea.org/downloads/actionplan/IRRS%20Mission%20to%20Germany___Sept_2008_1.pdf

the report of the 2009 IRRS mission to Canada[53] illustrates how a regulatory body can foster the involvement of the public in the regulatory process.

> "Canada fosters broad involvement of the public in the regulatory process. It has a well-developed programme for communicating information about its activities to the public. Communications plans and products are drafted for all significant programme and regulatory activities and the organization engages in public outreach activities in host communities that are open to all interested parties. The CNSC uses the Internet extensively as a communications vehicle, maintaining a Web site that is updated regularly as a source of information on the fulfilment of its mandate and discussion of current events and activities".

> "The public's primary opportunity to participate in the procedures for rendering major licensing decisions is in the Commission public hearings. Approximately 30 public hearings related to such decisions are held each year. They are a highly visible component of the work of the Commission. The Rules of Procedure, which set out the process for Commission hearings, include the opportunity for interested persons to intervene in the hearings and make presentations or challenge the evidence. Notices of hearings are posted on the Commission's Web site and in national and local newspapers, in sufficient time for the public to be apprised of the materials and to seek intervener status".

> "The Commission also holds public meetings to consider a wide range of topics related to the nuclear regulatory process and, in certain cases, to make legislative, policy or administrative decisions on matters of particular or general application".

The following extract from the report of the 2012 IRRS mission to Slovakia[54] illustrates a range of regulatory controls exercised during the lifetime of a nuclear installation.

> "Applications for authorization of each licensing stage of the NPP are assessed, reviewed or inspected by UJD SR to inform a regulatory decision on whether progress through to the next stage of construction, commissioning or operation should be authorized. The start of construction is a significant step, and UJD SR grants a construction licence, taking into account the views of other ministries and offices such as UVZ SR and the Ministry for Environment, in reaching its decision. Licensing decisions of UJD SR are issued in the form of written decisions. According to the Atomic Act, the authorized party has a right to appeal all written decisions of the regulatory body. The first avenue of appeal is the Chairperson of UJD SR. His/her decision can be further challenged in the courts. Details about the authorizations issued by UJD SR are published on the UJD SR website".

> "UJD SR authorizes the Operator to proceed through stages of commissioning and into operations in accordance with the Atomic Act. UJD SR may impose conditions and limitations on the Operator's activities – for example, relating to nuclear safety, physical protection, quality assurance or emergency preparedness, and modify these where it considers this to be necessary. Throughout the construction, commissioning and operation of a nuclear facility, UJD SR verifies the Operator's compliance with

[53] https://www-ns.iaea.org/downloads/actionplan/IRRS%20Mission%20to%20Canada__May-Jun_2009.pdf
[54] https://www-ns.iaea.org/downloads/actionplan/IRRS%20Mission%20to%20Slovakia_May-June_2012.pdf

the conditions of the licence or authorization, and has the power to repeal licences or authorizations if, for example, it is concerned with the Operator's compliance. UJD SR reviews and, as appropriate, authorizes NPP modifications".

"UJD SR is required to authorize certain job positions at an NPP, e.g. operational staff in control room, shift engineer, safety engineer etc. The required professional competencies are attained after successful completion of professional training and passing the final state exam in front of an Examination Committee appointed by UJD SR. The scope and content of the training is subject of authorization by UJD SR. The licence of special professional competence is valid three years from the date of issue".

"If there is a proposal to change the company that operates the nuclear site – i.e., to transfer the activities on the licenced site to a different corporate body, a new licence must first be granted".

The following extract from the report of the 2008 IRRS mission to Spain[55] illustrates how licences of limited duration are linked to the completion of a PSR.

"The operating licence for NPPs is granted for ten year periods, as appears in the Operating Licence itself, which establishes that for its renewal a Periodical Safety Review (PSR) must be submitted in the terms laid down by the CSN by means of a Complementary Technical Instruction. The renewal application must be submitted 1 year before the expiration of the validity period. The RINR determines when the CSN has to submit its Report to the MITYC (1 month before the deadline). Safety Guides establish the detailed content and scope of these reviews. Internal CSN procedures specify the review and assessment as well the time allowed for the necessary assessment".

The following extract from the report of the 2011 IRRS mission to Switzerland[56] illustrates the regulatory control in relation to nuclear installation upgrades.

"The IRRS team found that the back-fitting rule is very clear. It is clearly stated that an INES-2 worldwide (INES-1 at the NPP itself) shall be analyzed and might lead to back-fitting. If the analysis shows that the design basis is violated (e.g. dose criteria cannot be met), the NPP has to shut down immediately until the corresponding back-fit is complete. Fukushima Daiichi is such an example leading to measures which have to be implemented. However, no immediate shutdown was needed as none of the criteria of the DETEC Ordinance 732.114.5 on the Methodology and the General Conditions for Checking the Criteria for the Provisional Taking out of Service of NPPs have been met. Based on the back-fitting rule, numerous NPP improvements have been initiated".

4.1.8.3 Life extension

The following extract from the report of the 2010 IRRS mission to the USA[57] illustrates key features of the licence renewal process for life extension.

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[55] https://www-ns.iaea.org/downloads/actionplan/IRRS%20Mission%20to%20Spain__Jan-Feb_2008.pdf
[56] https://www-ns.iaea.org/downloads/actionplan/IRRS%20Mission%20to%20SWITZERLAND_Nov_Dec_2011_1.pdf

"The Atomic Energy Act authorizes the NRC[58] to issue licences for power reactor to operate for 40 years and allows the licence to be renewed. A 40-year term was selected on the basis of economic and antitrust considerations, not for technical limitations. In accordance with the NRC's regulation, a licensee may renew its operating licence up to an additional 20 years and may apply for renewal as early as 20 years before expiration of the current licence".

"The NRC licence renewal requirements are based on two key principles:

—The regulatory process for currently operating NPPs is adequate to ensure that they will continue to maintain adequate levels of safety during the extended operation, with the exception of detrimental effect of aging on certain SSCs, and a few other issues that may arise during the period of extended operation;

—The NPP's licensing basis is required to be maintained during the renewal term in the same manner and to the same extent as during the original licensing term".

"The licence renewal proceeds along two tracks, one for review of the safety issues (in accordance with the requirements of 10 CFR Part 54) and the other for the environmental issues (in accordance with 10 CFR Part 51). The extensive guidance prepared by the NRC, with stakeholder involvement, for implementing the rules has greatly improved the efficiency and effectiveness of the process for an applicant to prepare the application and for the NRC staff to perform its review".

"Public participation has extensively been involved in the licence renewal process. A number of meetings are held in the vicinity of the NPP to provide the public with information on the licence renewal process, solicit input on the environmental review, and to provide the results of the NRC's inspections. A hearing process has been held to deal with the concerns by members of the public".

The following extract from the report of the 2011 IRRS mission to Switzerland[59] summarizes the policy discussion that took place on long term operation.

"To maintain NPP safety it is very important to detect ageing effects of SSCs, to address associated reductions in safety margins and to take corrective actions before loss of integrity or of functional capability occurs. Effective ageing management is in practice accomplished by coordinating existing programmes, including maintenance, in-service inspection and surveillance, as well as operations, technical support programmes (including analysis of any ageing mechanisms) and external programmes such as research and development".

"With the aid of a programme for managing ageing effects, the licensee must systematically monitor ageing of all SSCs, the function and integrity of which are important with regard to safety and security (Art. 35 NEO). ENSI Guideline B-01, which is based on the IAEA Standards Series NS-G-2.12 [42], specifies the requirements for implementing and documenting the ageing surveillance

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[57] https://www-ns.iaea.org/downloads/actionplan/IRRS%20Mission%20to%20the%20USA__Oct_2010_1.pdf
[58] The United States Nuclear Regulatory Commission (USNRC or NRC) is the United States of America nuclear Regulator
[59] https://www-ns.iaea.org/downloads/actionplan/IRRS%20Mission%20to%20SWITZERLAND_Nov_Dec_2011_1.pdf

programmes. The ageing surveillance programme is in place for all NPPs and is a pre-requisite for long term operation in Switzerland".

"Requirements for long term operation are as follows:

- Ageing surveillance programme (ASP): Systematic ASP for classified SSC in the mechanical, civil and electric engineering areas;
- Verification of the shutdown criteria: Compliance with the shutdown criteria for ageing over the expected operation time (primary circuit, containment);
- Deterministic and probabilistic safety analysis: Compliance with the dose limits for DBA and the CDF limit for existing NPPs;
- Technological ageing: Assessment of realized and planned back-fitting projects".

"ENSI was prompted to give in-depth consideration to the issues related to long term operation in 2004. As part of the conversion of what was then a fixed-term operating licence for KKB2 (Beznau NPP2) into an unlimited operating licence, ENSI developed the current procedure for demonstrating the reliability of long term operation".

The following extract from the report of the 2006 IRRS mission to France[60] illustrates the importance of regulatory control of modifications throughout the life of the nuclear installation and for life extension. It also illustrates the link between a PSR and upgrading.

"In accordance with Decree No. 63-1228 and the Ministerial order of 10th August 1984 on QA, all modifications (hardware, software or procedures affecting the documents associated with the creation decree of a BNI such as SAR, GOR, EP or waste management programme) must be authorized by the ASN[61]. In order to optimize the process of authorization in accordance with the level of impact on safety, modifications are classified into 3 groups with different scopes of safety demonstration required from the licensee and different approval processes by ASN. Detailed information including risk analysis, human factor analysis, modification of the SAR and GOR, radiation protection impact and evaluation of feedback from previous modifications is required for all modifications with significant safety impact. Classification of modifications was explained in an ASN letter to EDF (dated 6th May 2002), describing how to classify modifications and what kind of documents are to be provided. The letter also contains a time schedule for submissions and the corresponding quality requirements. The modification classification is first proposed by EDF, usually reviewed by IRSN and finally agreed to or rejected by ASN. Although in the majority of 35 cases ASN follows IRSN[62] advice, the final decision can differ. One case was presented to the IRRS team where the final decision was different from both EDF and IRSN recommendations. The ASN decision was supported by written justification. Similarly, the statement/recommendation of IRSN was comprehensively documented. Typically ASN manages several tens of modifications per year. The milestones for planning NPP modifications are typically related to periodic safety reviews (PSRs), since according to the legal requirements one of the objectives for a PSR is to increase the

[60] https://www-ns.iaea.org/downloads/actionplan/IRRS%20Mission%20to%20France__Nov_2006.pdf
[61] Autorité de Sûreté Nucléaire (ASN) is the French nuclear regulator.
[62] Institut de Radioprotection et de Sûreté Nucléaire (IRSN) is a French TSO.

safety level. During the PSR a comparison with current requirements is made by the experts. This process provides for effective long-term planning of authorization of modifications. Every year ASN receives a file from EDF regarding all modifications planned for the next year so that ASN can be prepared including availability of TSO support. Recently, the 3rd PSR for 900 MW reactors was performed, and led to approximately 30 modifications for this group of reactors. This year, classification of modifications for 1300 MW reactors following their first 10 years of operation will be performed. However, since PSR is the primary tool for the identification and specification of modifications, it seems appropriate to check whether the PSR is comprehensive enough to ensure that some important issues are covered adequately".

"Time for implementation of a modification can take up to several years. Standing expert groups are extensively involved in the evaluation of proposed modifications. For example, for safety upgrading of 900 MW reactors, there were 8 meetings of standing expert groups to discuss the proposed modifications".

"Given that there currently exists a high level of standardization in NPPs, and in order to maintain a high level of standardization, implementation of the same modifications for a given group of reactors is usually proposed, although there can be specific requirements or modifications for individual reactors. Also, currently having only one NPP licensee allows for communication between ASN and EDF by means of letters; this is not considered desirable for the future, and more formal regulatory documents and guidance should be developed".

"Authorization of software is a specific case of authorization of modifications. As with other NPP modifications, three categories are recognized according to their impact on safety. Basic Safety Rule RFS II-4-1-a, May 2000 edition, applies for safety classified electrical system software as a reference document for assessment, together with the ASN letter of May 2002 defining the examination process for safety related NPP modifications and the NPP safety analysis report. Due to the complexity of software modifications, many organizations are involved and due to difficulties in justifying the quality of the product it may take 36-38 months to implement a modification. It is considered desirable to develop more general basic safety rules which will describe the process of authorization in more detail".

"In general, high attention is paid by ASN to monitoring the implementation of modifications. This includes monitoring of the quality of design, quality of implementation and associated experience feedback".

4.2 REVIEW AND ASSESSMENT

Learning Objective 1: To understand international requirements and guidance for review and assessment.

Learning Objective 2: To understand the purposes of review and assessment.

Learning Objective 3: To understand that the review and assessment must address all the radiation risks to all potentially affected individuals and population groups not only in the present, but over the life of the installation.

Learning Objective 4: To understand the topics that the review and assessment must cover.

Learning Objective 5: To understand how the review and assessment relate to the safety objectives and requirements.

Learning Objective 6: To understand the importance of regulatory body competence in conducting reviews and assessments.

Learning Objective 7: To understand the review and assessment methodology.

Learning Objective 8: To understand the concept of defence in depth.

Review and assessment is a critical appraisal, performed by the regulatory body, of information supplied by an applicant or licensee regarding the safety of the nuclear installation. The process of review and assessment typically begins with an applicant or licensee submitting information to the regulatory body, usually with a request for regulatory body approval. The review and assessment will form the basis for the decision by the regulatory body.

4.2.1 IAEA requirements and guidance

The main IAEA guidance on review and assessment is provided by:

- Governmental, Legal and Regulatory Framework for Safety (IAEA Safety Standards Series No. GSR Part 1 (Rev. 1)) [5];
- Safety Assessment for Facilities and Activities (IAEA Safety Standards Series No. GSR Part 4) [30];
- Review and Assessment of Nuclear Facilities by the Regulatory Body (IAEA Safety Standards Series No. GS-G-1.2) [23].

GSR Part 1 (Rev. 1) [5] Requirements 23 to 26 refer to review and assessment of nuclear installations by the regulatory body. The requirements include three steps: (1) the need for operators of installations and activities to apply for authorization from the regulatory body; (2) the demonstration of safety by the applicant for authorization, and (3) the review and assessment by the regulatory body of the request for authorization.

Requirement 25 in GSR Part 1 (Rev. 1) states:

> "The regulatory body shall review and assess relevant information—whether submitted by the authorized party or the vendor, compiled by the regulatory body, or obtained from elsewhere—to determine whether facilities and activities comply with regulatory requirements and the conditions specified in the authorization. This review and assessment of information shall be performed prior to authorization and again over the lifetime of the facility or the duration of the activity, as specified in regulations promulgated by the regulatory body or in the authorization" [5].

GS-G-1.2 [23] describes the review and assessment activities performed by the regulatory body on nuclear installations. GS-G-1.2 was published in 2002, and refers to GS-R-1 [64], published in 2000, which has been superseded by GSR Part 1 (Rev. 1) [5]. GS-G-1.2 is still valid, pending revision, and defines the review and assessment process and discusses performance and monitoring. It also includes an appendix listing the topics covering the safety review and assessment process.

GS-G-1.2 states:

> "The basic objective of review and assessment is to determine whether the operator's submissions demonstrate that the installation complies throughout its lifetime with the safety objectives stipulated or approved by the regulatory body" [23].

GS-G-1.2 also includes a long list of examples of specific objectives in the different phases in the life of the nuclear installation. The list includes technical objectives related to: siting; design; construction and procurement; pre-nuclear and nuclear testing; operating conditions and waste management; design changes; procedural questions related to management, staffing, expertise and training; as well as closure conditions and resources for dismantling.

Review and assessment is one of the most important and time consuming tasks a regulatory body performs. Even so, the extent of the review and assessment of information submitted by the licensees is not easy to define. The regulatory body needs to be able to weigh the safety importance of the information and then apply the necessary resources to the review and assessment. At the same time, the licensee has the prime responsibility for safety and regulatory body must guard against taking on this responsibility. A constant balance has to be found between regulatory oversight and responsibility of the licensee.

GSR Part 4 (Rev. 1) states:

> "The main factor to be taken into consideration in the application of a graded approach is that the safety assessment shall be consistent with the magnitude of the possible radiation risks arising from the facility or activity. The approach also takes into account any releases of radioactive material in normal operation, the potential consequences of anticipated operational occurrences and possible accident conditions, and the possibility of the occurrence of very low probability events with potentially high consequences." [30].

The depth and scope of the review and assessment depends on a number of factors including, but not limited to:

— The reason for the review and assessment (initial request, updating of previous information, operating experience, etc.)

— The stage of the nuclear installation in its lifetime (site approval, construction approval, first criticality, operating, decommissioning, etc.);
— The approval, if any, the licensee is requesting;
— Experience with previous submissions.

An example for the graded approach in the regulatory oversight of an operating NPP is the review and assessment of design changes. Not all design changes need to be reviewed and assessed by the regulatory body. Therefore, every regulatory body establishes a level, below which it does not assess a change. For these changes, the regulatory body will expect the licensee to establish and follow a change control process. The regulatory body will periodically audit this change control process to ensure compliance with regulatory requirements. For changes that might have an impact on nuclear safety, the regulatory body will define the scope of the review and assessment in advance.

The following extract from the report of the 2009 IRRS mission to Russian Federation illustrates the graded approach.

> "If the licensee plans to modify any system or component that may affect safety, the licensee submits the modification to Rostechnadzor for approval. If the modification requires a change to any licence condition, then it is assessed by Rostechnadzor's headquarters staff. However, if there is no change to any licence condition then the modification is assessed by the resident (site) inspector".

4.2.2 General requirements for review and assessment

The review and assessment of a site preparation licence requires: expertise on earth sciences to determine compatibility between the site characteristics with the nuclear installation's demands from the site; an analysis of the potential social and economic impacts of the installation on the population, industrial and other uses of the surrounding territory; and the potential effects of the site development on the installation itself.

The review and assessment for a construction licence is more complicated as it will require coordination with the inspection of construction activities and must be maintained until commissioning activities are complete. It is mainly based on the preliminary safety analysis report. Safety assessment and review for a construction licence requires many engineering disciplines, experts on the use of complex computing codes and standards applied in designing and construction of SSCs and experts on deterministic and probabilistic nuclear safety assessments. During construction, regulatory body inspectors must confirm licensee activities, be present for relevant tests and analyze and accept test results.

The review and assessment for a commissioning and first operating licence is the most extensive, with oversight maintained throughout the operating life of the nuclear installation. For commissioning, the review and assessment activities must be closely aligned with regulatory inspection activities. For operation, the review and assessment activities are based on the final safety analysis report reflecting the nuclear installation as built and using actual data from commissioning.

Nuclear installation decommissioning includes a preparation for shutdown, shutdown and dismantling. The major regulatory interests are radiation protection and the management of spent fuel and radioactive waste.

Every change in the nuclear installation must be the subject of a review and assessment by the licensee and in many cases, the licensee will require the approval of the regulatory body, which will conduct its own review and assessment prior to giving approval. The regulatory body may require the licensee to conduct a PSR, which the regulatory body will also review and assess.

The regulatory body must also require the licensee to review and assess:

- Any changes that may significantly affect the safety of the installation;
- Significant developments in knowledge and understanding (such as developments arising from research or operating experience);
- Emerging safety issues due to a regulatory concern or a significant incident;
- Safety significant modifications to the computer codes, or changes in the input data used in the safety analysis.

Once a nuclear installation is operational, the regulatory body must establish a number of performance indicators that can be used to assess, on an ongoing basis, the performance of the licensee and the nuclear installation. The regulatory body will need to review and assess these performance indicators for trends and substandard or unacceptable performance.

Each time the regulatory body carries out a review and assessment, the conclusions and any resulting should become part of the installation's integrated safety assessment. The integrated safety assessment assembles, in a systematic way, results of reviews and assessments and inspections, as well as other information obtained from the licensee. The regulatory body can then review and assess the integrated safety assessment for trends and overall conclusions, which should be fed back to the licensee.

4.2.3 Review and assessment topics

4.2.3.1 Physical nature of the installation and its environment

- Detailed installation description, supported by drawings as necessary;
- Functional capability of the installation and its SSCs;
- Results of tests which validate the functional capability;
- Results of inspections of SSCs;
- Maintenance records;
- Description of the present physical condition of SSCs based on inspections or tests;
- Description of the support facilities available both on and offsite, including maintenance and repair shops;
- Geological, hydrogeological and meteorological conditions;
- Description of offsite characteristics, including population densities, land use, industrial developments and transportation arrangements.

4.2.3.2 Waste management and transport of radioactive materials

Throughout the lifetime of the installation, the licensee must propose and implement arrangements for waste management. The regulatory body reviews and assesses proposals for onsite treatment and storage to ensure that the processed waste and waste packages are compatible with national strategy, relevant waste acceptance requirements for subsequent

waste management steps and regulatory requirements. Specifically, the regulatory body assures itself that the waste or waste packages:

— Are properly characterized and compatible with the anticipated nature and duration of storage pending disposal;
— Can be subjected to regular surveillance;
— Can be retrieved for further waste management steps.

Transport of radioactive materials and waste and equipment, both on and offsite, needs adequate arrangements. The regulatory body reviews and assesses these arrangements and assures itself that all national and regulatory requirements are met.

4.2.3.3 Safety analysis

— A compilation of the safety analysis and its assumptions;
— SSCs important to safety;
— Limits and permitted operational states;
— Anticipated operational occurrences;
— Postulated initiating events for the safety analyses;
— Provisions for defence in depth;
— Analytical methods and computer codes used, including verification and validation methods;
— Radioactive releases and radiation exposures under normal operation and fault conditions;
— Licensee's safety criteria for analyses of operator action, common cause events, crosslink effects, single failure criterion, redundancy, diversity and separation.

4.2.3.4 The operating organization and the management system

— The licensee organizational structure;
— Licensee safety policy;
— Licensee provisions for:
  - Compliance with regulatory requirements;
  - Adequate resources for the entire lifetime of the installation;
  - Change control procedures, both organizational and engineering;
  - Safety and engineering analysis and associated audit and review functions;
  - Financing of continuing liabilities and decommissioning;
  - Setting of operating and safety targets;
  - Problem identification and corrective action programme;
  - Roles and responsibilities of individuals and groups;
  - Operating experience feedback;
  - Configuration management;
  - Employing and controlling contractors;
  - Staff education, training and qualification;
  - Regular audits with independent assessors;
  - Records management;
  - Adequate numbers of staff;

- Attaining and maintaining a strong safety culture;
- Human factors, including fitness for duty.

4.2.3.5 Operational procedures

— Formal approval and documentation for all safety related procedures;
— A formal system for modification of a procedure;
— Understanding and acceptance of the procedures by management and staff;
— Verification that the procedures are followed;
— Procedures that are adequate in comparison with international good practice;
— Arrangements for regular review and, if necessary, revision of the procedures;
— Clear procedures taking into account human factor principles;
— Procedures which comply with the assumptions and findings of the safety analysis, design and operating experience; and
— Adequate emergency operating procedures.

4.2.3.6 Equipment qualification

— A list of SSCs covered by the equipment qualification programme;
— A list of control procedures;
— A qualification report and other supporting documents;
— Verification that the installed equipment matches the qualification requirements;
— Procedures to maintain qualification during the installed life of the equipment;
— Information on mechanisms for ensuring compliance with these procedures;
— Documentation on maintenance, testing and inspection programme;
— Documentation on an analysis of the effect of equipment failure on other equipment qualification;
— Information on the physical integrity and functionality of qualified equipment;
— Records of all qualification measures taken during the installed life of equipment.

4.2.3.7 Management of ageing

— Methods and criteria for identifying SSCs covered by the ageing management programme;
— SSCs covered by the ageing management programme;
— Potential ageing degradation that may affect the safety functions of SSCs and proposed countermeasures;
— Extent of understanding of dominant ageing mechanisms of SSCs;
— Programme for timely detection and mitigation of ageing processes and effects;
— Acceptance criteria and required safety margins for SSCs;
— Actual physical condition of SSCs, including actual safety margins.

4.2.3.8 Safety performance

— System for identifying and classifying safety related incidents;

— Arrangements for analysis of incidents and implementation of lessons learned;
— Methods for selecting and recording safety related operational data, including those for maintenance, testing and inspection;
— Trend analyses of safety related operational data;
— Feedback of safety related operational data into the operating regime;
— Identification and analyses of safety performance indicators;
— Radiation doses to persons on site;
— Offsite radiation monitoring;
— Quantities and characteristics of radioactive waste generated and stored at the installation;
— Quantities of radioactive effluents discharged.

4.2.3.9 Experience from other installations and research findings

— Feedback of experience relevant to safety from other installations;
— Assessment of and actions on the basis of the above experience;
— Determining the need for research and development;
— Research programmes and related findings;
— Assessment of and actions on the research information.

4.2.4 Safety objectives and requirements

Safety objectives and requirements specify safety goals or protection levels to be achieved at the nuclear installation. In some cases, the safety objectives and requirements are included in the nuclear law. If they are not included in the nuclear law, the regulatory body must develop safety objectives and requirements as part of its regulatory requirements. They may be developed by the regulatory body itself or adopted from safety objectives and safety requirements developed and published by regulatory bodies in other Member States or by international organizations.

4.2.5 Competence of the regulatory body

The purpose of the review and assessment by the regulatory body is to confirm that:

— Available information demonstrates the safety of the installation and the optimization of protection;
— Information provided in the submissions is accurate and is sufficient to permit confirmation of compliance with regulatory requirements;
— Operational and technical provisions, and in particular any novel provision, have been proven or qualified by experience or testing, or both, and will enable the required level of safety to be achieved.

Although the regulatory body does not redo the work done by the licensee, regulatory body staff must have the knowledge, skills and attitudes to be able to understand the submissions and provide the necessary confirmation. In some cases, regulatory body staff may use different analytical tools to assess the submission. Regulatory body staff must have a good understanding of the installation design, SSCs and provisions for safety. The review and

assessment requires a level of competence normally attained through education, training and experience with the analytical techniques.

The following extract from the report of 2010 IRRS mission to the USA[63] illustrates this.

> "High attention is paid to adequate qualification of staff involved in review and assessment. This is done first of all through the qualification program, which includes both general and position specific training. In addition, prior to review associated with a specific submission there is a practice that a senior staff or the branch chief shares with new individuals his views on scope and details from review of previous applications".

4.2.6 Purpose of the safety assessment and general approach

The safety requirements in force in the Member State are the basis for the assessment performed by the licensee, and provide the licensee with a frame for the scope of the assessment. The assessment must demonstrate that the licensee has made adequate provisions such that no safety issue will arise from the licensee request and that radiation risks are being controlled within regulatory requirements and are ALARA.

When reviewing any licensee assessment, the regulatory body must ensure that the licensee assumptions are based on the worst probable case and that the licensee has thought through all possible scenarios. On occasion, licensees have made changes that have resulted in unforeseen or unintended negative consequences. The depth of the assessment carried out by the licensee will vary. For every assessment, the licensee will have to determine whether:

- Adequate measures have been taken to control radiation risks to an acceptable level;
- SSCs and barriers incorporated into the design fulfill their required safety functions;
- Adequate measures have been taken to prevent anticipated operational occurrences and accident conditions and whether any radiological consequence can be mitigated if accidents do occur.

The safety assessment must address all radiation risks to individuals and population groups that arise from operation of the installation, both in the present and into the future, possibly for several generations. In case of a comprehensive assessment, such as prior to commissioning or for PSRs, the licensee must review and assess all safety functions. This assessment must consider defence in depth and whether the safety related SSCs and barriers that are provided have an adequate level of reliability, redundancy, diversity, separation, segregation, independence and equipment qualification and whether potential vulnerabilities have been identified and eliminated.

For other changes, the licensee will not necessarily need to conduct a comprehensive reassessment of safety. If an issue has been previously examined, the licensee will need to confirm that all safety functions remain as previously understood and that the change does not threaten safety relevant SSCs or barriers.

The level of detail of the safety analysis is determined by use of a graded approach. The regulatory body must issue guidance to set the expectations for the level of detail of safety

[63] https://www-ns.iaea.org/downloads/actionplan/IRRS%20Mission%20to%20the%20USA__Oct_2010_1.pdf

assessments. The following extract from the report of the 2012 IRRS Mission to Finland[64] illustrates this.

> "The scope of the review of NPP modifications depends mainly on the safety classification of the systems/components and on the scope of a modification. There are several other submissions requiring review and assessment by STUK (such as operational event reports, application for approval of selected organizations), which are less complex in comparison with licensing steps and less demanding in terms of manpower needed for the review".

4.2.7 Review and assessment methodology

The review and assessment process must be based on a common understanding between the regulatory body and the licensee, using common requirements. Depending on the nature of the licensee submission, the regulatory body may need to take into account some or all of the following considerations and factors:

- Regulatory requirements;
- Nature and categorization of the associated hazards;
- Site conditions and the operating environment;
- Basic design of the installation or the conduct of the activity;
- Records provided by the licensee or its suppliers;
- Best practices;
- Applicable management system;
- Competences and skills necessary for operating the installation;
- Arrangements for protection of workers, the public, and the environment;
- Arrangements for preparedness for, and response to, emergencies;
- Arrangements for nuclear security;
- System of accounting and control of nuclear material;
- Relevance of applying the concept of defence in depth to take into account inherent uncertainties;
- Arrangements for the management of radioactive sources, radioactive waste and spent fuel;
- Relevant research and development plans or programmes;
- Feedback of operating experience nationally and internationally, and especially of relevant operating experience from similar installations;
- Information compiled from regulatory inspections;
- Information from research findings;
- Arrangements for the termination of operations.

The following extract from the report of the 2009 IRRS mission to Russian Federation[65] illustrates this.

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[64] https://www-ns.iaea.org/downloads/actionplan/IRRS%20Mission%20Report%20to%20Finland%20Oct_2012.pdf

[65] https://www-ns.iaea.org/downloads/actionplan/IRRS%20Mission%20to%20Russia_Nov_2009_1.pdf

"Rostechnadzor has access to several items of information relating to licensee safety performance. Examples include inspection reports, enforcement actions issued by Rostechnadzor, reports from the licensee on the results of its event investigations, and the annual report submitted to Rostechnadzor by the licensee that describes the current operational safety status of each unit. The licensee annual report contains a variety of information such as number of equipment failures per unit, types of effluent releases, amount of solid/liquid radioactive waste, number of safety-related modifications installed, completed maintenance activities, etc. Rostechnadzor uses these documents to conduct an integrated assessment of licensee safety performance and provides the results in quarterly summary reports and an annual report".

4.2.7.1 Before the assessment

Scope and level of detail of the assessment

The regulatory body must define its review and assessment prior to the licensee submitting information so that the application will be as complete as possible.

The following extract from the report of the 2008 IRRS Mission to Spain[66] illustrates this.

"Safety significant changes at NPPs require authorization before implementation, whereas changes with minor or no safety significance may be implemented by the NPP operator and reported to the CSN subsequently. The criteria for seeking prior authorization are set out in conditions attached to NPP permits".

When necessary, the regulatory body must ask for additional information during the evaluation of the submission provided by the licensee. As the safety assessment progresses and a better understanding is obtained of the risks arising from the installation, the application of the graded approach needs to be reassessed and the scope and level of detail of the safety assessment modified accordingly.

Provisions to be made

The necessary preparations should be made to ensure that:

- There are a sufficient number of people with the necessary skills and expertise available to carry out the work, and adequate funding is available;
- Background information relating to the location, design, construction, commissioning, operation, decommissioning and dismantling of the installation is available, together with any other evidence that is required to support the safety assessment;
- Necessary tools for carrying out the safety assessment are available, including the necessary computer codes for carrying out the safety analysis;
- Safety criteria defined in national regulations or approved by the regulatory body to be used for judging whether the safety of the installation is adequate have been identified. This could include applicable industrial safety standards and associated criteria.

The following extract from the report of the 2012 IRRS mission to Finland[67] illustrates this.

[66] https://www-ns.iaea.org/downloads/actionplan/IRRS%20Mission%20to%20Spain__Jan-Feb_2008.pdf
[67] https://www-ns.iaea.org/downloads/actionplan/IRRS%20Mission%20Report%20to%20Finland%20Oct_2012.pdf

"There are annual plans for the regulatory activities prepared sufficiently well ahead of the beginning of the year. They are prepared by the project or subproject managers, in communication with the licensees. The plans identify needs of manpower for individual tasks down to the level of individual reviewers. The plans allow allocating necessary internal resources, as well as determining necessary external support".

Criteria for judging safety

The regulatory body must define the criteria for judging whether the fundamental safety objective and the fundamental safety principles are met. In addition, the regulatory body may need to develop detailed criteria to assist in assessing compliance with these higher level objectives, principles and requirements. These may include risk criteria that relate to the likelihood of anticipated operational occurrences or the likelihood of accidents occurring that give rise to significant radiation risks.

It is not feasible to define safety criteria for every issue. However, as a minimum, the regulatory body should establish the design basis events, the acceptable releases for a given accident and the level of redundancy that is necessary for a safety function. While some of these might be specific to a Member State or design, the IAEA Safety Standards provide guidance for some of these criteria.

The following extract from the report of the 2012 IRRS mission to Finland[68] illustrates this.

"STUK performs thorough review and assessment by comparing the methods and results of the assessments provided in the licensee's submissions with safety requirements specified in the legally binding documents, and to more detailed level in YVL and ST guides. In addition to legally binding documents with safety requirements to be verified in review and assessment, STUK has a comprehensive system of regulatory guides. The most relevant are YVL guides (~71 guides) for use of nuclear energy and ST guides (~53 guides) for use of radiation…".

"Internal STUK guidance for organization of the review and assessment is given in YTV guides. It was shown that this system of internal guides is very well developed. Nevertheless, STUK intends to continue developing additional internal guides in selected technical areas, such as automation, in order to further increase consistency and reduce the risk of subjectivity of the reviews. The IRRS team supports STUK's planned activities in this area".

Another example is from the report of the 2011 IRRS mission to Switzerland[69].

"The IRRS team considered that a defined closure criteria to shut down an NPP based on the status of the reactor vessel and the containment is an example of an effective ageing management".

When objective criteria are not available, the regulatory body might consider using a defence in depth approach to establish safety criteria.

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[68] https://www-ns.iaea.org/downloads/actionplan/IRRS%20Mission%20Report%20to%20Finland%20Oct_2012.pdf

[69] https://www-ns.iaea.org/downloads/actionplan/IRRS%20Mission%20to%20SWITZERLAND_Nov_Dec_2011_1.pdf

Management of the safety assessment

The regulatory body must establish a managed process for review and assessment. As a minimum, this managed process should consider:

- Organization of the review and assessment (e.g. management, time frame);
- Interactions with the licensee;
- Gathering of necessary material for the assessment.

For comprehensive assessments, various units within the regulatory body may be involved in the review and assessment. The regulatory body must assign a project manager to the review and assessment to ensure adequate planning, organization and coordination.

The following extract from the report of the 2011 IRRS mission to Republic of Korea[70] illustrates this.

> "Any submission requiring review and assessment is managed as a project under control of a Project Manager (PM), who is an appointed expert from the Nuclear Regulation Division. PM coordinates the whole process of review and assessment and is responsible for high quality results to be achieved in timely manner. There are 11 PMs selected from the senior staff of the Nuclear Regulation Division (for each of 4 sites there is 1 manager for review and assessment and 1 for inspection tasks, and in addition there are 3 managers for new constructions). PM prepares the plan for the review and is responsible to distribute the review material to the right experts of KINS".

4.2.7.2 During the assessment

Interactions between regulator and licensee

Throughout the review and assessment process, the regulatory body and licensee must constantly communicate. As either the licensee or the regulatory body identify issues, they must use a 'no surprises' approach and inform the other using established communication channels.

The following extract from the report of the 2011 IRRS mission to Republic of Korea illustrates this.

> "During the review, regular contacts are arranged between the licensee and KINS project manager (PM). PM is assigned to manage all submittals from a given site. PM serves as a single contact point for the site, communicates directly with the NPP and is aware of all potential submissions from that NPP. During the review process the regulatory body maintains open communication with the licensee through exchange of letters. There are frequently held case specific explanatory meetings between the licensee and KINS, initiated by both sides as needed".

Another example comes from the report of the 2012 IRRS mission to Finland.

[70] https://www-ns.iaea.org/downloads/actionplan/IRRS%20Mission%20to%20Korea_Jul_2011_1.pdf

"STUK has in place an effective communication mechanism with the licensees, including organization of frequent project meetings, workshops, topical meetings and exchange of documents".

Assessment of defence in depth

This is the heart of the review and assessment and the regulatory body will devote most of its effort to reviewing the licensee's provisions for defence in depth.

The purpose of the regulatory review is not to repeat the licensee's assessment. Rather, the regulatory body must assess whether the licensee has made adequate provisions at each level of defence in depth and is capable of:

- Addressing deviations from normal operation or from its expected evolution in the long term;
- Detecting and terminating safety related deviations from normal operation or from its expected evolution in the long term, should deviations occur;
- Controlling accidents within the limits established for the design;
- Specifying measures to mitigate the consequences of accidents that exceed design limits;
- Mitigating radiation risks associated with possible releases of radioactive material.

In addition, the regulatory body must verify the adequacy of the analysis. The analysis will be adequate if it identifies the necessary layers of protection, including physical barriers to confine radioactive material at specific locations and the necessary supporting administrative controls for achieving defence in depth, including:

- Safety functions that must be fulfilled;
- Potential challenges to these safety functions;
- Mechanisms that give rise to these challenges, and the necessary responses to them;
- Provisions made to prevent these mechanisms from occurring;
- Provisions made to identify or monitor deterioration caused by these mechanisms, if practicable; and
- Provisions for mitigating the consequences if the safety functions fail.

To determine whether defence in depth has been adequately implemented, the regulatory body must decide whether in the safety assessment:

- Priority has been given to: reducing the number of challenges to the integrity of layers of protection and physical barriers; preventing the failure or bypass of a barrier when challenged; preventing the failure of one barrier leading to the failure of another barrier; and preventing significant releases of radioactive material if failure of a barrier does occur;
- Layers of protection and physical barriers are independent of each other as far as practicable;
- Special attention has been paid to internal and external events that have the potential to adversely affect more than one barrier at once or to cause simultaneous failures of safety systems;

— Specific measures have been implemented to ensure reliability and effectiveness of the required levels of defence.

Deterministic and probabilistic approaches

Both deterministic and probabilistic approaches should be included in the safety analysis. The two approaches complement one another and result in a more complete assessment.

The deterministic approach specifies and applies a set of conservative rules and requirements for the design and operation of installations. These rules and requirements are usually determined in the national regulation, and when met are expected to provide a high degree of confidence that the resulting level of radiation risks to workers and the public will be acceptably low. The deterministic approach uses conservative assumptions to compensate for uncertainties in SSCs and human performance.

An example of the use of a deterministic approach is the set of design basis events a nuclear installation must be able to withstand. The event is assumed to have happened without considering the origin of the event or its frequency. Most existing NPPs have used deterministic analysis to specify the requirements for at least some of the safety related SSCs.

The probabilistic approach determines all significant contributing factors to the radiation risks arising from the nuclear installation and evaluates the extent to which the overall design is well balanced. The probabilistic approach provides insights into system performance, reliability, interactions and weaknesses in the design, the application of defence in depth and risks.

The probabilistic approach can identify the weak and the strong points of the installation and is useful for comparing alternatives. The probabilistic approach will also identify the impact of a change on the installation as a whole, and can cover numerous threats in the same time. However, the probabilistic approach relies on many assumptions from several origins, some of which are difficult to justify.

The core damage frequency, or the seismic probabilistic approach, combining various seismic threats and weighing them based on their likelihood, are two typical examples of the use of the probabilistic approach.

The deterministic and probabilistic approaches complement each other. If for example, the probabilistic approach identifies that flooding is a major contributor to core damage frequency, then the deterministic approach can evaluate the various barriers to mitigate the risk.

The following extract from the report of the 2008 IRRS mission to Spain illustrates this.

> "CSN recognizes both PSAs and deterministic analyses, and the different insights that each provide. Licensees are conservative in their use of PSA and around 90% of safety submissions are based upon deterministic analyses. CSN seeks an appropriate balance between the two approaches, and has developed a Guide on PSA applications such as Risk Informed Regulation. The latter is an option for licensees, but not mandatory, and both probabilistic and deterministic criteria must be satisfied".

Independent verification

Before it is submitted to the regulatory body, the licensee should have an independent verification of the safety assessment carried out by qualified and experienced individuals, either within the operating organization or by external experts. The independent verification combines an overall review to determine whether the safety assessment is comprehensive with spot checks in which a much more detailed review focuses on those aspects of the safety assessment that have the highest impact on the radiation risks arising from the installation.

This independent verification by the licensee gives the regulatory body two analyses to review and assess. However, this is only useful if there is true independence between the two assessments.

The regulatory body then carries out a separate independent verification to determine whether the safety assessment is acceptable and provides an adequate demonstration that regulatory requirements are met. If the regulatory body notices omissions in the licensee's independent assessment, it should take action to correct this.

The scope and extent of the review and assessment by the regulatory body should be outlined in the nuclear law or the regulatory body's processes and procedures. In some cases, the regulatory body may decide to ask another regulatory body or international organization to independently assess the licensee submission.

4.2.7.3 After the assessment

Output of the safety assessment

The results of the safety assessment will form the basis for any regulatory decisions that need to be made. In most regulatory bodies, the persons making the decisions are separate from those conducting the review and assessment. The output of the safety assessment must therefore summarize the conclusions of the review and assessment and make recommendations for the decision makers. The regulatory body should establish a process and procedures, including specifying a standard format for the output. The output will usually include both quantitative and qualitative statements.

In some regulatory bodies, the results of major assessments are presented to a separate expert committee prior to a decision by the regulatory body. The expert committee might ask additional questions before the assessment can be considered as complete.

Documentation of the safety assessment

The regulatory body records the results and decisions deriving from reviews and assessments and the results of reviews and assessments are used as feedback information for the regulatory process. The main documentation of the safety assessment is the safety report. It presents the assessments and the analyses that have been carried out for the purpose of demonstrating that the installation is in compliance with the fundamental safety principles, and any other regulatory requirements. In the safety report, the outcomes of the safety assessment are supplemented by supporting evidence for and reasoning about the robustness and reliability of the safety assessment and its assumptions, including information on the performance of individual SSCs as appropriate. The safety report, as well as all the assessments performed for the installation, is retained until the installation has been fully decommissioned and dismantled and released from regulatory control.

Tracing the result of the review and assessment and the bases for the decision making in a report will ensure stability and consistency of regulatory control if other similar reviews and

decisions are to be made. The regulatory body must organize the documentation in a way that will ensure easy and permanent access to these reports.

The following extract from the report of the 2011 IRRS mission to Republic of Korea illustrates this.

> "High attention is paid to continuous monitoring, evaluation and feedback from the review and assessment process in order to enhance its efficiency. KINS records the review and assessment results in accordance with the relevant Rules for Entrusted Regulatory Activities. When conducting a review and assessment for an authorization application, KINS develops a review report for each authorization activity (construction permit, operating licence, amendment approval, or notification of a minor change). By maintaining and controlling various records including review results in MIDAS, KINS has made these documents readily available for the reviewers. Safety Evaluation Reports from previous cases provide sufficiently detailed source of information. Training of the KINS staff is also devoted to presentation of lessons learned from the reviews".

Communication

A regulatory body must recognize that other interested parties will have an interest in the decisions taken on the basis of the review and assessment process. The regulatory body must therefore consider ways in which results and insights from the safety assessment can best be communicated to the wide range of interested parties.

4.2.8 Examples of assessment processes

4.2.8.1 Periodic safety review

Before the assessment

(1) Purpose

PSR provides an effective way to obtain an overall view of installation safety and the quality of the safety documentation, and to determine reasonable and practical modifications to ensure or improve safety. To do this, the PSR needs to identify any lifetime limiting features at the installation to plan future modifications and to determine the timing of future reviews.

International experience shows that performing a PSR every ten years is optimum. A frequency of less than ten years does not add any significant safety benefit, while extension beyond about ten years could delay the identification of important safety issues and could lead to a loss of the direct knowledge and experience gained in previous reviews and a loss of continuity.

(2) Scope and level of detail

The objective of PSR is to determine by means of a comprehensive assessment:

- The adequacy and effectiveness of the arrangements and the SSCs that are in place to ensure NPP safety until the next PSR;
- The extent to which the installation conforms to current national and/or international safety standards and operating practices;

— Safety improvements and timescales for their implementation;
— The extent to which the safety documentation, including the licensing basis, remains valid.

SSG-25: Periodic Safety Review for Nuclear Power Plants [65] suggests that the 14 safety factors shown in Table 36 will cover all aspects important to the safety of an operating NPP:

TABLE 36. SUGGESTED SAFETY FACTORS FOR A PSR

Safety factors relating to the NPP	1. NPP design 2. Actual condition of SSCs important to safety 3. Equipment qualification 4. Ageing
Safety factors relating to safety analysis	5. Deterministic safety analysis 6. Probabilistic safety assessment 7. Hazard analysis
Safety factors relating to performance and feedback of experience	8. Safety performance 9. Use of experience from other NPPs and research findings
Safety factors relating to management	10. Organization, the management system and safety culture 11. Procedures 12. Human factors 13. Emergency planning
Safety factors relating to the environment	14. Radiological impact on the environment

(3) Provisions to be made

The licensee is responsible for conducting and reporting the findings of the PSR.

The regulatory body is usually responsible for:

— Specifying or approving the requirements to perform the PSR;
— Approving the documentation to be provided by the licensee prior to the PSR (i.e. the PSR basis document including the project plan);
— Reviewing the scope, conduct and findings of the PSR and the resulting safety improvements;
— Assessing the prospects for safe operation for the period until the next PSR;
— Taking appropriate licensing actions;
— Informing interested parties about the results of the PSR and resulting safety improvements.

(4) Management

Milestones and time frames provided by the licensee are reviewed by the regulatory body for approval.

The regulatory body appoints a project manager for review and assessment of the PSR. The responsibilities of the project manager include:

— Preparation of the regulatory assessment plan, including assessment criteria and identification of technical experts;
— Coordination of all PSR related activities within the regulatory body (and any external sources of assistance);
— Acting as a focal point for communication with the licensee.

During the assessment

(1) Interactions between regulator and licensee

The starting point of a PSR is the agreement between the licensee and regulatory body on the general scope and requirements for the PSR and its expected outcome, as described in a basis document. To ensure consistency across all parts of the PSR, the licensee and regulatory body need to agree on the appropriate time to 'freeze' the set of documents to be reviewed and the status of the installation that will be the basis for the PSR.

During the assessment process, the regulatory body communicates with the licensee to clarify issues, including discussion of any additional issues identified by the assessor, and to acquire any necessary additional information. The results of these interactions are documented for future reference.

(2) Assessment of defence in depth

Individual regulatory body assessors prepare reports that clearly identify all significant issues that need to be resolved. These assessment reports also give an initial indication of the acceptability of safety improvements proposed by the licensee. The review must determine the status of each safety factor, both at the time of the PSR and at the end of the next operating period (usually at the time of the next PSR). This includes a review of the licensee's capability to identify and prevent potential failures or mitigate their consequences. Ageing related degradation mechanisms that could lead to failures of SSCs important to safety that could potentially limit the installation's operating lifetime are identified to the extent possible.

Negative findings are divided into:

— Deviations for which no reasonable and practicable improvements can be identified;
— Deviations for which identified improvements are not considered necessary;
— Deviations for which safety improvements are considered necessary.

In the case of negative findings for which no reasonable and practicable improvements can be identified, the reasons must be documented and the issue revisited after an appropriate period of time to determine whether a practicable solution is available. For negative findings for which safety improvements are not considered necessary, the reasons must be documented and the action considered completed. Negative findings for which safety improvements are necessary, including updating/or extending of documentation or operating procedures, are categorized and prioritized according to their safety significance. Safety improvements from the safety factor reviews, together with safety improvements resulting from the global assessment, are included in the licensee's integrated implementation plan.

If the assessor identifies a deficiency that poses an immediate and significant risk to workers, the public or to the environment, this should be reported immediately to the licensee, and the licensee must take urgent steps to correct the deficiency.

(3) Deterministic and probabilistic approaches

PSRs will use both deterministic and probabilistic approaches in the analysis. The categorization and prioritization of safety improvements may also require a combination of deterministic analyses, probabilistic safety assessment and expert judgement.

(4) Independent assessment

The regulatory body should conduct an independent review of the licensee's PSR report and assess the PSR analyses, findings and proposals for safety improvements. To do this, the regulatory body may use its own analysis methods and verification and validation calculations, such as using alternative computer codes.

After the assessment

(1) Output

The results of the PSR are used to confirm that the installation continues to meet all necessary regulatory requirements. In the case where safety improvements are required, the results will be used to establish the priority and schedule for these improvements.

(2) Documentation

Using the individual assessment reports, the PSR project manager will coordinate the preparation of an integrated project report. The integrated project report presents:

- The regulatory body's view of the adequacy of the PSR, including the safety improvements already implemented by the licensee;
- The regulatory body's view of the adequacy of safety improvements identified by the licensee but not yet implemented;
- An evaluation of the licensee's schedule for the implementation of the safety improvements.

(3) Communication

The regulatory body discusses the integrated project report with the licensee. This may involve several meetings, but should lead to an agreement from both parties on an updated integrated implementation plan of safety improvements. The regulatory body then takes appropriate licensing or other regulatory action as required.

4.2.8.2 Return on operating experience

The investigation and reporting of events contribute to improvements in nuclear safety and have the following objectives:

— Identify and quantify events and conditions that are precursors to significant degradation and that have the potential to cause accidents that can lead to damage to SSCs or releases of radioactive material;
— Identify safety concerns and to determine the adequacy of corrective actions;
— Identify emerging trends or patterns of potential safety significance;
— Assess how situations could have developed;
— Assess the generic applicability of events;
— Prevent recurrence.

In addition, ongoing research and analysis as a result of reassessments generates information that other installation may benefit from. One strength of the nuclear industry is its willingness to share operating experience. The primary objectives of operational experience feedback are to ensure that no safety related event remains undetected and that corrections are made to prevent the recurrence of safety related events.

Before the assessment

(1) Scope and level of detail

The scope of investigations of events will vary:

— In the case of a serious event, a Panel or a Board of Inquiry may be convened involving many people and using extensive investigation and analysis techniques; or,
— For events with no consequences, minor events, or for adverse trends, a single trained person may conduct a straight-forward investigation.

Factors that would influence the size of an investigation may include:

— Actual or potential consequences of the event and the extent of damage to SSCs;
— Injury to workers;
— A similar occurrence has taken place earlier at the same installation or at an installation of a similar type;
— Significant radiological release or an overexposure of personnel;
— Operation exceeded the operational limits and conditions or was beyond the design basis of the installation;
— A pattern that is complex, unique or poorly understood.

(2) Criteria for judging safety

Most regulatory bodies have established event reporting criteria. In addition, WANO has established an operating experience programme. Licensees should develop an operating experience program that, in addition to meeting regulatory and WANO requirements, meets its own needs for problem identification and corrective action.

The criteria for judging safety are regulatory requirements and the installation safety case.

(3) Management

The licensee must assign responsibility for operating experience. The operating experience feedback programme should be part of the management system and subject to review to ensure continued effectiveness of the programme.

During the assessment

(1) Interactions between regulator and licensee

The licensee must report incidents and events as required by the regulatory body. The reporting should also include the results of the investigation and any corrective actions taken by the licensee. The regulatory body should ensure that the licensee has also communicated this information to other licensees with similar installations. However, in some cases, such as for generic safety issues, the development of the corrective actions will involve other organizations including the regulatory body.

(2) Defence in depth

Event analysis is conducted on a timescale consistent with the safety significance of the event. The main phases of event analysis can be summarized as follows:

— Establishment of the complete event sequence (what happened);
— Determination of the deviations (how it happened);
— Cause analysis:
— Direct causes (why it happened);
— Root causes (why it was possible);
— Assessment of the safety significance (what could have happened);
— Identification of corrective actions.

Actions to prevent recurrence can include:

— Modifications to SSCs;
— Modifications to operating conditions;
— Correction of deficiencies in documents;
— Modifications to the working environment;
— Modifications to work planning and scheduling;
— Improvement of personnel training and qualification;
— Addition of administrative checks and controls.

(3) Probabilistic and deterministic approaches

Both deterministic and probabilistic approaches can be used to assess events.

(4) Independent assessment

The licensee should establish a process for the independent assessment of the operating experience feedback programme. This will include assessment by an independent group

within the licensee's organization, as well as peer review. For selected events, the licensee may decide to have an independent review.

The regulatory body should review all events reported by licensees and in some cases, may determine that it will conduct an independent assessment of a particular event.

After the assessment

(1) Output

The results of an individual event review will be corrective actions to prevent recurrence. In addition, the group responsible for operating experience should analyze reports for trends regarding events.

(2) Documentation

In addition to the documentation and tracking of actions associated with each single event, the licensee should systematically compile actions to provide a historical database of lessons learned. When these actions are compiled and sorted on the basis of the systems affected or the safety issues raised, they can serve as solutions for similar problems in the future.

The licensee should also issue a periodic report, at least annually, that summarizes the operating experience feedback activities performed.

(3) Communication

Disseminating information on events allows:

- Licensees to enhance the safety of the installation;
- Operating personnel to improve their understanding of the operating conditions and response characteristics of the installation;
- Vendors to improve their design and manufactured products;
- Contractors providing maintenance services to anticipate potential problem;
- Research establishments to improve their knowledge and prioritize research.

For maximum impact and benefit, appropriate information relating to the feedback of operational experience must be widely disseminated at the installation level, the operating organization level, the national level and the international level.

4.2.8.3 Assessment of vulnerabilities in light of the Fukushima Daiichi accident

In its Action Plan on Nuclear Safety [50], the IAEA encouraged Member States to undertake assessments of the safety vulnerabilities of installations in light of the lessons learned from the Fukushima Daiichi accident.

Instead of assessing whether a technical requirement is met, the purpose of these assessments was to evaluate the existing safety margins. These assessments are actually a combination of the previous two examples. The assessments reviewed the design against specific hazards (similar to the PSR process) and were required as a consequence of an event (the return on operating experience process). However, the assessment of vulnerabilities went further than either a PSR or a return on operating experience review. The evaluation looked beyond

compliance with national regulations to examine existing margins and potential cliff edge effects. A cliff edge effect[71] is when a minor change in an input parameter causes a large change in the resulting output.

Various initiatives were launched around the world, including the European Union (EU) stress tests for NPPs in Europe. The EU stress tests are an example of a methodology for a comprehensive assessment.

EU stress tests

The EU defined a stress test as a targeted reassessment of the safety margins of NPPs in the light of the Fukushima Daiichi accident: extreme natural events challenging the NPP safety functions and leading to a severe accident. The reassessment consisted of:

— Evaluation of the response of the NPP when facing a defined set of extreme situations;
— Verification of the preventive and mitigative measures.

(1) Scope and level of detail

The technical scope of the stress tests has been defined considering the issues that have been highlighted by the Fukushima Daiichi accident, including combination of initiating events and failures. The focus will be placed on the following issues:

— Initiating events:
  - Earthquake;
  - Flooding;
  - Severe weather;
— Consequence of loss of safety functions from any initiating event conceivable at the NPP site:
  - Loss of electrical power, including station black out;
  - Loss of the ultimate heat sink;
  - Combination of both;
— Severe accident management issues:
  - Means to protect from and to manage loss of core cooling function;
  - Means to protect from and to manage loss of cooling function in the spent fuel storage pool;
  - Means to protect from and to manage loss of containment integrity.

For a given NPP, the reassessment reported on the response of the NPP and on the effectiveness of the preventive measures, noting any potential weak point and cliff edge effect, for each of the considered extreme situations. This evaluates the robustness of the defence in depth approach, the adequacy of current accident management measures and identifies the potential for safety improvements, both technical and organizational (such as procedures, human resources, emergency response organization or use of external resources).

[71] Examples of cliff edge effects include: exceeding a point where significant flooding occurs due to water topping over a protection dike; and exhaustion of the batteries following a station blackout.

(2) Provisions to be made

Due to the timeframe of the stress test process, some of the engineering studies supporting the licensees' assessment may not be available for scenarios not included in the current design. In such cases expert judgment was used.

(3) Criteria for judging safety

The European Nuclear Safety Regulators Group (ENSREG) established specifications [62] for the stress test methodology.

(4) Management

The EU specified that, in accordance with the prime responsibility for safety licensees must perform the reassessments and the national regulatory body would independently review them. The EU also specified deadlines for the completion of both the individual licensee reassessments and the regulatory body reviews.

(5) Assessment of defence in depth

The stress tests focused on measures that could be taken after a postulated loss of the safety systems that provide protection against accidents considered in the design. Assumptions concerning their performance were reassessed in the stress tests and they are shown as provisions in place.

(6) Deterministic and probabilistic approaches

In these extreme situations, sequential loss of the lines of defence is assumed in a deterministic approach, without considering probabilities.

(7) Independent assessment

NPP licensees conducted the reassessments and prepared reports, which were then reviewed by the national regulatory body. The national regulatory body in turn prepared a national report.

4.3 INSPECTION AND ENFORCEMENT

Learning Objective 1: To understand IAEA requirements and guidance on inspection and enforcement.

Learning Objective 2: To understand how regulatory body staff behaviour during inspections can affect credibility.

Learning Objective 3: To understand the need for, and how to prepare, an inspection programme.

Learning Objective 4: To understand how to plan, conduct and report an inspection.

Learning Objective 5: To understand the need for the graded approach to enforcement actions.

The overall purpose of regulatory inspections is to verify that the licensee is operating the installation in a manner that protects people and the environment and in compliance with the regulatory requirements and with the conditions specified in the licence. Enforcement is action designed to respond to non-compliance with regulatory requirements or with any condition specified in the licence. Resident inspectors, if any, should be authorized to take corrective action if there is an imminent likelihood of safety significant events. Enforcement may include prosecution in appropriate circumstances.

4.3.1 IAEA requirements and guidance

The main IAEA guidance on inspection and enforcement is provided by:

- Governmental, Legal and Regulatory Framework for Safety (IAEA Safety Standards Series No. GSR Part 1 (Rev. 1)) [5];
- Organization and Staffing of the Regulatory Body for Nuclear Facilities (IAEA Safety Standards Series No. GS-G-1.1) [22];
- Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body (IAEA Safety Standards Series No. GS-G-1.3) [24];
- Application of the Management System for Facilities and Activities (IAEA Safety Standards Series No. GS-G-3.1) [48];
- Conduct of Operations at Nuclear Power Plants (IAEA Safety Standards Series No. NS-G-2.14) [66].

GSR Part 1 (Rev. 1) [5] Requirements 27, 28 and 29 define the inspection process. The regulatory body has the duty of oversight of all safety related activities in all phases in the life of a nuclear installation—site characterization, design, construction, commissioning, commercial operation and shut down and dismantling—to verify that the limits and conditions in the licence are complied with and that all applicable regulations are properly respected. These oversight activities do not diminish the licensee's prime responsibility for safety. Oversight can be conducted by analyzing licensee reports and through inspections.

GSR Part 1 (Rev. 1) [5] Requirements 30 and 31 address the enforcement function when non-compliance with regulations are discovered by inspectors or reported by the licensee. The

enforcement response can vary from warnings to prosecution, depending on the nature of the non-compliance. In all cases, the licensee should be provided with an opportunity to provide arguments against the enforcement action.

GS-G-1.1 [22] states that the regulatory body should be organized in a way that ensures that inspection activities are coordinated. GS-G-1.1 also provides advice on the personal qualities needed of inspectors and outlines an inspector training programme. On enforcement, GS-G-1.1 notes the need to ensure that the formal authority granted to inspectors is aligned with the structure of the regulatory body and the experience and role of the inspector.

GS-G-1.3 [24] provides extensive guidance on regulatory inspection and enforcement by the regulatory body. GS-G-1.3 identifies a large number of areas in addition to compliance matters that the regulatory body may need to inspect to provide a high level of confidence that safety objectives are met. GS-G-1.3 also provides extensive guidance on how to manage, organize, conduct and report on inspections over the entire installation lifetime. GS-G-1.3 also recommends that the regulatory body periodically assess the inspection programme for its continued effectiveness.

On enforcement, GS-G-1.3 discusses the factors relating to various enforcement options and highlights the importance of management of the enforcement process and the need to document enforcement decisions.

GS-G-3.1 [48] provides extensive guidance on safety management, which provides a sound basis for the regulatory inspection of this important area. This is particularly relevant in light of the highlighting of the importance of management systems and safety culture in the Action Plan on Nuclear Safety [50].

Although intended primarily for the licensee, NS-G-2.14 [66] provides guidance on shift rounds that the regulatory body may find useful in developing its inspection programme.

4.3.2 Beyond compliance

Although inspection for compliance with legislative and regulatory requirements is essential, the overall goal is to obtain objective evidence that the licensee is fulfilling its prime responsibility for safety. It is therefore appropriate for the inspection programme to go beyond compliance and include anything that may undermine safety. The following areas may be of interest:

- Licensee management system, safety culture and self-assessment systems for ensuring safety and the protection of workers, the public and the environment;
- The quality and performance of safety related activities and SSCs;
- Sufficient staffing levels and competence of staff;
- Licensee problem identification and corrective actions programmes;
- Other safety issues not specified in legislative or regulatory requirements or the licence;
- Funding bodies;
- Licensee headquarters organizations;
- Design organizations;
- Tendering, contracting and supply chain organizations;
- Safety case providers;
- Consultancy organizations, including TSOs;

— Other regulatory bodies (including those related to overseas designs);
— Certification and accreditation bodies;
— Training and education organizations;
— Industry/trade bodies;
— Local government authorities (with regard both to planning authorization and emergency preparedness);
— Research organizations.

Inspections are performed to obtain objective and independent evidence that the installation and the licensee comply with the safety objectives and meet all regulatory requirements. This should be achieved by confirming that, for the entire lifetime of the installation:

— The licensee is complying with all relevant laws, regulations and licence conditions, and all relevant codes, guides, specifications and practices;
— The licensee has a strong and effective management, good safety culture and self-assessment systems for ensuring the safety of the installation and the protection of workers, the public and the environment;
— SSCs and safety related practices of the licensee maintain the required quality and performance;
— The licensee maintains sufficient numbers of competent personnel for the safe operation of the installation;
— The licensee promptly identifies, evaluates and corrects deficiencies and abnormal conditions and reports these to the regulatory body as required;
— The licensee identifies and appropriately considers any other safety issue that is neither specified in the licence nor contained in legislation.

Regulatory inspection includes a range of planned and reactive inspections over the lifetime of the installation, including inspections of relevant parts of the licensee's organization and its contractors to verify compliance with regulatory requirements.

Regulatory enforcement actions are actions to deal with non-compliance by the licensee with specified conditions and requirements. The primary purposes of enforcement actions are to return the licensee to compliance and prevent future non-compliances. Enforcement actions may also include the imposition or recommendation of civil penalties and other sanctions.

The regulatory body must have the legal authority for conducting and coordinating its inspection and enforcement responsibilities during the site evaluation, design, construction, commissioning, operation, decommissioning or closure of installations under its regulatory control.

With regard to inspection, the regulatory body must have the authority to:

— Enter the installation at any time for the purposes of inspections;
— Require licensees, and their contractors where necessary, to prepare and submit reports and documents;
— Seek the cooperation and support of other governmental agencies and consultants;
— Communicate information, findings, recommendations and conclusions from inspections to interested parties, including high level officials, as appropriate.

With regard to enforcement, the regulatory body must have the authority to:

— Require the licensee to take action to remedy deficiencies and prevent recurrence;
— Curtail activities or to shut down the installation when the results of inspection or other regulatory assessments indicate that the protection of workers, the public and the environment might be inadequate;
— Impose or recommend civil penalties and other sanctions for non-compliance.

The regulatory body must have a sufficient number of staff capable of performing activities required by its inspection programme or, if outside consultants are used, staff capable of adequately supervising the consultants' work and independently evaluating the results. It is neither necessary nor practicable for the regulatory body to be entirely self-sufficient in every technical area relating to inspection. The regulatory body may need to use outside experts for specialized areas or during periods of high inspection workloads.

4.3.3 Action on site and regulatory credibility

Although inspectors have legal authorities, in practice the ease with which an inspector can gather the necessary information to verify compliance is greatly affected by the inspector's credibility. Credibility is therefore key if an inspector is to be effective and efficient. How an inspector behaves at the installation or during interactions with licensees will affect the inspector's credibility in the eyes of licensee staff.

In most cases, licensee staff will have more in-depth training and understanding of the installation and licensee processes than the regulatory body inspectors do. This is to be expected, and indeed, if it were not true, then the ability of the licensee to ensure safety would be suspect. The inspector's role is not to outsmart the licensee, but to verify that the licensee is in compliance with regulatory requirements and is capable of fulfilling its prime responsibility for safety.

Licensee staff members generally take a very responsible attitude to their duties towards nuclear safety and to the regulatory body. However, the gathering of information will be easier if the possessor of the information respects the requestor. The inspector can earn the respect of licensee staff members using the following practices:

— Maintain an open and effective dialogue;
— Develop a "no surprises" approach;
— Avoid unnecessary confrontation;
— Comply with the licensee's procedures, except where they are in direct conflict with the regulatory body's procedures;
— Respect licensee staff;
— Develop sound listening skills;
— Work within licensee processes to achieve results;
— Apply any necessary criticism in private;
— Follow up on regulatory commitments and safety issues;
— Act with obvious personal care and integrity;
— Treat privileged information appropriately;

— Make the effort and take the time to understand the installation and the way in which it is managed.

4.3.4 Regulatory inspection programme

4.3.4.1 General provisions

Once the regulatory body has issued a licence for an installation, it must verify that the licensee performs in accordance with the requirements of that licence. To do this, the regulatory body must establish a comprehensive regulatory inspection programme as part of its overall regulatory strategy. The inspection programme must provide a high level of confidence that the licensee is in compliance with regulatory requirements and is proactive in identifying and solving actual and potential safety problems.

The regulatory body should consider the following when establishing or modifying its inspection programme:

— Resources available to conduct inspections;
— Results of previous inspections;
— Safety analysis performed by the licensee and the results of regulatory review and assessment;
— Performance indicator programmes or other methods used to assess licensee performance;
— Operational experience and lessons learned from the installation and similar installations;
— Results of research and development;
— Inspection programmes of other regulatory bodies.

The regulatory body must have the authority and capability to undertake inspection activities at installations at any time.

The planning of the programme of inspections will also be influenced by the geographical location of the regulatory body in relation to the installation to be inspected, as well as whether the regulatory body has assigned resident inspectors to the installation.

In addition to inspections at licensee sites, it may be appropriate to inspect or influence activities elsewhere that can have significant implications for the safety of the installation, such as key suppliers, contractors and support organizations.

To ensure that similar installations in a Member State are inspected to a common standard and that the level of safety is consistent, the regulatory body must provide written guidance in sufficient detail for its inspectors. The guidelines must ensure a systematic and consistent approach to inspection, while allowing sufficient flexibility for inspectors to take initiative in identifying and addressing new concerns as they arise. Regulatory inspection is a specialized activity and the regulatory body must ensure that its inspectors are given adequate training.

4.3.4.2 Types of inspections

The regulatory body conducts two general types of inspection, namely planned inspections (including special inspections) and reactive inspections. Inspections may be conducted by

individuals or teams and may be announced or unannounced as part of a general programme or with specific aims.

Planned Inspections

The regulatory body should prepare an annual inspection plan outlining the inspections that will be conducted during the year. The planned inspections should cover the safety areas of interest to the regulatory body and are not normally the result of unusual or unexpected circumstances. Planned inspections provide an opportunity for the regulatory body to verify that the licensee is operating the installation in accordance with regulatory requirements and expectations. These inspections may be linked to the licensee's schedule for the performance or completion of certain activities at a point in the licensing process.

Reactive Inspections

The regulatory body will initiate reactive inspections in response to an unexpected, unplanned or unusual situation or an incident. The regulatory body may also conduct a reactive inspection in response to a series of minor events, in response to a generic problem identified at another installation or during review and assessment. Unlike planned inspections, which are scheduled during the regulatory body's planning cycle, the exact timing and subject of reactive inspections are not known in advance. Nevertheless, the regulatory body should assume that it will conduct some reactive inspections during the year and make whatever plans it can. For example, the list of planned inspections should not require all of the inspection resources available to the regulatory body. The regulatory body could also establish a graded approach in responding to unforeseen circumstances. All available resources may be needed in responding to a serious event, whereas in some cases only a single inspector is needed. This pre-established graded approach in responding to special circumstances will assist in determining the appropriate level of resources for use in inspections.

Special Inspections

Special inspections are carried out to consider specific issues that may be of interest to the regulatory body, such as new research and development findings and experience from other installations. This type of inspection may range from a single inspector reviewing a specific inspection area to a team inspection of several inspectors reviewing several different inspection areas. Special inspections are usually in the category of planned inspections, since they are scheduled in advance; however, in certain circumstances they may be reactive inspections.

Team Inspections

Team inspections, which may be multidisciplinary, provide an in-depth, independent and balanced assessment of the licensee's performance. This type of inspection may vary in both scope and complexity. Team inspections are of particular value once safety problems have been identified, since normal inspections cover only small samples of the licensee's activities in any particular area. Inspections of this type will identify underlying causes of problems to determine whether a safety concern represents an isolated case or is part of a broader, more serious problem.

Different approaches may be used in planning team inspections. Some team inspections will be broad in focus and cover a wide subject area ('horizontal slice') in the programme area of interest. For example, during operation a team of inspectors may assess the performance of installation operations or assess activities during an outage. Other team inspections will be narrow in focus and cover a single subject area ('vertical slice'). For example, a team of

inspectors may inspect a single safety system to confirm that the system is in full compliance with the regulatory requirements or may inspect the same subject at all similar installations.

Announced Inspections

Announced inspections are inspections where the licensee has been notified in advance by the regulatory body. The timing of the announcement may vary according to the circumstances of the inspection to be performed. Inspections may be announced, for example, when the regulatory body wishes to observe a specific test or activity or review a specific self-assessment by the operator while it is in progress. The main advantage of announced inspections is that the inspector is able to discuss plans and needs with the licensee in advance to ensure that documentation will be available for inspection, personnel will be available for interview and activities can be inspected.

Unannounced Inspections

The advantage of unannounced inspections is that the actual state of the installation and the way in which it is being operated can be observed. Inspections may be carried out at any time of the day or night so as to provide a more complete picture of the situation at the installation. Note that although the inspection is not announced to the licensee, most unannounced inspections are planned in advance.

4.3.4.3 Implementation of an inspection programme

The regulatory body must have an overall inspection plan for each installation that covers all areas of safety importance. The safety significance of each area will determine the level of effort, including inspection frequency, the inspection plan must include. To assist in the preparation of the inspection plan, the regulatory body should request the licensee to provide its schedules for carrying out activities and tests of regulatory interest.

Particular aspects that need to be considered in determining the intervals of inspection in the various areas and the level of inspection effort to be applied include:

- Safety significance of the issues;
- Inspection methods and approaches used (for example, the use of resident inspectors may affect the frequency and intensity of inspections);
- Qualified personnel and other resources available to the licensee;
- Performance record of the licensee and the installation;
- Results of regulatory review and assessment;
- Installation type;
- Personnel and other resources available to the regulatory body;
- Results of previous inspection programmes.

The inspection plan must be flexible enough to permit the regulatory body to respond to changing needs and situations. The regulatory body should establish a process for periodically evaluating inspection findings, identifying generic issues and making arrangements to enable inspectors to meet to exchange views and discuss the findings and issues.

4.3.5 Inspection areas for NPPs

4.3.5.1 The site evaluation stage

Before construction of the NPP begins, the regulatory body will, in addition to verifying with regulatory requirements, inspect to verify that the licensee:

- Conducts only those site preparation activities authorized by the regulatory body;
- Confirms that the site characteristics remain consistent with the description in the application and in the subsequent supporting documentation.

4.3.5.2 The design and construction stages

During the design and construction stages, reviews and assessments and inspections are closely linked. The reviews and assessments will normally identify features or characteristics that the regulatory body will want to verify through inspections. Some specific activities the regulatory body should include, in addition to compliance with regulatory requirements, in its design and construction inspection programme are:

- Regular inspections of general on-site activities including witnessing licensee inspections;
- Mixing and placement of concrete and its reinforcement, especially in foundations, and safety related SSCs, particularly containment structures;
- Construction of cooling intake and discharge systems;
- Installation of safety related SSCs, particularly containment and shielding boundaries, internals of vessels that will contain fissile and radioactive material and equipment to be used in radioactive areas.
- Installation of safety related control, protection and power SSCs;
- Areas of the NPP that are inaccessible after construction is completed, particularly SSCs embedded in the foundation or building structure;
- Targeted on-site inspections of safety critical items at time of construction or installation (for example, concrete pour for containment);
- Targeted off-site inspections of selected manufacturers of safety critical SSCs (for example, pressure vessels, safety system components);
- As-built configuration of SSCs conforms with the assumptions made in the review and assessment and any deviation is analyzed and justified;
- Technical assessments of engineering documentation;
- Technical assessments of safety significant deviations from design specifications;
- Licensee's oversight processes.

4.3.5.3 The commissioning stage

Activities associated with commissioning will normally begin before construction is completed. Accordingly, the regulatory body prepares to inspect areas of commissioning activity in parallel with activities of the construction phase. Most regulatory bodies will establish hold points, where the licensee must obtain regulatory body approval before proceeding. In some Member States, the regulatory body approves the commissioning programme.

Inspection by the regulatory body during the commissioning stage focuses on four broad areas of activity:

- Testing before introduction of fissile and radioactive material;
- Initial introduction of fissile and radioactive material;
- Testing of operations involving fissile and radioactive material;
- Other commissioning activities.

Testing before introduction of fissile and radioactive material

This encompasses those activities and tests performed to demonstrate that SSCs function properly and conform to design requirements. The regulatory inspection programme includes:

- Examination of procedures to verify compliance with review and assessment conclusions;
- Review of the implementation of these procedures;
- Direct observation of the performance of key pre-operational tests;
- Examination of the results of selected tests;
- Confirmation of the integrity of engineered barriers.

The regulatory body must use a graded approach in determining which tests will be inspected. Typical tests the regulatory body will inspect include:

- Safety related SSCs (e.g. instrument and control systems, shutdown systems and standby systems);
- Integrity of the containment and shielding boundaries;
- Susceptibility of SSCs to vibration or to other design loads;
- Secondary containment integrity (e.g. leak rate tests);
- Emergency power systems;
- Communication capabilities;
- Ventilation systems;
- Integrated cold and hot functional tests.

Initial introduction of fissile and radioactive material

In this phase, regulatory body inspectors should be on-site to inspect:

- Tests of the main control room;
- Access control and radiation protection programme;
- Emergency preparedness and demonstration of the emergency plan;
- Systems for monitoring radioactive releases and meteorological conditions;
- Distribution of fissile and radioactive material and checks on process and/or criticality calculations;
- SSCs involved in the handling of radioactive and fissile material.

Testing of operations involving fissile and radioactive material

The regulatory inspection programme should examine and assess the safety aspects of the licensee's commissioning procedures and verify that the licensee:

- Tests SSCs to confirm they are capable of functioning in accordance with design requirements;
- Confirms the adequacy of shielding; and
- Conducts operational checks at various power levels and is recording and analyzing key operational data, such as temperatures, pressures, radiation levels, flows and variations in process parameters.

Other commissioning activities

Other areas requiring inspection by the regulatory body during commissioning include:

- Licensee's transition from construction to operation;
- Licensee emergency preparedness;
- Training and qualification of licensee staff, especially operating staff.

4.3.5.4 The operation stage

Once the NPP is operating, the regulatory body implements an inspection programme to systematically verify that the licensee is in compliance with regulatory requirements and meets the general safety objectives.

The inspection programme must cover, using a graded approach, compliance with all regulatory requirements. It is not reasonable to inspect every licensee activity or every SSC. The regulatory body must establish a regulatory inspection programme that samples key activities and SSCs so the regulatory body can gain an overall view of a licensee's compliance.

Some key areas that the inspection programme should cover include:

- **Management system**: The licensee's management system describes how it intends to operate and maintain the NPP and the regulatory inspection programme should include inspections that verify the effectiveness of the management system. An important aspect of the management system is the safety culture of the licensee.
- **Operating processes**: The regulatory inspection programme should examine the adequacy, usability and effectiveness of the licensee's operating processes for normal, abnormal and emergency conditions;
- **Training programme**: The regulatory inspection programme should examine the adequacy and effectiveness of the licensee's training programmes for staff involved in activities important to safety;
- **Safety systems**: the regulatory inspection programme should inspect a sample of the NPP safety systems to confirm that they are capable of performing their safety related functions and that the licensee oversight is adequate.

4.3.5.5 Outages

In addition to providing opportunities to observe modifications to the NPP, outages provide opportunities to observe activities in areas that are not always accessible during normal operation. The regulatory body may conduct a special inspection before the licensee returns the NPP to service. Outage inspection topics requiring specific attention include:

— Management systems;
— Radiation protection;
— Maintenance, inspection and testing;
— Engineering;
— Modifications;
— Emergency preparedness;
— Security.

4.3.5.6 The decommissioning stage

During the decommissioning stage of a NPP, inspection activities will focus on licensee compliance with the decommissioning plan, integrity of the relevant SSCs, radiation protection, decontamination and dismantling activities, management of spent fuel and radioactive waste and the physical condition of the NPP.

4.3.6 Inspection process

Once the regulatory inspection programme has been created, the planning, conduct and reporting of each inspection can begin. The regulatory inspection process typically includes the following steps:

— Preparatory activities;
— Entrance meeting;
— Collection of data;
— Analysis of data;
— Preparation of draft report;
— Exit meeting;
— Preparation of final report and follow-up.

4.3.6.1 Preparatory activities

For routine inspections involving only one inspector, the preparatory activities are straightforward. The inspector will review previous inspection reports, prepare the inspection checklist or confirm the existing inspection checklist is still valid and confirm the timing for the inspection.

For team inspections, the preparatory activities are more complex and may include:

— Identification of the inspection team, including the team leader;
— Confirmation of the inspection topic and scope;
— Confirmation of the inspection criteria;

— Confirmation of the inspection timing and logistics.

The inspection team will then prepare for the inspection by:

— Reviewing regulatory requirements;
— Reviewing previous inspection reports;
— Requesting and reviewing licensee documentation;
— Reviewing the licensing basis;
— Preparing inspection checklists for the on-site portion of the inspection.

For larger inspections, the team leader should consider whether a pre-inspection visit is necessary.

4.3.6.2 Entrance meeting

For straightforward inspections, the entrance meeting may consist simply of the inspector informing the licensee (usually through the control room) of the inspection. For team inspections, the entrance meeting is more formal. The inspection team leader should chair the entrance meeting. Following introductions, the team leader should review the topic and scope, the criteria the team will use, the schedule, logistics for the inspection and the time and place for the exit meeting.

4.3.6.3 Collection of data

Inspectors have four basic methods to collect data:

— Direct observation;
— Discussions and interviews;
— Review of licensee documents;
— Taking measurements or samples for laboratory analysis.

Most inspections will use a combination of these methods. Inspectors should always be looking for ways to validate the data they collect. For example, if during an interview someone makes a statement, the inspector should consider how to confirm the validity of the statement.

4.3.6.4 Analysis of data

As the inspection continues, the inspector (or team) will begin to analyze the data to identify trends and findings. In some cases, more data will need to be collected and the inspection must be adapted to collect this additional data. In some cases, the inspection will identify a negative trend. It is important that the licensee be made aware of this as soon as possible so that corrective actions can begin.

4.3.6.5 Preparation of draft report

Once the inspection has established its findings, the report can be drafted. Each regulatory body will have its own process for the drafting and issuing of reports.

The inspection report documents the results of the inspection and provides the mechanism for notifying the licensee of the inspection findings and enforcement action. The report will also

provide important information for other regulatory body staff and contribute to knowledge management.

Inspection reports typically contain:

- Topic and scope of the inspection;
- Inspectors' names;
- Date of the inspection;
- Criteria used in the assessment;
- Details of observations, interviews, documents reviewed, samples taken and tests conducted;
- Details regarding the inspection findings;
- Details of any corrective actions required, including the schedule for completion;
- Details of any regulatory action taken by inspectors and any consequent action taken by the licensee;
- Recommendations for future inspections or proposals for enforcement actions.

4.3.6.6 Exit meeting

The inspection team leader also chairs the exit meeting. Topics discussed at the exit meeting should include:

- A summary of the draft inspection report;
- Findings;
- Any proposed enforcement actions;
- Next steps for both the regulatory body and the licensee.

The inspection team should comment on the cooperation of licensee staff and remind participants that the draft inspection report may change as the analysis continues. The licensee should be given a reasonable but finite amount time to provide additional information or clarifications.

4.3.6.7 Preparation of final report and follow-up

The inspection team leader will then finalize the report, taking into account any additional information received from the licensee and any additional analysis conducted by team members. The report is then issued.

The regulatory body must then assign actions to follow-up actions on the inspection findings and licensee corrective actions. Many regulatory bodies have established a database for this.

4.3.7 Special considerations for the inspection of new build NPP projects

Recent regulatory body experiences on new build projects that other regulatory bodies should take into account when preparing its new build inspection programme include:

- Detailed design work is completed just in time for construction activities, leaving the regulatory body limited time to perform any technical assessment prior to construction;
- Inadequate licensee oversight of engineering, procurement and construction activities;

- Inadequate quality management of manufacturing and supply activities allowing the potential introduction of fraudulent components;
- Inadequate construction processes, especially related to concrete pour and welding activities;
- Safety culture issues;
- If the NPP project is part of the Multinational Design Evaluation Programme (MDEP), the regulatory body should conduct technical assessments of other regulatory bodies' inspection reports where these are available.

In addition, inspection activities during commissioning of the first NPP are critical. Commissioning is the phase where the licensee confirms that: the NPP has been constructed in accordance with the design; the safety functions of the NPP will operate as required by the design; the NPP will respond as expected during unplanned and accident conditions; and operating procedures are adequate. To do all this without damaging the NPP is a major challenge. Therefore, it is highly recommended that the regulatory body obtain assistance from the regulatory body of the NPP vendor State and the IAEA when establishing and implementing its commissioning inspection programme.

The regulatory body must prepare a detailed baseline compliance plan for new build NPPs. This plan will need to be reviewed and revised as necessary throughout the construction phase to take into account feedback from previous inspections and other compliance activities, changes in the schedule and technical changes to the NPP.

4.3.8 Enforcement actions

The regulatory body must have the authority to compel a licensee to comply with regulatory requirements. This authority will depend on the regulatory framework in the Member State, but should include a graduated series of actions that the regulatory body can take, ranging from verbal warnings to prosecution. Enforcement actions are not intended to be punitive, but are designed to protect the health and safety of persons and the environment.

The regulatory body needs to establish a clear enforcement policy that details how the regulatory body will enforce its regulatory requirements. Processes, procedures and work instructions should support the policy and provide guidance to regulatory body staff. The policy should include a graded approach and that enforcement actions will be commensurate with the seriousness of the non-compliance. In all cases, the licensee must get back into compliance, investigate why the non-compliance occurred and take remedial action to prevent recurrence. In all cases, the regulatory body will need to follow up to ensure this is done.

Many regulatory bodies have given their inspectors the authority to take on the spot enforcement actions, usually in the form of stopping unsafe work. The degree of authority given to an inspector will depend on the structure of the regulatory body and on the inspector's role and experience. Where on the spot enforcement authority is not granted to individual inspectors, inspectors need clear direction on how and to whom to communicate any non-compliances so that necessary actions are taken in a timely manner. Most regulatory bodies have established a review or appeal mechanism for enforcement actions so that licensees have an opportunity to present their side of the story.

4.3.8.1 Factors determining enforcement actions

The regulatory body must take into account a number of factors when deciding which enforcement action is appropriate, including:

— Safety significance of the non-compliance;
— Complexity of the correction action required;
— Seriousness of the non-compliance;
— Whether the same non-compliance has occurred before;
— Whether the non-compliance was deliberate or willful;
— Who identified and reported the non-compliance;
— If reported by the licensee, the timeliness of the reporting;
— Past performance of the licensee;
— Need for consistency and transparency in the treatment of licensees.

4.3.8.2 Enforcement actions

The regulatory body must have clear administrative procedures and guidelines governing the use and implementation of enforcement actions and all inspectors must be trained in and knowledgeable about these procedures and guidelines.

The regulatory body should implement enforcement actions using a graded approach. Typical enforcement actions include:

— Verbal warnings;
— Written warnings;
— Written directives;
— Orders;
— Modification, suspension or revocation of the licence;
— Monetary or other civil penalties;
— Prosecution.

In the case of a minor non-compliance, in the first instance a verbal warning may be all that is necessary. Even though the warning is verbal, the regulatory body should record that the warning has been given. It is also not necessary to always progress through all of the actions. In the case of a serious non-compliance an order, licence modification or prosecution may be appropriate. In general, it is preferable to impose serious penalties on the licensee, rather than on individuals, as this is more likely to improve safety performance. In some Member States, the regulatory body can only recommend monetary penalties or prosecution.

Depending on the safety risk, the seriousness of the issue and the complexity of the corrective action, the regulatory body must allow the licensee a reasonable period of time to complete corrective actions. An integrated approach to safety will consider the contribution to the total risk to the installation of each individual non-compliance.

The regulatory body should confirm all enforcement actions in writing and records kept to allow for both audit purposes and for knowledge management. The regulatory body should review its enforcement process as part of its self-assessment programme.

4.3.9 Openness and transparency

The regulatory body's inspection and enforcement processes must be open and transparent, although the extent will vary with the Member State.

When dealing with a licensee, the regulatory body must be open and transparent regarding how it will conduct its inspections and on how the findings for each inspection were determined. The regulatory body must also be open and transparent regarding its enforcement policy and procedures and on how particular enforcement actions were determined.

For interested parties, the regulatory body will need to establish the extent to which it will be open and transparent regarding inspection and enforcement activities. As a minimum, the regulatory body should inform the public of the types and frequencies of the inspections it conducts at nuclear installations and provide at a summary of the licensee's compliance with regulatory requirements. Some regulatory bodies publish all inspection reports on its public website. Regarding enforcement, as a minimum the regulatory body should inform the public of its enforcement policy and will need to decide what information it will make available regarding actual enforcement actions. Many regulatory bodies publish summaries of the most serious enforcement actions.

4.3.10 Good practices identified by IRRS missions

4.3.10.1 France (2006)[72]

- ASN inspectors develop detailed agendas based upon off-site preparation activities that are used to facilitate on-site inspection conduct;
- ASN inspectors document inspection findings in at least three documents related to an inspection. Documentation of inspection results is readily retrievable for use in inspection programme development as well as serving as a readily available resource for recalling the regulatory history of an installation;
- ASN has a robust and comprehensive accreditation programme for its inspectors;
- Given that the regulatory system for radiation protection in medical exposures places significant reliance on approved persons and organizations performing radiation protection controls, it is commended that ASN has a system for inspecting the activities of such organizations, with feedback into their authorizations;
- ASN is to be commended for developing in-depth guidelines for the conduct of its inspections in medical practices using radiation;
- The preparation of inspections prior to their execution;
- The explanations and information provided by ASN inspectors to the operator at the end of inspections on identified good practices and deficiencies or deviations.

4.3.10.2 Spain (2008)[73]

- CSN management of the inspections with all the documents available on the intranet across all installations and activities is highly effective. The processes include the regular review of inspections and their findings as well as the follow up of plans with

[72] https://www-ns.iaea.org/downloads/actionplan/IRRS%20Mission%20to%20France__Nov_2006.pdf
[73] https://www-ns.iaea.org/downloads/actionplan/IRRS%20Mission%20to%20Spain__Jan-Feb_2008.pdf

associated resources. The conduct of the inspection programmes in this area as well as others covered by the IRRS review is made in a transparent and traceable way;

- The SIC's programme results are thoroughly presented on the CSN web site. The status of the utility is clearly presented and the related safety questions if any are presented in an easily understandable way. Also in-depth information can be found;
- Inspection reports for radiation facilities and X-ray facilities for medical diagnosis are published on the CSN website. The only information that is excluded is information that is considered sensitive (personal data, commercial, security aspects etc.). This makes the CSN activity transparent to the public, raises public credibility in the regulatory system and can promote the safety of the facilities;
- The CSN inspection programme for facilities for operational waste disposal and for discharge control, and the verification of the protection of the public and the environment from operating and decommissioned facilities through environmental monitoring, is highly structured, conducted in a highly competent manner, and followed up according to clear procedures.

4.3.10.3 Canada (2009)[74]

- The targeted use of inspections to focus limited regulatory resources on poor performance is an excellent example of optimization of regulatory resources to encourage licensees to improve their regulatory performance;
- The CERTS application developed for event inspection, assessment and corrective action tracking constitutes an efficient tool for event tracking, related inspections and corrective actions;
- The implementation of a robust and detailed inspection programme for radiation facilities (medical, industrial, and research) associated with high quality consistent documentation and a database carried out by CNSC[75] allow a high level of feedback into the regulatory process;
- The use of a licensing and inspection mapping system is an excellent method for tracking compliance and maintaining continuity from inspection to inspection. It is also valuable tool for knowledge transfer as the history of a licensee's performance is recorded in the database.

4.3.10.4 USA (2010)[76]

- Inspection programme has clear goals and a logical structure to verify that NPPs are operated in compliance with the USNRC regulations and licence conditions;
- Inspection procedures, NPP specific inspection reports and assessment results are publicly available at the NRC website;
- USNRC has provided training and procedures to its inspectors to observe safety culture factors in licensee's performance. These observations are collectively evaluated according to an assessment process every six months;
- There are effective ways to support inspection activities and share inspection findings within the region and HQ. This enables that generic inspection findings can be

[74] https://www-ns.iaea.org/downloads/actionplan/IRRS%20Mission%20to%20Canada__May-Jun_2009.pdf
[75] Canadian Nuclear Safety Commission (CNSC) is the Canadian nuclear regulator.
[76] https://www-ns.iaea.org/downloads/actionplan/IRRS%20Mission%20to%20the%20USA__Oct_2010_1.pdf

identified and adequately addressed with the licensees and also taken into account in different regulatory processes;

- USNRC has established several ways for inspectors to share experience and compare practices. This enables development of inspection practices and promotes consistent way of working of the inspectors and implementation of the inspection programme;
- Resident inspectors have risk tools (including SAPHIRE models) available to focus their inspections on risk significant items and to perform risk calculations to evaluate risk significance of component unavailability.

4.4 DRAFTING OF NATIONAL REGULATIONS AND GUIDES

Learning Objective 1: To understand how the IAEA Safety Standards can be used as a basis for national nuclear and radiation safety regulations and guides.

Learning Objective 2: To understand the principles for developing national regulations and guides.

Learning Objective 3: To understand the factors that influence the extent and detail of national regulations and guides.

Learning Objective 4: To understand the need for regular reviewing of regulations and guides.

4.4.1 The IAEA Safety Standards as a basis for national regulations

The IAEA Safety Standards reflect an international consensus on what constitutes a high level of safety for protecting people and the environment from harmful effects of ionizing radiation. Figure 25 shows the correlation between the IAEA Safety Standards and the national legal and regulatory framework. International conventions contain requirements similar to those in the IAEA Safety Standards, but are legally binding on Contracting Parties. The IAEA Safety Standards, supplemented by international conventions, establish a consistent basis for protecting people and the environment and are written in a way that Member States can readily incorporate into its national regulations and guides.

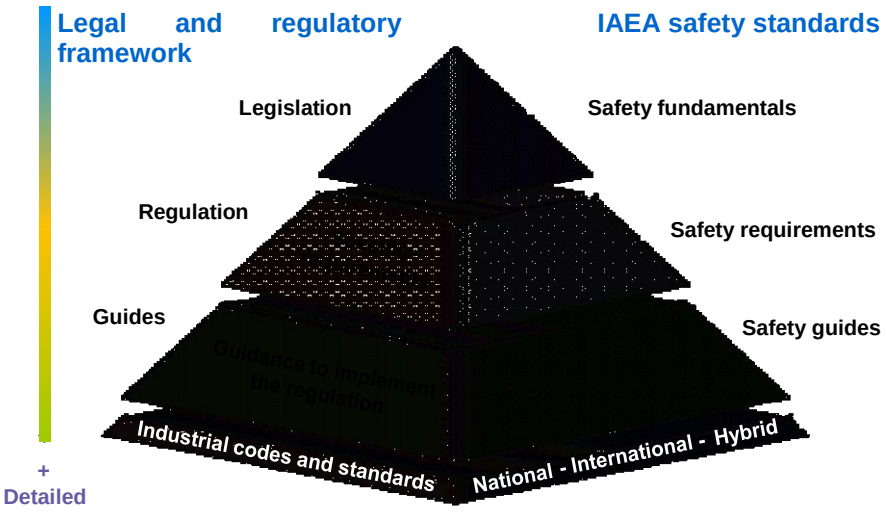


FIG. 25. IAEA safety standards and national legal and regulatory framework.

Typically, the general safety principles and administrative requirements for regulatory oversight are presented in national legislation. Mandatory technical requirements and radiological acceptance criteria are presented in national regulations. The responsibility for

issuing mandatory requirements varies between Member States (in some it is the government, in others it is the regulatory body). National guides present advice on how to implement the regulations and they are typically issued by the regulatory body.

The requirements established in the IAEA Safety Standards might not be fully met at installations that were built to earlier standards. Each Member State must decide how the IAEA Safety Standards will apply to these installations.

The basic principles used by the IAEA in developing its safety standards are also relevant for creating national regulations and guides and include:

- Clear categories;
- Clear, logical and integrated structure;
- User friendliness;
- Manageable number;
- Efficiency of the processes;
- Involvement of interested parties;
- Effective feedback mechanisms;
- Harmonized terminology.

The leading document for nuclear safety infrastructure is GSR Part 1 (Rev. 1) [5], which requires the establishment of an appropriate governmental, legal and regulatory framework for safety that includes:

- Safety principles for protecting people;
- Authority and responsibility of the regulatory body for promulgating regulations and preparing guidance for their implementation.

GSR Part 1 (Rev. 1) [5] Requirements 32 to 34 identify the regulations that the regulatory body should enact and maintain. The basic nuclear laws are enacted by the government. The legislative powers of the regulatory body depend on the nature of the Member State. In most Member States, the regulatory body has the authority to enact technical regulations on nuclear safety and security, radiation protection, radioactive waste management and transport of radioactive and nuclear materials.

The legal framework must also set out:

- Type of authorization that is required for the operation of installations;
- Basis for the authorization of new installations, as well as the applicable decision making process;
- Provision for the inspection of installations and for the enforcement of regulations;
- Provision for appeals against decisions of the regulatory body;
- Provision for the involvement of interested parties and their input to decision making;
- Provision for preparedness for, and response to, a nuclear or radiological emergency.

The system of regulations and guides must suit the legal system of the Member State and the nature and extent of the installations to be regulated. The main purpose of regulations is to establish requirements with which all licensees must comply. The regulations provide a

framework for more detailed conditions and requirements to be incorporated into individual licences. In accordance with Fundamental Safety Principle 5, the regulatory body should use a graded approach in developing and issuing regulations and guides.

GSR Part 1 (Rev. 1) [5] also discusses the stability and consistency of regulatory control. It states that the regulatory body is required to emphasize the continuous enhancement of safety as a general objective, but that the regulatory body must also recognize the risks associated with making modifications to well established procedures. Prospective changes in regulatory requirements must be subject to careful scrutiny.

4.4.2 Drafting national regulations and guides

The development of regulations and guides is a principal function of the regulatory body. A large regulatory body may establish a separate organizational unit for drafting regulations and guides. Similarly, if many new or revised regulations and guides are needed, establishing a separate organizational unit should be considered. Where the need is infrequent, it may be sufficient to put in place mechanisms whereby such resources can be drawn upon when necessary. In either case, the most knowledgeable regulatory staff should be assigned to the production of regulations and guides since these documents will form the basis for all other activities of the regulatory body.

GS-G-1.1 [22] gives more detailed guidance on the organization of the regulatory body.

GS-G-1.4 [25] states that the regulatory body should use a systematic approach for the production of regulations and guides and the regulatory body's management system should cover these activities. The regulatory body must develop procedures that establish the general method for the development and review of regulations and guides in accordance with the Member State's legal system.

Regulations which have the force of law are issued either by the government or the regulatory body, depending on the national practice and should specify the requirements for the licensing of nuclear installations and for ensuring the protection of workers, the public and the environment.

Regulations establishing general design criteria, such as defence in depth, use of multiple barriers, redundancy and diversity, should be developed first. Subsequently, more detailed regulations or guides should be developed which cover the details of design requirements for SSCs and requirements for the analysis of normal and accident conditions and their consequences.

Guides are prepared by the regulatory body and usually provide detailed information on how to satisfy the requirements in the regulations. Guides can also be used to clarify requirements and explain their basis or rationale.

The extent and detail of the system of regulations and guides established or adopted by the regulatory body will depend on several factors, including:

- Regulatory philosophy and the level of detail with which regulatory controls will be applied;
- Nature of the nuclear programme and the risks posed by the installations;
- Extent of regulatory experience with the technologies.

The procedure for establishing regulations and guides should include the following steps:

— Determination of the national approach in drafting regulations and guides;
— Determination of the overall structure of regulations and guides;
— Determination of the scope of regulations and guides;
— Determination of the correct level of regulation in the national hierarchy;
— Defining the process for preparing regulations and guides;
— Setting the priorities for development of regulations and guides;
— Organizing the work and determination of the resources to be employed;
— Establishing a system for recordkeeping and version management;
— Drafting of the proposed regulations and guides;
— Review of the proposed regulations and guides;
— Establishing and issuing the regulations and guides.

The national approach in drafting regulations and guides should be defined in early phases. A number of regional and national approaches are discussed in Section 4.4.5.

The regulations and guides should have a clear structure and be user friendly. This involves the following aspects:

— The structure of regulations and guides should be such that the users can easily identify those that are applicable to them;
— The hierarchy of the regulations and guides should be established and easy to understand;
— The overall number of regulations and guides should be manageable;
— The internal structure and layout of regulations and guides should be uniform;
— Each discrete requirement should be clear, unambiguous and numbered.

The scope of each regulation and guide should be clearly defined to ensure that all necessary installations are covered and there is no unnecessary duplication. The preparation and approval of a document preparation profile prior to starting development of a regulation or guide will facilitate the process.

The procedures to establish regulations and guides should be clear, rigorous, transparent and efficient. A general procedure should be prepared that details the general format for regulations and guides including guidance on the contents and style of language. The detailed preparation process of regulations and guides should be defined, including the necessary recordkeeping requirements and version control. The regulatory body should establish an overall plan for the production of regulations and guides that reflects the priorities of the regulatory body. Once this is developed, individuals responsible for the development of each regulation and guide can be identified. Regulatory body staff should be in charge of the drafting of regulations and guides, with external consultants only used for support.

The preparation process includes typically several steps of drafting and review. A working group, including the necessary technical and legal staff depending on the document, should be established for each regulation and guide to be produced. After the working group produces a first draft, it should be distributed within the regulatory body for comments, especially to those experts who later will use the regulation or guide in their own work.

After considering internal comments, the draft should be sent to external interested parties for comment. The draft should also be published on the website of the regulatory body with an invitation for comments from the public. Feedback should be provided for every comment received.

After the comments from interested parties and the public have been considered, the regulation or guide may be sent to any advisory group of the regulatory body for final review. After the comments of the advisory commission are considered, the regulatory body approves the regulation or guide. Usually, the regulatory body has the authority to publish guides, but the publishing of a regulation depends on Member State practice. All decisions concerning regulatory documents should follow the regulatory body's normal decision making procedures described in Section 3.3.

An important issue regarding drafting regulations and guides is the use of harmonized terminology. The regulatory body can either use the IAEA Safety Glossary [31] or create its own. In either case, definitions should be used consistently across the various regulations and guides.

4.4.3 Review and continuous improvement of regulations and guides

Fundamental Safety Principle 3 states that processes must be in place for the feedback and analysis of operating events, including initiating events, accident precursors, near misses, accidents and unauthorized acts, so that lessons may be learned, shared and acted upon. Major lessons need to be reflected in regulations and guides as necessary, taking into account the need for stability.

GSR Part 1 (Rev. 1) [5] states that technological advances, research and development work, relevant operational lessons learned and institutional knowledge can be valuable and has to be used as appropriate in revising regulations and guides.

The regulatory body should ensure that regulations and guides are kept up to date and periodically reviewed. The procedures applicable in the establishment of regulations and guides should also be followed for making any necessary revisions. In revising regulations and guides, care should be taken to ensure that no contradictions or inconsistencies arise between the retained and the revised parts of the document. The extent to which the proposed changes are applicable to current installations should also be considered. It is helpful to have a procedure and database to collect suggestions for changes to regulations and guides and these suggestions should be periodically reviewed and prioritized.

Regulations and guides should also be reviewed when major changes are introduced in the IAEA Safety Standards, especially in Requirements documents. IRRS missions can also identify the need to revise regulations or guides.

An example where regulations and guides may require updating is as a result of lessons learned from the Fukushima Daiichi accident. The IAEA has made plans and initiated studies on how the lessons from the Fukushima Daiichi accident will be included in the IAEA Safety Standards. Issues that regulatory bodies should consider when reviewing their regulations and guides include:

— Independence and competence of the regulatory body;
— Assessment of safety culture of the licensee and regulatory body;

— Consideration of extreme weather conditions;
— Defence in depth and reliability of safety functions;
— Management of severe accidents;
— Integrity of spent fuel pools;
— Emergency preparedness and response arrangements in case of an accident influencing several units on the same site.

4.4.4 Developing regulations and guides in Member States embarking on nuclear power

INSAG-22: Nuclear Safety Infrastructure for a National Nuclear Power Programme [63] recommends that the regulatory body in the importing country establish and maintain a knowledge transfer relationship with the regulatory body of the exporting country. INSAG-22 also states that for innovative or unproven technologies any necessary specific regulations will have to be established early in the process.

INSAG-26: Licensing the First Nuclear Power Plant [67] recommends that the regulatory body should first establish technology neutral regulations, such as the IAEA safety standards, as a foundation. These technology neutral regulations can then be complemented by more design specific regulations once the technology is chosen.

In the case where the Member State must revise or create the entire set of regulatory documents, the first step will be to establish the overall regulatory document structure. The structure of the IAEA Safety Standards serves a reference in this respect, especially if the Member State intends to base its regulations on the IAEA Safety Standards. The national approach and the scope of the regulatory body's activities will also influence the overall structure.

SSG-16: Establishing the Safety Infrastructure for a Nuclear Power Programme [27] provides guidance on the progressive implementation of the IAEA Safety Standards in the different phases of infrastructure development. In the first phase, before deciding to launch a nuclear power programme, the Member State should perform a complete assessment of the need for legislation, regulations and guides to support the licensing and effective oversight of a NPP. On the basis of this assessment, the Member State should then develop a plan to enhance its existing legal and regulatory framework to incorporate all elements.

A nuclear law should be established in this first phase. Among other things, the nuclear law should define the authority and responsibility of the regulatory body for preparing regulations and preparing guidance for their implementation. The nuclear law should also reflect the provisions of the relevant international instruments.

The regulatory body may adopt a prescriptive approach, a performance based approach, or a combination of the two as discussed in Section 3.2.4. The approach chosen will have a major influence on the resources needed by the regulatory body and the qualifications needed by its staff. In developing the detailed regulations and guides, the regulatory body can adapt either the IAEA Safety Standards or regulatory documents from other Member States or a combination of the two.

In general, no matter the approach, the safety objectives should be defined, preferably in the nuclear law. In addition, the regulatory body must avoid including specific solutions in regulations. Guides may identify acceptable solutions but usually leave open the possibility for the applicant or licensee to propose alternatives.

The regulatory body should ensure that a full and comprehensive set of regulations and guides is in place for regulating construction, commissioning and operational activities at the appropriate time. Regulations concerning site evaluation, design, construction and manufacturing should be prepared early enough so that they can be considered in the bidding process.

The regulations should define the licensing steps and corresponding documentation to be submitted by an applicant. In addition to technical guidance, basic guidance on the format of documents to be submitted to the regulatory body in support of an application for licensing should be provided.

4.4.5 Examples of regional and national regulations and guides

This section describes how WENRA and some Member States have used the IAEA safety standards to develop regional or national regulations[77].

4.4.5.1 Western European Nuclear Regulators Association reference levels

In 2006, the Western European Nuclear Regulators Association (WENRA) published a set of reference levels (RLs) for NPPs in operation at that time in WENRA countries. The process for their development and the boundary conditions are described in detail in *WENRA, Harmonization of Reactor Safety in WENRA Countries, RHWG Report*, January 2006.

The safety areas and issues included in the RLs were selected to cover important aspects of NPP safety where differences in substance between countries might be expected. WENRA did not seek to cover everything that could have an impact upon safety or to judge the overall level of safety in existing NPPs. It was decided that the RLs should cover nuclear safety, excluding radiation protection and physical protection. Some radiological aspects have been included since they are closely related to nuclear safety.

WENRA used the most recent versions of the IAEA Safety Requirements as a basis for the RLs. Following the publication of GS-R-3 [29], WENRA updated the RLs in *WENRA, Reactor Safety Reference Levels, RHWG Report, January 2008*. In 2011, WENRA published a status report on progress towards harmonization of safety for existing NPPs in WENRA countries.

All of WENRA's reports are available at their website.

Table 37 compares the WENRA RLs with the IAEA Safety Standards.

TABLE 37. ISSUES FOR WENRA REFERENCE LEVELS AND RELATED IAEA SAFETY STANDARDS

Issues for WENRA Reference Levels	**IAEA Safety Standards**
Issue A: Safety Policy	NS-R-2, NS-G-2.4
Issue B: Operating Organization	NS-R-2, NS-G-2.4
Issue C: Management System	GS-R-3

[77]National examples are based on presentations made at CSS meetings, available at the IEAE website.

Issue D: Training and Authorization of (NPP) staff	NS-G-2.8, NS-R-2
Issue E: Design of existing Reactors	NS-R-1, NS-G-1.2
Issue F: Design extension of existing reactors	NS-R-1, NS-G-1.2
Issue G: Safety Classification of SSCs	NS-R-1, NS-G 1.2
Issue H: Operational Limits and Conditions	NS-G-2.2, NS-R-2
Issue I: Ageing Management	NS-G-1.2, NS-G-2.6, NS-R-1
Issue J: System for Investigation of Events & Operational Experience Feedback	NS-G-2.4, NS-R-2
Issue K: Maintenance, In-Service, Inspection & Functional Testing	NS-G-2.6, NS-R-2
Issues L&M: Emergency Operation & Severe Accident Management Guidelines	NS-R-1, NS-R-2, NS-G-2.2, NS-G-2.8
Issue N: Contents and updating of Safety Analysis Report	GS-G-4.1
Issue O: Probabilistic Safety Analysis	NS-G-1.2
Issue P: Periodic Safety Review	NS-G-2.10
Issue Q: Plant modifications	NS-R-2, NS-G-2.3
Issue R: On-site Emergency Preparedness	NS-R-2, GS-R-2
Issue S: Protection against internal fires	NS-G-1.2, NS-G-1.7, NS-G-2.1, NS-R-1

Following the Fukushima Daiichi accident, WENRA initiated updating of RLs to take into account the lessons learned, insights from the EU stress tests [62] and revisions to IAEA Safety Standards since 2008. As a result, a new issue on natural hazards was developed and significant changes were proposed to several existing issues, especially concerning design extensions. The updated Reference Levels are described in report [68].

4.4.5.2 Canada

In Canada the regulatory body, Canadian Nuclear Safety Commission (CNSC), relies heavily on IAEA Safety Standards as core components of new draft documents, best practice when updating current documents and as additional guidance on how to meet existing requirements.

Older Canadian regulatory documents were generally CANDU specific, but since 2008, Canada's regulatory documents have been technology neutral, allowing direct use of the IAEA safety standards.

Canada is consistent with the requirements of GSR Part 1 (Rev. 1) [5]. The regulatory document on NPP design used NS-R-1 [69] extensively, with numerical dose acceptance criteria and safety goals added. The document was updated to include the lessons and observations from the Fukushima Daiichi accident and SSR-2/1. The design extension conditions were added, as were expanded requirements for electrical systems. In a similar

way, the regulatory document dealing with site evaluation was originally based directly on NS-R-3, but was updated to incorporate Fukushima Daiichi accident lessons learned. Canada uses the IAEA BSS as a reference for its radiation protection regulations.

Several CNSC regulatory documents are based on or are informed by, IAEA safety standards such as those dealing with deterministic and probabilistic safety analysis. There is now clear management direction that regulatory documents will be based on or informed by IAEA safety standards.

4.4.5.3 Finland

The current nuclear energy legislation in Finland was originally based on the Nuclear Energy Act from 1987. In 2008, the nuclear energy legislation was updated to correspond to current level of safety requirements. Based on the revised Nuclear Energy Act, the government issued the following regulations:

— Government Decree on the Safety of NPPs;
— Government Decree on the Security in the Use of Nuclear Energy;
— Government Decree on Emergency Response Arrangements at NPPs;
— Government Decree on the Safety of Disposal of Nuclear Waste.

These regulations established the basis for the overall revision of the Finnish Regulatory Guides called YVL Guides. Decrees dealing with safety of NPPs and emergency response arrangements of NPPs were amended in 2013 to account for WENRA Safety Objectives issued in 2010 and lessons learned from the Fukushima Daiichi accident.

After amending the nuclear energy legislation, the revision of all YVL Guides was initiated to:

— Restructure the guide system to better reflect various areas of safety;
— Limit the overall number of guides;
— Compile requirements concerning related safety issues to the same guide making it easier to use by the licensees and interested parties; also they will be coupled to the stage of the licensing process;
— Rewrite the separate requirements in such a way that each requirement will have its own number, be short and clear;
— Provide descriptive text only when necessary in the guide itself, additional information is provided in a separate justification memorandum (basis of the guide);
— Pay special attention to opportunities to limit unnecessary prescriptiveness.

When formulating the general objectives of the revision of the YVL Guides, IAEA practices were followed very closely. The preparation process of YVL Guides resembles the IAEA process for preparing safety standards. The format of IAEA Safety Standards was used to define the standard format and contents for the YVL Guides. The IAEA Safety Glossary [31] was used to the extent possible to establish consistent terminology.

Concerning the contents of the new YVL Guides, the objectives were to include the lessons from the Olkiluoto 3 project and later on the lessons from the Fukushima Daiichi accident.

The main references in drafting the new YVL Guides were the WENRA Reference Levels, WENRA Safety Objectives for new NPPs and IAEA Safety Standards, especially the Requirements documents. Internal and external reviews were made to ensure that the YVL Guides implement at least the same safety level as is presented in the IAEA Requirements documents. The new YVL Guide system includes 44 Guides (compared to 71 in the old structure) divided into five groups.

To keep the regulations current, there is a requirement that individual YVL Guides has to be reviewed not later than five years after issue. The deadline for updating a guide is ten years after date of the issue.

4.4.5.4 Germany

In Germany the regulatory functions are divided between federal government authorities and state (Länder) authorities. Establishing national safety requirements is the responsibility of Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU). BMU uses advisory bodies such as RSK (Reaktor-Sicherheitskommission) and GRS as a TSO. BMU issues guidelines and recommendations. RSK issues guidelines and KTA safety standards. The licensing of nuclear installations is regulated in the Atomic Energy Act.

The international references for German regulations are IAEA Safety Requirements, IAEA Safety Guides, INSAG reports, WENRA Reference Levels and WENRA Safety Objectives for new NPPs.

The new German Safety Requirements for NPPs (SR-NPP) were published on January 24, 2013. They take into account existing German requirements and regulations, IAEA safety standards, existing WENRA Reference Levels and also WENRA Safety Objectives for new NPPs and especially lessons learned from the Fukushima Daiichi accident. The Safety Requirements consist of one main document and five annexes. The main document comprises the general requirements for design and operation of NPPs and it is comparable to the level of detail of IAEA Safety Requirements and the WENRA Reference Levels. In addition, there are eight additional interpretation documents for specific important safety related issues. These interpretation documents are comparable to the IAEA Safety Guides and take into account relevant IAEA Safety Guides.

4.4.5.5 Pakistan

The regulatory framework in Pakistan consists of:

- Acts and Ordinances, issued by the Government, presenting objectives, structure, functions and responsibilities of the regulatory body (PNRA);
- Regulations issued by PNRA specifying the basic requirements to ensure safety and covering both requirements for regulatory processes and technical issues;
- Regulatory guides of a non-mandatory nature issued by PNRA, providing recommendations for implementation of regulatory requirements.

The development process of regulations includes preparation of a document production profile, internal reviews within the PNRA, review by interested parties and approval by PNRA.

The PNRA regulations are mainly based on IAEA Safety Standards supplemented by good practices such as those from China, Finland and USA.

PNRA has developed a Management System Manual and is in the process of implementing an integrated management system mainly based on GS-R-3 and GS-G-3.1 [48].

4.4.5.6 United Arab Emirates

The United Arab Emirates (UAE) is an example of a Member State embarking on a nuclear power programme. UAE established and empowered an independent regulatory body (FANR) to assure nuclear safety in this programme. UAE is a Contracting Party to several international conventions, ratified the Additional Protocol to the Safeguards Agreement and issued the UAE Nuclear Liability Law (October 2012).

The strategy of the UAE is to implement a national regulatory framework to enable operations and to customize, implement and communicate operational and administrative regulations and guides necessary to fulfil UAE laws, international agreements and other commitments.

FANR started by implementing an integrated management system and setting up management processes and strategic directions to developing UAE regulations and regulatory guides. The focus is on developing high level, performance based regulations focusing on essential aspects of safety. The regulations conform to the IAEA Safety Standards, are risk-informed and follow best international practice. UAE has adopted a 3S+ approach in its activities (Safety, Security, Safeguards, and Emergency Preparedness). FANR develops regulatory guides only if no equivalent international guidance is available (IAEA/country of origin/USNRC).

The use of IAEA Safety Standards enabled FANR to develop a set of regulations over a relatively short period of time. FANR has selected to use regulatory guides from the country of origin. This has led, through Republic of Korea practice, to the use of many USNRC regulatory guides. The integrated management system enabled FANR to have efficient and effective procedures and methodology to develop and approve regulations and regulatory guides.

4.4.5.7 UK

The UK is an example of a performance based, goal setting nuclear regulatory framework. Under UK legislation, the licensee is required to ensure the risks to personnel and the public are reduced so far as is reasonably practicable. The regulatory body (ONR) does not prescribe compliance with the IAEA safety standards. Still, IAEA safety standards are integrated into the UK nuclear regulatory system.

The Safety Assessment Principles (SAPs) are principles used by ONR to guide regulatory decisions on nuclear installations. The IAEA requirements are reflected in the principles. The 2006 SAPs were benchmarked against IAEA Safety Standards and WENRA Reference Levels are currently under review. This review has confirmed that the SAPs are consistent with IAEA safety standards.

Technical Assessment Guides (TAGs) provide detailed guidance to ONR staff on how licensees can demonstrate compliance with legal requirements. The IAEA Safety Standards are identified as relevant good practice in the TAGs. The regulatory body also expects that the licensees use IAEA Safety Standards and perform a gap analysis against the organization’s own standards and arrangements, and update them where appropriate.

4.4.5.8 USA

The USNRC takes into account IAEA safety standards across different regulatory programs. The IAEA safety standards are used as a point of reference in reactor, radiation protection and waste programs and more directly in transportation program. The IAEA BSS is considered in developing US radiation protection requirements. The future revision of Part 20 includes a consideration of GSR Part 3 [70].

The USNRC now requires staff to consider IAEA Safety Standards as a point of reference and to consider direct endorsement of the IAEA safety guides. This remains a challenge since most USNRC Regulatory Guides are written at a more detailed level than the IAEA safety guides. The USNRC regulatory guidance is closer in detail to what would be considered a TECDOC in the IAEA structure and currently includes about 450 Regulatory Guides.

4.5 EMERGENCY PREPAREDNESS AND RESPONSE

Learning Objective 1: To understand the international framework for nuclear and radiological emergency preparedness and response in particular, the IAEA Safety Standards in Emergency Preparedness and Response.

Learning Objective 2: To understand the role of the government, the regulatory body and the licensee regarding nuclear and radiological emergency preparedness and response.

Learning Objective 3: To be aware of what the appropriate coverage of regulations for on-site emergency preparedness and response is.

Learning Objective 4: To understand the responsibilities of the licensee and the regulatory body in emergency preparedness and response.

Learning Objective 5: To be aware of lessons learned with implications on the regulatory framework from several past nuclear emergencies.

Nuclear and radiological emergency preparedness and response is a part of the overall framework for safety at the national level as well as at the international level. The scope of nuclear and radiological emergency preparedness and response considers all foreseeable incidents and accidents that may give rise to an emergency, warranting actions to mitigate the consequences for human life, health, property and the environment including those of very low probability.

Appropriate branches of government will have various responsibilities from enacting the legal basis to development of various emergency arrangements and their execution should an emergency occur. The licensee is responsible for dealing with the on-site emergency preparedness and response and for cooperating with appropriate branches of the government at different levels in cases that emergency has the potential to affect third parties or the environment or may warrant off-site support. The role and responsibilities the regulatory body may have in emergency preparedness and response are discussed in 3.7.1.

4.5.1 The international framework for emergency preparedness and response

The international emergency preparedness and response framework is comprised of international legal instruments, IAEA Safety Standards, and relevant operational arrangements as shown in Figure 26.



FIG. 26. The international emergency preparedness and response framework.

4.5.1.1 International legal instruments

The two international conventions associated with nuclear and radiological emergencies are the Early Notification Convention and the Assistance Convention [8], both adopted in 1986. Contracting Parties to the Early Notification Convention are committed to notify, directly or through the IAEA, those other Member States that are or may be affected by the transboundary consequences of radiological significance, of an accident occurring in their territory. The Contracting Parties to the Assistance Convention are committed to cooperate among themselves and with the IAEA to facilitate prompt assistance in case of a nuclear accident or radiological emergency in a Contracting Party or a Member State.

More information on the two conventions is provided in Section 2.1.3.

4.5.1.2 Fundamental safety principle on emergency preparedness and response

Fundamental Safety Principle 9 states that:

> "Arrangements must be made for emergency preparedness and response for nuclear or radiation incidents" [21].

The scope and extent of these arrangements:

> "have to reflect the likelihood and the possible consequences of an emergency, the characteristics of the radiation risks, and the nature and location of the facilities and activities" [19].

They cover on-site arrangements for which responsibility remains with licensee as well as off-site arrangements for which responsibility remains at authorities at local, regional, national levels and, as appropriate, at international level.

Emergency preparedness and response is the last protection barrier in the defence in depth concept.

4.5.1.3 Safety requirements for emergency preparedness and response

In November 2015, the new Safety Requirements publication No. GSR Part 7: *Preparedness and Response for a Nuclear or Radiological Emergency* [40] was published in the IAEA Safety Standards Series in a joint sponsorship by thirteen international intergovernmental organizations[78]. This publication establishes requirements for an adequate level of preparedness and response for any nuclear or radiological emergency irrespective of the initiator of the emergency (technical failure, human error, natural disaster or a nuclear security event). This publication is a revised and updated version of the Safety Requirements publication No. GS-R-2[79] issued in 2002.

IAEA Safety Standards Series No. GSR Part 7 builds on the experience gained from responses to actual emergencies and from conducted emergency as well as on recent developments in the area. It sets common goals to be achieved in emergency preparedness and response and it addresses the common concepts and approaches to be applied for adequate preparedness to effectively respond to nuclear or radiological emergencies. In addition, this publication sets comprehensive safety requirements for operational arrangements to be made to support the functions performed in an emergency response for achieving the goals of emergency response.

This publication defines five emergency preparedness categories to provide a basis for a graded approach in developing emergency arrangements within a State. The emergency preparedness category I corresponds to:

> "Facilities, such as NPPs, for which on-site events (including those not considered in the design) are postulated that could give rise to severe deterministic effects off the site that would warrant precautionary urgent protective actions, urgent protective actions or early protective actions, and other response actions to achieve the goals of emergency response in accordance with international standards, or for which such events have occurred in similar facilities" [40].

GSR Part 7 consists of six sections, two appendices and one annex.

Section 3 elaborates the goal of emergency preparedness and goals of emergency response. The goal of emergency preparedness is to ensure that an adequate capability is in place within the operating organization and at the local. Regional and national levels and, where appropriate, at the international level, for an effective response to a nuclear or radiological emergency [39]. The goals of emergency response include:

(a) To regain control of the situation and to mitigate consequences;
(b) To save lives;

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[78] FAO, IAEA, ICAO, ILO, IMO, INTERPOL, OECD/NEA, PAHO, CTBTO, UNEP, OCHA, WHO AND WMO.

[79] 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 OFFICE FOR THE COORDINATION OF HUMANITARIAN AFFAIRS, WORLD HEALTH ORGANIZATION, Preparedness and Response for a Nuclear or Radiological Emergency, IAEA Safety Standards Series No. GS-R-2, IAEA, Vienna (2002).

(c) To avoid or to minimize severe deterministic effects;
(d) To render first aid, to provide critical medical treatment and to manage the
(e) treatment of radiation injuries;
(f) To reduce the risk of stochastic effects;
(g) To keep the public informed and to maintain public trust;
(h) To mitigate, to the extent practicable, non-radiological consequences;
(i) To protect, to the extent practicable, property and the environment;
(j) To prepare, to the extent practicable, for the resumption of normal social and economic activity [39].

Section 4 addressed the general requirements that need to be fulfilled before detailed arrangements can be developed and they include:

— Establishment of an emergency management system;
— Allocating roles and responsibilities;
— Assessment of hazards; and
— Development of a protection strategy.

Section 5 addresses the necessary functions to be performed for efficient emergency response as following:

— Managing and coordinating operations in an emergency response at all levels (facility level and local, regional and national levels) and setting up a unified and clear command and control system taking into account the 'all-hazards' approach;
— Identifying an emergency on the basis of observable or measurable conditions, declaring an emergency class, notifying relevant authorities through a designated off-site notification point and activating a preplanned emergency response on-site and off-site, as appropriate;
— Taking actions to mitigate the development of hazardous conditions resulting in exposure due to, or a release of, radioactive material warranting response actions to be taken on-site and/or off-site, including provision of off-site emergency services to support the on-site response efforts;
— Taking urgent protective actions and other response actions to avoid severe deterministic effects and to reduce the risk of stochastic effects including consideration for the criteria to be used for this purpose and other arrangements (e.g. defining emergency planning zones and distances) necessary for their effective implementation as well as preparing for making as assessment of hazardous conditions as a basis to refine the protection strategy;
— Providing instructions, warnings and relevant information to potentially or actually affected public, particularly to the population within emergency planning zones and distances;
— Protecting emergency workers and helpers in an emergency through ensuring they are identified and designated at the preparedness stage, aware of their duties and trained, provided with instructions and personnel protective equipment;
— Managing the medical response in an emergency through provision of medical services and medical treatment for those affected by the emergency;
— Communicating timely and consistently with the general public throughout an emergency placing the health hazards in perspective of any technical information and data;

- Taking early protective actions and other response actions to further reduce the risk of stochastic effects and setting criteria and other arrangements (e.g. capabilities and strategy for monitoring and assessment) for their effective implementation;
- Managing radioactive waste in an emergency so that it does not compromise the protection strategy;
- Mitigating the adverse psychological, social and economic consequences (i.e. non-radiological consequences) of the emergency, and of an emergency response;
- Requesting, providing and receiving international assistance should this be necessary with account taken of bilateral and multilateral arrangements put in place for this purpose;
- Terminating an emergency to facilitate the resumption of social and economic activities in a timely manner;
- Analyzing the emergency and the emergency response to identify the circumstances surrounding the emergency, necessary revisions of existing arrangements and to prevent similar event from happening.

Section 6 discusses the infrastructure requirements essential to providing the capability for fulfilling the function contained in Section 5, including:

- Legally assigned authority for developing, maintaining and regulating arrangements for emergency preparedness and response;
- Organizational relationships and interfaces between all the major response organizations and staffing necessary positions;
- Arrangements for the coordination of emergency response and protocols for operational interfaces between licensees and relevant organizations at the local, regional and national levels;
- Developing and maintaining emergency plans, procedures and other operational arrangements by licensee and by relevant organizations at the local, regional and national levels;
- Training, drills and exercises;
- Logistical support and facilities for enabling emergency response functions to be performed effectively;
- Quality management programme for ensuring the availability and reliability of all supplies, equipment, communication systems and facilities, plans, procedures and other arrangements necessary for effective response.

GSR Part 7 provides a comprehensive set of generic criteria for taking protective actions and other response actions in a nuclear or radiological emergency. States may decide to use them directly when they are developing national protection strategy or as a basis for developing their own national generic criteria. These generic criteria provide basis for taking actions to prevent severe deterministic effects, to reasonably reduce the risk of stochastic effects, to mitigate non-radiological consequences by providing for the resumption or continuation of international trade following an emergency and for enabling the transitioning from an emergency exposure situation to an existing exposure situation.

4.5.1.4 Safety Guides in emergency preparedness and response

In 2007, the IAEA published the Safety Guide No. GS-G-2.1[80] [71] to elaborate on how to implement selected safety requirements in emergency preparedness and response. In addition, GS-G-2.1 describes appropriate responses (so called concepts of operations[81]) to a range of nuclear or radiological emergencies including a general emergency[82] at a NPP and includes:

- A description of emergency planning zones and areas and their suggested radius;
- A description of abnormal facility conditions associated with a specific emergency class and immediate actions to be taken on-site and off-site upon declaration of the emergency class;
- A description and overview of protective actions and other response actions;
- A description of adequate emergency related facilities and locations necessary to support emergency response.

GS-G-2.1 recommends the response time objectives for selected critical response functions or tasks that can be used by the regulatory body, licensees and response organizations in relation to an emergency at a NPP.

GS-G-2.1 stresses the need for integrated approach in emergency preparedness and response under an all-hazards approach to allow for effective and efficient use of resources and capabilities within a State. Integration of arrangements for response to a nuclear or radiological emergency at all levels with the arrangements for response to conventional emergencies is represented in Figure 27.

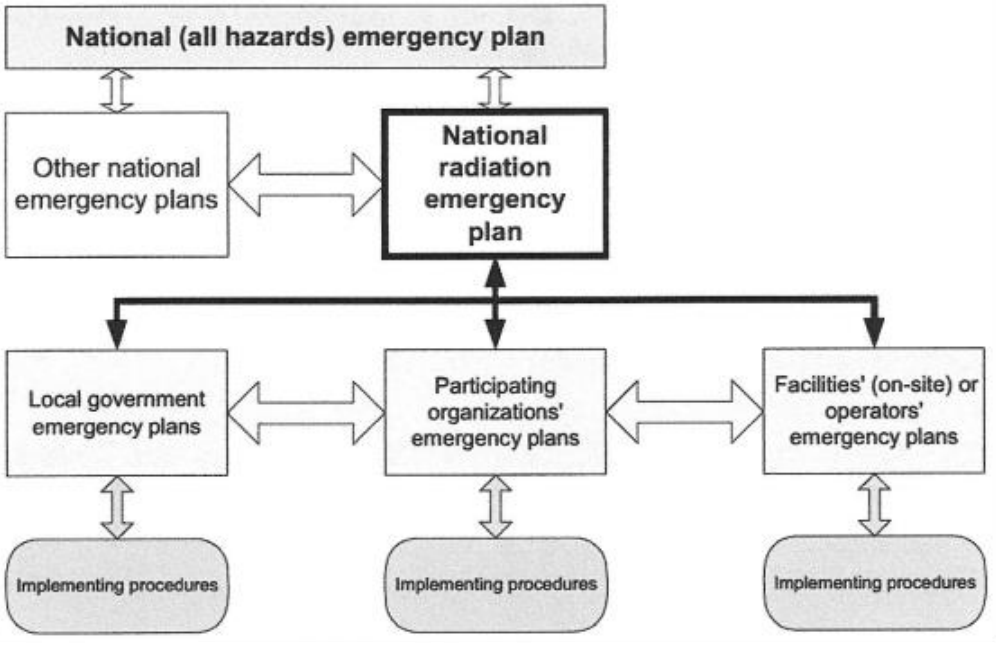


FIG. 27. Integration of nuclear and radiological emergencies under an all-hazard approach.

[80] GS-G-2.1 is jointly sponsored by FAO, IAEA, ILO, PAHO, OCHA and WHO.
[81] Brief description of the ideal response to an emergency that is developed at the beginning of the preparedness process to ensure that everyone involved shares a common vision and understanding.
[82] An event resulting in an actual release, or substantial probability of a release, requiring implementation of urgent protective actions off-site. [31]

GS-G-2.1 highlights the importance of providing reliable public information on the hazards involved and the actions people can take, as well as the actions being taken to ensure that people are safe and their interests are being protected.

In 2011, the IAEA published *GSG-2: Criteria for Use in Preparedness and Response for a Nuclear or Radiological Emergency*[83] [72] to provide framework for protective actions and other response actions in an emergency and to present a coherent set of generic and operational criteria (expressed numerically in terms of radiation dose and measurable quantities) for taking emergency response actions. GSG-2 advises that protective actions and other response actions are not based on radiation protection considerations alone and that decision makers should consider various social, economic, environmental and psychological factors before making any final decision on actions to be taken in response to an emergency to ensure that the actions taken do more good than harm and are optimized.

Table 38 summarizes the system of protective and other response actions in a nuclear or radiological emergency as elaborated in GSG-2.

TABLE 38. SYSTEM OF PROTECTIVE ACTIONS AND OTHER RESPONSE ACTIONS IN AN EMERGENCY

Types of possible health consequences of exposure	Basis for implementation of protective actions and other response actions	
	Projected[84] dose	Dose received
Severe deterministic effects[85]	Implementation of precautionary urgent protective actions, even under adverse conditions, to prevent severe deterministic effects	Other response actions[86] for treatment and management of severe deterministic effects
Increase in stochastic[87] effects	Implementation of urgent protective actions[88] and initiation of early protective actions to reduce the risk of stochastic effects as far as reasonably possible	Other response actions[89] for early detection and effective management of stochastic effects

4.5.1.5 Technical guidance and tools

The IAEA has also developed technical guidance and tools (including associated standardized training materials) covering, in detail, various aspects of emergency preparedness and response in order to support Member States and relevant international organizations in

[83] GSG-2 is jointly sponsored by IAEA, FAO, ILO, PAHO and WHO.
[84] The dose that would be expected to be received if planned protective actions were not taken [31].
[85] Deterministic effect that is fatal or life threatening or results in a permanent injury that reduces quality of life [40].
[86] Such actions include: immediate medical examination, consultation and treatment; contamination control; decorporation; registration for long term health monitoring; and comprehensive psychological counseling.
[87] A stochastic effect is a radiation induced health effect, the probability of occurrence of which is greater for a higher radiation dose and the severity of which (if it occurs) is independent of dose [31].
[88] Such actions include relocation and long term restriction of consumption of contaminated food.
[89] Such actions include screening based on individual doses to specific organs, considering the need for registration for medical follow-up and counseling to allow informed decisions to be made in individual circumstances.

implementation of the IAEA safety standards in the area of emergency preparedness and response. They are covering various aspects from development of facility and national emergency plans, preparing and conducting emergency exercises, procedures for assessment of reactor emergencies, considerations in emergency preparedness and response for countries embarking on a nuclear power programme etc. In addition, the IAEA has been regularly publishing reports from past accidents. They can be found on the IAEA website[90].

4.5.2 Responsibilities for nuclear emergencies

The overall organization for managing emergencies depends upon the national legal and administrative structure and comprises of response organizations at different levels (national, regional and local authorities), the regulatory body and licensees. The government is responsible for enacting basic legislation in which the basic responsibilities will be allocated among all the organizations taking into account existing mechanisms for managing conventional emergencies of any type (all hazard approach). On the other hand, the regulatory body will be responsible for developing regulations and issuing guides to regulate the on-site emergency arrangements of the licensee and to verify that they are appropriate fulfilled before the commencement of operation and, thereafter, on a regular basis. It is important that the emergency planning at all levels does not finish with the end of the emergency phase but allows also for the resumption of normal social and economic activity and for the long term recovery operations.

4.5.2.1 Enacting basic legislation and regulations

The government is responsible for making "adequate preparations to anticipate, prepare for, respond to and recover from a nuclear or radiological emergency" [40]at all levels. As part of these preparations, the government is responsible for creating a legal and organizational infrastructure for effectively governing the emergency preparedness and response taking into account its arrangements for coping with conventional emergencies of any type. Some governments have enacted specific emergencies laws and decrees of government, while others have included such considerations as a part of the nuclear law.

The IAEA 2010 Handbook on Nuclear Law [53] recommends that the government needs to consider four emergency issues at least:

- Every licensee must prepare and put into place an appropriate emergency plan;
- The regulatory body must assess and approve licensees' emergency plans and oversee their maintenance and improvement;
- As the emergency plan generally involves several government bodies and the public, the regulatory body must provide expert advice to such bodies and help in informing the public. Those Member States that are parties to the Early Notification and the Assistance Conventions must comply with the requirements of those conventions;
- Regulations must ensure a clear allocation of responsibilities; establish procedures for decision making; and provide funds and human resources for an efficient response.

[90] http://www-ns.iaea.org/tech-areas/emergency/technicalproducts.asp?s=1&l=1

4.5.2.2 Functions and responsibilities of the regulatory body in emergency preparedness and response

The government is also responsible to "ensure that arrangements for preparedness and response for a nuclear or radiological emergency for facilities and activities under the responsibility of the operating organization are dealt with through the regulatory process" and that "the on-site emergency arrangements provide, to the extent practicable, assurance of an effective response to a nuclear or radiological emergency" [39].

To fulfil these responsibilities, the regulatory body's functions must include:

- Establishing or adopting regulations and guides that specify principles, requirements and associated criteria for emergency preparedness and response for the licensee;
- Assessing the adequacy of the on-site emergency arrangements of the licensees throughout the authorizations process and verifying compliance with the regulatory requirements through inspection and oversight;
- Observing and evaluating some of licensee's exercises; and
- Implementing enforcement activities in the case of non-compliance.

In this regard, the regulatory body need to develop and implement appropriate procedures for review and assessment of on-site emergency arrangements and to plan for inspection of on-site emergency preparedness prior to licensing and, thereafter, regularly, as part of the overall plan for inspections. Moreover, the regulatory body need to plan and agree upon observing and evaluating some of licensee's exercises periodically on the basis on predefined exercise objectives.

As mentioned in section 3.7.1, the regulatory body may be assigned with specific responsibilities in an emergency response. They may include:

- Ensuring compliance with the obligations under the Early Notification and Assistance Conventions and any bilateral agreements the Member State may have with others in the area of early notification, sharing of information and assistance in the event of an emergency;
- Assessing the situation and providing advice to government authorities;
- Contributing to provision of information to the public, etc.

Whatever the role and responsibility has been assigned to the regulatory body in an emergency response, the regulatory body needs to develop its own emergency arrangements to fulfil this role and responsibility. This includes: emergency plan and procedures, staffing, training, exercises, quality management system, tools, equipment and putting in place an emergency response facility/center from where this role is fulfilled.

Cooperation of the regulatory body with off-site response organizations and other competent authorities

The regulatory body needs to require that on-site emergency arrangements of the licensee are coordinated and integrated with those of other response organizations, when appropriate, and with other plans such as security and contingency plans established in the area of nuclear security [40]. The procedures to be used by the regulatory body to assess and review this coordination and integration and to verify that they provide for an effective emergency

response may necessitate inputs by other relevant off-site response organizations and other competent authorities with responsibilities in nuclear security.

At the preparedness stage, the regulatory body must work with respective authorities responsible for local, regional and national emergency preparedness and response, as appropriate, to ensure that they have the necessary relevant information and basis for emergency planning either directly from the licensees or through the regulatory processes and functions. In some States, the regulatory body is assigned as a lead authority for the development of national emergency plan. Whatever is the national situation, effective cooperation of the regulatory body with all relevant authorities and response organizations should be based on trust, transparency and openness.

Establishing and maintaining effective working relationships of the regulatory body with off-site response organizations and other competent authorities with responsibilities in nuclear security is essential in the area of emergency preparedness and response. In many cases, formal arrangements and coordinating mechanisms may be necessary to be established and maintained to allow for this function of the regulatory body to be effective and efficient.

Regulatory requirements and guides for on-site emergency preparedness and response

The regulations and guides developed by the regulatory body to regulate the licensee's emergency arrangements need to account for all the requirements contained in Ref. [40]and elaborated in 4.5.1.3 above. Additional guidance that can support the development of adequate regulations and guides in this regard may also be found in Ref. [71], [72].

The regulations for on-site emergency arrangements should include requirements for clear assignment of roles and responsibilities at the organizational level, for performing a hazard assessment to provide a basis for establishing adequate emergency arrangements and for developing, justifying and optimizing a protection strategy for the on-site emergency response.

These regulations should also include requirements for all the functions necessary to be perfomed in the emergency response as suggested in GSR Part 7 [40] such as:

- for managing the on-site emergency response and for coordination with off-site authorities, -
- for identifying and notifying an emergency and activating the emergency response,
- for taking mitigatory actions including for arrangements to be made for obtaining off-site support and assistance,
- for taking urgent protective actions to protect all the individuals present at the site and to protect emergency workers,
- for providing a medical response,
- for contributing to provision of information, instructions and warning to the public, as appropriate,
- for waste management following the emergency,
- for provisions to mitigate non-radiological consequences, as appropriate, and
- for preparing for the recovery and for the termination of the emergency.

The regulatory body should also require that the licensee analyses an emergency and the emergency response to draw lessons and to identify any necessary improvements.

Regulations should also require licensees to put in place an infrastructure in terms of plans, procedures, instructions, staffing, training, drills, exercises, supplies, tools, equipment, emergency response facilities and logistical support and quality management programme. The regulatory body should require that all these elements are part of the integrated management system of the licensee.

The time allowing for effective decision-making in an emergency may be short. Thus, the regulatory body need to ensure, at the preparedness stage, that the licensee is given authority to decide on and to take necessary mitigatory actions on-site including those that may result in off-site consequences (e.g. controlled venting to enable keeping the integrity of the containment). In these circumstances, the off-site authorities may be required to be informed by the licensee; however, no pre-approval from the regulatory body for implementing these actions should be requested.

4.5.2.3 Responsibilities of licensees in EPR

The Licensee is responsible to establish and maintain arrangements for on-site preparedness and response for an emergency related to facilities or activities under its responsibility [40]]. The regulatory requirements and guides as discussed in 4.5.2.2.2 need to elaborate what these arrangements should encompass in details. In this regard, the licensee will be responsible to:

- Perform hazard assessment to identify the level of preparedness necessary taking into account events of very low probability and to identify consequences it may need to cope with as well as to define its strategy for response;
- Allocate roles and responsibilities among its staff for different positions relevant to emergency preparedness and response and to assign authorities for fulfilling these responsibilities;
- Integrating all processes, structures and functions in EPR within its management system taking into account the need for coordination and consistency with the national emergency management system;
- Establish and maintain arrangements to fulfil all the expected functions in an emergency response:
  (a) For managing the emergency response and for coordination with off-site response;
  (b) For establishing a system to recognize emergencies, to activate an emergency response and to notify and keep off-site authorities, including the regulatory body as appropriate, informed;
  (c) For taking mitigatory actions and for obtaining support by off-site emergency services;
  (d) For taking protective actions on-site to protect non-essential personnel and others present at the site;
  (e) For carrying out continuous monitoring and assessment of the situation as a basis for further actions and for sharing this information with off-site authrotities;
  (f) For establishing and maintaining provisions (including designation, training, instructions, drills, protective equipment, dosimetry service etc.) to protect emergency workers irrespective of the organizations they are coming from;
  (g) For the medical response to the emergency and obtaining support of public health authorities and designated medical hospitals;
  (h) For communicating with the public throughout the emergency and coordinating with other responsible organizations in this regard;
  (i) For managing radioactive waste generated on-site as a result of the emergency;

(j) For dealing with non-radiological consequences such as psychosocial consequences among emergency workers;
(k) For terminating the emergency and for fulfillment of specific conditions to do so;
(l) For analyzing the emergency and the emergency response, for identifying lessons to be learned and addressing them in the respective arrangements when revised;

- Establish and maintain adequate emergency plans and procedures and for submitting them to the regulatory body and for providing the regulatory body enough evidence that the emergency arrangements elaborated provide assurance for an effective response;
- Training staff on the emergency plan and its related processes and procedures;
- Performing periodic drills and exercises on the basis of predefined programmes, some of which can be observed by the regulatory body, and critically analyzing the results;
- Development of comprehensive quality management programme to account for the need to maintain and improve the emergency plan and procedures based on operating experience, lessons learned from exercises and real events and recent developments and to ensure availability and reliability of all the equipment, supplies, tools etc.;
- Effectively implementing the established emergency arrangements.
- The licensee needs to recognize its unique responsibility for the safety of the installation under normal as well as during an emergency and for effective implementation of on-site emergency response. The licensee may need to participate in the third party liability arrangements established by the Member State.

4.5.3 The role of IAEA in emergency preparedness and response

The responsibility for establishing and maintaining adequate emergency preparedness and response remains with the individual State. However, the IAEA has some statutory responsibilities that are complemented with specific functions deriving from the Early Notification and Assistance Conventions [8] as described in sections 2.1.3 of this publication and the IAEA safety standards [40].

The roles of the IAEA in emergency preparedness include:

- Developing safety standards, technical guidance and practical tools in the area of emergency preparedness and response and providing for their implementation,
- Assisting Member States in establishing or enhancing their emergency preparedness and response frameworks and capacity building,
- Providing peer-review services, such as the Emergency Preparedness Review (EPREV) mission, and
- Maintaining and strengthening the IAEA’s in-house and inter-agency preparedness.

The roles of the IAEA in emergency response include:

- Notification and official exchange of information,
- Provision of advice and assistance, if requested,
- Provision of assessment and prognosis,
- Provision of public information, and
- Coordination of inter-agency response.

The IAEA has setup an Incident and Emergency System (IES) to discharge its roles in emergency preparedness and response. The Incident and Emergency Centre (IEC) of the IAEA is a custodian of the IES and a global focal point for emergency preparedness and response and for the coordination of the provision of international assistance.

4.5.4 INSAG and emergency preparedness and response

INSAG has considered emergency preparedness and response on several occasions.

One of INSAG's first tasks was to review the Chernobyl accident. INSAG's work on this is discussed in Section 4.5.4. Emergency preparedness is considered as a specific principle in INSAG-12 [34]. INSAG-20 [73] states that persons living near an NPP would gain greater understanding of any risks they are exposed to if they were given an opportunity to participate in the development of its emergency plan, in planning for drills and exercises and in the analysis of lessons learned in other emergencies. Local authorities should be aware of their responsibilities in the response and in any long term recovery should an emergency occur. For those Member States considering a nuclear power programme, INSAG-22 [63] recommends that the emergency preparedness programme be initiated before deciding to launch a nuclear power programme, fully implemented during the commissioning phase of the first NPP and considerably improved and exercised periodically during operation.

4.5.5 Experience from IRRS missions in emergency preparedness and response

The past IRRS missions demonstrate that there are well established working relationships between the regulatory bodies and licensees in the most Member States hosting such missions. The regulatory bodies recognize their role to regulate the on-site emergency preparedness and response of the licensee and to cooperate with off-site response organizations and authorities in this regard. In most cases, the regulatory body are also assigned with other roles and responsibilities in nuclear or radiological emergency preparedness and response which vary from one to another State.

In general, several areas appear commonly to require further attention for improvement as following:

- Strengthening regulations and guides for emergency preparedness and response to cover comprehensively all important aspects consistently with IAEA Safety Standards in emergency preparedness and response including those for:
  (a) Hazard assessment which considers severe accidents of very low probability;
  (b) Transitioning to recovery and for the recovery;
- Establishing and maintaining a capability (e.g. plans and procedures, staffing, training, drills, exercises, equipment, supplies, logistics, etc.) of the regulatory body to fulfil assigned roles in an emergency response;
- Establishment of exercise evaluation criteria and forms to systematically evaluate some of licensee's exercises;
- Establishing inspections plans and checklists to support systematic verification of compliance with the requirements for emergency preparedness and response.

However, several good practices have also been found in this area:

— Studying the effectiveness of the licensees' public awareness programme to find out how the public understands the information on risks and actions to be taken in case of an emergency (United States of America, October 2010);
— Integration of nuclear or radiological emergency preparedness and response in the national structure for coping with all other emergencies (Czech Republic, November 2013);
— The conduct of unannounced exercises at nuclear power plants and their evaluation against specific objectives (France, November 2014);
— Incorporating lessons learned from the Fukushima Daiichi Nuclear Power Plant Accident by updating national requirements for multi-unit accidents and proactively conducting an evaluated multi-unit severe nuclear accident emergency exercise (Hungary, May 2015).

4.6 COMMUNICATION WITH INTERESTED PARTIES

Learning Objective 1: To understand the IAEA guidance on communication with interested parties.

Learning Objective 2: To understand the regulatory body's interested parties and their characteristics.

Learning Objective 3: To understand the difference between information and participation, as well as the various levels of participation.

Learning Objective 4: To understand the key elements of a communication programme.

For some time, it has been known that the public and other interested parties need to be better informed and more involved in decision making processes in the nuclear domain. In addition to requiring that applicants and licensees inform interested parties regarding their plans and activities, the regulatory body must also communicate with interested parties.

The regulatory body role in public communication depends on Member State government practices. In some Member States only necessary information is provided by the regulatory bodies while in other Member States regulatory bodies are as open and communicative as possible and take a more active role. The CNS and the Joint Convention expect the regulatory body to be open and transparent and to arrange for interested party participation.

In undertaking communication activities, the regulatory body must maintain its independence, especially when asked to participate in communications activities involving either proponents or opponents of nuclear energy. However, in most situations, with careful planning the regulatory body can successfully participate in most communications activities.

Early interested party involvement is usually beneficial for the regulatory body. First it is a matter of fairness as it makes it possible for all interested parties to influence the process and to contribute their perspectives at a stage when they still can be incorporated. Second, it provides not only an early warning system for potential conflict situations but also a chance to solve problems early. Third it can ensure that no issue is overlooked.

4.6.1 IAEA requirements and guidance

The main IAEA guidance on communication with interested parties is provided by:

- Fundamental Safety Principles (IAEA Safety Standards Series No. SF-1) [21];
- Governmental, Legal and Regulatory Framework for Safety (IAEA Safety Standards Series No. GSR Part 1 (Rev. 1)) [5];
- Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards (IAEA Safety Standards Series No. GSR Part 3) [70];
- Predisposal Management of Radioactive Waste (IAEA Safety Standards Series No. GSR Part 5) [74];
- TECDOC-1076: Communications on Nuclear, Radiation, Transport and Waste Safety; A Practical Handbook [75].

Fundamental Safety Principle 2 includes the statements that the regulatory body has to:

> "[…] set up appropriate means of informing parties in the vicinity, the public and other interested parties, and the information media about the safety aspects (including health and environmental aspects) of facilities and activities and about regulatory processes".

And:

> "[…] consult parties in the vicinity, the public and other interested parties, as appropriate, in an open and inclusive process".

GSR Part 1 (Rev. 1) Requirement 21 states:

> "The regulatory body shall establish formal and informal mechanisms of communication with licensees on all safety related issues, conducting a professional and constructive liaison" [5].

GSR Part 1 (Rev. 1) Requirement 27 includes the statement that the regulatory body must provide feedback to licensees on results of inspections [5].

GSR Part 1 (Rev. 1) Requirement 34 states that the regulatory body must inform interested parties about regulations and guides [5].

GSR Part 1 (Rev. 1) Requirement 36 states:

> "[…] the regulatory body, in its public informational activities and consultation, shall set up appropriate means of informing interested parties, the public and the news media about the radiation risks associated with facilities and activities, the requirements for protection of people and the environment, and the processes of the regulatory body. In particular, there shall be consultation by means of an open and inclusive process with interested parties residing in the vicinity of authorized facilities and activities" [5].

GSR Part 3 Requirement 3 states:

> "[…] the regulatory body shall establish a regulatory system for protection and safety that includes provisions of information to, and consultation with, parties affected by its decisions and, as appropriate, the public and other interested parties" [70].

GSR Part 5 Requirement 3 states:

> "[…] the regulatory body has to encourage dialogue between and participate in dialogues with the operator and other interested parties" [74].

And:

> "[…] the regulatory body must establish a mechanism by means of which information on incidents significant to safety is disseminated to interested parties" [74].

The IAEA published TECDOC-1076 in 1999 to provide practical guidance for regulatory bodies when communicating with interested parties [75].

4.6.2 Research and studies into communication

The need for establishing and improving public participation processes has led to many studies around the world, including those relevant to regulatory bodies below.

4.6.2.1 ENEF Working Group on Information and Transparency

The ENEF (European Nuclear Energy Forum) established a Working Group on Information and Transparency in November 2007. The working group is dedicated to establishing a roadmap for better information and transparency in the nuclear field, developing an appropriate consultative process and initiating structured interested party dialogues. The working group has developed the following recommendations regarding participation:

- Governments should establish an effective legal and/or institutional framework for public participation, especially defining the rights and responsibilities of individuals and organizations to create a level playing field;
- Information about the public participation process should be known before the process starts and participation should be continuously evaluated throughout the process. A stepwise procedure may be an effective approach;
- Key elements of an open and transparent public participation process are:
  - The process of public participation should be initiated as early as possible;
  - All options should be open until the participation process comes to a conclusion while recognizing that a decision cannot be allowed to be postponed indefinitely;
  - Whenever a public participation process is initiated, it should be made clear what its purpose is and at what point it takes place in the decision making process;
- A good participation process would be based on:
  - Shared language and understanding, with a view to collective learning;
  - Respect and value for the expression of different perspectives;
  - Ensuring regular feedback to those who contributed;
- Financial resources could be made available to enable effective public participation. Some funding could be made available to civil society organizations, local committees or similar structures, with a view to acquiring additional expertise. The decision to allocate financial support and its amount should be based on clear and publicly known set of criteria;
- Cooperation between host and neighbouring communities should be encouraged.

4.6.2.2 The PIPNA report

In 2012, Baudé, Hériard-Dubreuil, Réaud and Schneider published the Public Information and Participation in Nuclear Activities (PIPNA) report [76], which included the following basic principles:

- Provide a safe space for discussion;
- Give access of civil society to expertise to encourage their engagement in the process while developing their own understanding of the issues at stake and preserving their autonomy;

- Have flexibility in the design of the dialogue process to give opportunity to the interested parties to adapt the dialogue process to their needs and constraints;
- Organize the power sharing within the dialogue process;
- Develop the inclusiveness of the process to encourage the participation of all interested parties;
- Ensure the independence of the dialogue process;
- Ensure the responsiveness of decision makers engaged in the process;
- Develop a collective learning process in which every engaged person and/or organization can learn from others;
- Allow the participants to reframe the issues at stake;
- Ensure the accountability of the initiator of the process;
- Ensure the availability of adequate resources for supporting stakeholder engagement;
- Enable the participants to exert some reflexivity over the process itself, by assessing its quality on the course of the process to adapt it to emerging needs.

4.6.2.3 Resources for the future

Beierle and Cayford [77] reviewed public participation processes in the USA, identifying five social goals in their review:

- Incorporating public values into decisions;
- Improving the substantive quality of decisions;
- Resolving conflict among competing interests;
- Building trust in institutions;
- Educating and informing the public.

The review evaluated 239 cases spanning over 30 years and grouped participation mechanisms into four main types: 1) public meetings and hearings; 2) advisory committees not seeking consensus; 3) advisory committees seeking consensus; and 4) negotiations and mediations. Among the five social goals "educating and informing the public" was the easiest to achieve, while "building trust" was the most difficult. The report concludes that processes with more intensive mechanisms and processes where agencies are responsive to interested parties are more likely to be successful.

4.6.2.4 Institute of Food Research

In Europe, the UK has been one of the leading countries in the area of research driven public participation, in particular on the issues in food safety and biotechnology. Rowe and Frewer [78] of the Institute of Food Research presented nine criteria for the evaluation of processes: representativeness (participants should comprise a representative sample of the population); independence; early involvement; influence; transparency; resource accessibility (participants should have adequate resources for their participation); task definition (a clearly defined process); structured decision making; and cost effectiveness.

4.6.2.5 The IPPA project

In the first IPPA Knowledge Base report overarching principles for good public participation processes are given:

- Legitimacy of the process and of the decisions;
- Clarity of the level of influence the public have in the process;
- Following the aim of fairness so that all parties and the public in a broader sense benefit from the cooperation;
- Ensuring transparency of the process;
- Enhancing quality of decision making;
- Supporting positive economic, ecological and societal development of the region affected by the planned measures/installations;
- Accompanying evaluation of the process.

The report also gives principles of the organizational framework within which the processes take place:

- A supporting national policy and framework setting;
- Strong interaction between the national and the regional governance level;
- Institutionalized cooperation based on an agreed target and common understanding of perspectives and goals amongst all the actors;
- A regular working practice assuring the integration of all relevant interested parties with clear accountabilities;
- Inclusive working methods assuring integration of all relevant issues;
- Professional coordination of the whole process (e.g. by an institution or an intermediary) ensuring focusing on the issue and transfer of results;
- Sufficient resources (finances, personnel, knowledge, time) for all necessary activities and all stakeholder groups;
- Integration of the public participation process into the formal decision making procedure;
- Transparent roles and responsibilities of all actors in general and a clear definition of the specific interested parties' roles in the decision making process.

4.6.3 Regulatory body interested parties

A regulatory body will have several interested parties, each with its own needs and expectations. Based on these needs and expectations, the regulatory body must choose from a range of communication strategies and approaches.

4.6.3.1 General public

The regulatory body works on behalf of the general public ensuring that the peaceful uses of nuclear energy and materials do not pose undue risk to health, safety security or the environment. Accordingly, the majority of the regulatory body's communication effort should be directed to the public. The general public is made up of many subgroups and the regulatory body will need to deal with these subgroups differently. The needs of the public living near a nuclear installation will be different from the needs of the public living elsewhere. Different approaches will be necessary for children and teenagers than for adults.

Members of the public rely on various sources of information, including the internet, television and the media. The regulatory body must always keep in mind the needs of the public and ensure that its communications are written in clear language. The regulatory body

must also establish an efficient process for answering questions from the public. Some regulatory bodies hold meetings in the vicinity of nuclear installations to allow for local public participation.

A public outreach programme is necessary and should include providing materials for classrooms, news media and persons living near nuclear installations. The public should always be informed when the regulatory body is considering a major regulatory decision, and all major regulatory decisions should be published.

Radiation accidents can have significant consequences for members of the public and the regulatory body has a responsibility to keep the public informed.

4.6.3.2 Government representatives

Government representatives serve the public interest and need to understand the regulatory body's perspective in order to achieve an acceptable balanced policy position and will appreciate clear and concise publications that make specific points in unambiguous terms. The communication of nuclear safety with governmental representatives and legislators will facilitate decisions such as those related to the approval of adequate budget and organizational infrastructure for nuclear safety and improves relationships and coordination of joint activities.

4.6.3.3 The news media

The news media is an important source of information for the public. Although some studies have shown that the public believes the news media often confuse the facts, the public also believes that the media play an important role in keeping government and industry accountable. Most reporters, like the average citizen, do not have much knowledge of nuclear matters. While some reporters are willing to listen to all sides of an issue, others are advocates for a particular point of view.

Because the news media work on a news cycle, they need to have quick access to information and to high level spokespersons from a regulatory body, especially in emergencies. Editors and publishers are also very influential in deciding what information is published and setting the balance of an article. It is important to remember that editors and publishers prepare the headlines and decide the placement of articles, not the reporters.

The regulatory body should establish working relationships with both the national media and media located near nuclear installations. The regulatory body can provide background material, training seminars and access to senior regulatory body staff on an ongoing basis, which will provide a solid foundation should an urgent situation require information.

4.6.3.4 Special and public interest groups

Special and public interest groups are linked to particular constituencies that are often motivated to achieve specific goals. Special groups include organizations with specific interests, which are often tied to their livelihoods or to a shared demographic characteristic. Public interest groups are those which claim to represent some aspect of the public interest and usually have a membership as evidence of their legitimacy. They include consumer and environmental groups and groups opposed to nuclear energy. Labour and trade unions are another key audience with whom it may be necessary to communicate. Environmental groups

and antinuclear groups may be very useful in pointing out deficiencies, however must be provided with factual information to help avoid misconceptions.

4.6.3.5 Applicants and licensees

Applicants and licensees are also interested parties and the regulatory body's communication strategy must ensure that they are included in any communication efforts, but do not receive preferential treatment. It is important that the regulatory body's communications are seen to be independent of applicant or licensee programmes.

4.6.3.6 Professional categories

Medical and health professionals are among the most credible sources of information to the public. The information from the regulatory body to medical and health professionals may be more effective when it is provided in a newsletter format in which each edition explains a specific issue. Booklets containing basic information about exposure to radiation and its effects could be prepared and distributed among medical personnel. Informative material about diagnostic and therapeutic applications of radiation can be provided via medical associations and medical journals. An increased level of knowledge on the part of medical personnel in these areas will help to establish and maintain greater public awareness and confidence.

The regulatory body needs to play a part in the dissemination of information to professionals in the nuclear industry and other industries using radiation sources or using and/or processing radioactive materials. This should cover information on new developments relating to safety, lessons learned from accidents, new regulatory issues and other topics that could be of interest to those professionals.

Academics and researchers in the nuclear field and third party experts who are not involved in the commercial uses of nuclear technologies or with regulatory activities provide information to the news media and to the public and are often considered to be neutral experts. The regulatory body should consider establishing a working relationship with this audience, perhaps through professional associations and societies.

4.6.3.7 Academics and teachers outside the nuclear community

To understand and address the concerns of the scientific community and civil society, regulatory bodies should consult broadly and work with universities and colleges, non-governmental organizations and professional organizations and societies to exchange information, increase awareness of the work of the regulatory body and remain up to date on scientific and technical developments.

Academics and teachers who are not from the nuclear community are an important source of training and information for young people and the regulatory body should provide them with up to date and factual information on nuclear issues. The regulatory body's website with an interactive area dedicated to teachers and students can be very effective. Science classes at the elementary or secondary level of education are a natural setting for the regulatory body to provide unbiased and factual information on nuclear and radiation safety.

The regulatory body should also consider specific seminars for elementary or secondary school science teachers. Teachers can be introduced to educational materials for radiation safety that can be used to teach radiation safety to their students.

4.6.3.8 International organizations and national regulatory bodies

Regulatory bodies should establish links with other national regulatory agencies and international organizations such as the IAEA, OECD/NEA, UNSCEAR and WHO. It is beneficial to ensure the free flow of safety related information with these agencies on a regular basis.

4.6.3.9 Staff from the regulatory body (internal communications)

It is important to keep regulatory body staff informed of key regulatory activities and decisions and information about nuclear and radiation safety. Staff must also know how to respond to a request for information. Staff responsible for responding to interested party requests must also be trained and have access to up to date information.

4.6.4 Information versus participation

In some cases, the regulatory body simply needs to inform interested parties, while in other cases the regulatory body will want interested parties to participate in the regulatory process. It must be clear what interested parties can expect and what they cannot expect, especially with respect to influence. Setting the rules of the game at the outset is necessary so that the regulatory body does not create expectations that cannot be fulfilled.

4.6.4.1 Informing interested parties

The regulatory body should routinely provide interested parties with as much objective, scientific, technical and regulatory information as possible concerning its activities and the safety, including the radioactive risks, of the installations it regulates. This includes legal and regulatory requirements, review and assessment conclusions, inspection programme, inspection findings and regulatory decisions. The regulatory body may also inform interested parties on its strategy plan, policies and management system.

The regulatory body should also provide interested parties with information regarding events. The OECD/NEA and IAEA jointly manage the INES, discussed in Appendix IV, which regulatory bodies can use for promptly and consistently informing interested parties of the safety significance of events. The INES is discussed in Appendix IV.

The regulatory body should have a process and procedures for responding to requests for information from interested parties. Any information provided must be understandable, reliable, factual, accessible and provided in a timely manner. The regulatory body should be scrupulous in providing information, neither overstating nor understating the significance of the communicated information. Plain language should be used without adversely affecting the quality of the information. Special attention should be taken to avoid inconsistency of information delivered over time. Background information and key messages should be developed to support consistency over time.

The regulatory body should ensure that documents created by its staff are developed and issued without improper influence, real or perceived, from special interested parties such as licensees.

Information channels should be tailored and combined to ensure the intended audiences receive the information. Some information channels, such as websites, press releases and interviews by journalists, are intended for a wide audience, while others, such as speeches,

mailings or meetings, target a specific interested party. In some cases, such as the website or publications, the regulatory body has control over the information channel, while in other cases, such as internet forums or interviews, the regulatory body does not always have control. The communication channels used must suit the intended audience and most communications will probably require more than one channel.

Different types of printed materials may be used to provide information such as information sheets, leaflets and brochures. Most regulatory bodies are required to produce a periodic (usually annual) report on its activities and many regulatory bodies have expanded these reports to inform interested parties about nuclear and radiological safety.

Most, if not all, regulatory bodies have established a website, which is a very effective channel of communication. Information published on the website is widely available and, if the website is updated frequently, the information will always be current. The website can also provide for some feedback from interested parties. Every document published by the regulatory body should be available on its website. To be effective, the website must be user-friendly and properly maintained. In most cases, this will require the assistance of experts in website design.

Many regulatory bodies have established restricted websites to facilitate information exchange with particular interested parties, usually applicants and licensees.

Obviously, not all information the regulatory body has can be made available to the public. Member State laws may limit the amount of information a regulatory body can release. In addition, information of a sensitive nature, such as proprietary or security information, must remain confidential. As long as the regulatory body explains itself properly, interested parties generally understand that not all information can be made available.

4.6.4.2 Participation of interested parties

Type of interested party participation

Unlike informing, where the regulatory body makes information available to interested parties, with participation, the regulatory body engages interested parties. There are three different levels of participation:

- Consultation: interested parties are invited to comment—usually on a regulatory body proposal—before regulatory decisions are made;
- Dialogue: the regulatory body actively seeks out and engages an interested party (or parties) in a conversation;
- Collaboration: the regulatory body and the interested party (or parties) work together to develop a product or a solution.

The three levels are not mutually exclusive and a regulatory body may end up using all three on one issue.

There are many reasons why a regulatory body requires participation from interested parties. First and foremost, participation is an important component of transparency and openness. Participation can also result in better, more accepted decisions if it is undertaken at the appropriate time. In some cases, the regulatory body is required by law to undertake participation activities with interested parties.

Participation also results in increased expectations from interested parties. From the outset, the regulatory body must make purpose of the consultation clear and must be prepared to act on the results of the participation. In all cases, the regulatory body must ensure that the time allotted for participation is adequate.

In some cases, it may be appropriate to ask a professional and impartial facilitator to organize the participation activity. They can bring state of the art ideas and methods to make the process more effective and provide a neutral perspective which can improve mutual understanding. In some cases, foreign expertise can be useful in bringing a broader perspective to the issue.

Some regulatory bodies provide funding for interested party participation.

Consultation

The regulatory body should consult with interested parties before finalizing regulations, establishing regulatory requirements or issuing nuclear installation licences. Many Member States have established legal requirements for regulatory bodies to consult interested parties in various circumstances.

Although many communication channels can be used for consultation, the regulatory body's website, targeted mailing lists and meetings are particularly effective. In the case of meetings, it is important that all participants understand their responsibilities and the meeting must be well organized.

Every consultation should consider the following:

- Equitable treatment of all interested parties;
- Clarification of consultation objectives;
- Identification of targeted interested parties;
- Identification of applicable legal and regulatory requirements;
- Planning and timeframes that are sufficient and adapted to the interested parties;
- Preparation and availability of all relevant documents well in advance;
- Establishment of consultation mechanisms and tools and for interested parties to comment directly or through representative consultative bodies;
- Announcement of meetings and hearings well in advance;
- Arrangements for the review and assessment of consultations and the publication of consultation results;
- Provisions to consider the result in the decision making process.

Dialogue

In some cases, it is not sufficient to just consult with interested parties. The regulatory body may need or want to have an in-depth understanding of the interested party's perspective or the regulatory body may need the interested party input before it can come to a decision. This is particularly true where the regulatory body has the possibility of deciding between two or more equally effective alternatives. For a dialogue, the regulatory body must actively seek out interested parties and encourage their participation. The goal of dialogue may not be

consensus, but at the conclusion, every participating interested party must believe it had the opportunity to give, express and discuss its positions and views.

The regulatory body must establish an atmosphere of trust for effective dialogue and must not have any hidden agenda. It must also create a safe space where participants will believe they can speak openly and as an equal. Meetings, whether conducted as workshops, seminars or working groups, are the only practical communication channel for dialogue. These meetings do not need to be face-to-face, but only meetings provide the atmosphere necessary for dialogue. As with consultation, participants must have timely access to all necessary and available information.

Sometimes interested parties have blocked positions at an early stage which makes it difficult to establish a fruitful two way dialogue. It is then important to establish working formats, such as safe space already mentioned above, that allow all interested parties to participate in the dialogue without further positioning themselves. Different options exist to establish a safe space: it may be a meeting; a more structured event like hearings tailored for the purpose of clarification of issues and arguments; seminars; workshops; etc. According to the complexity or sensitivity of the issue, the process may take time and it may be may needed to organize a series of events where interested parties can influence the agendas. To give the process a better chance of success, specified arrangements should be agreed to and followed by participants. These arrangements may include scheduling, venues, discussion management, facilitation methods and reporting of the discussion. A reference group with broad representation, based on a formal agreement between the participating interested parties, may also enhance the credibility of the process itself. The involvement of external resources (professional organizers, mediators, facilitators, foreign experts, etc.) could be considered to help implementing fruitful dialogues.

Collaboration

Collaboration takes participation further and interested parties become partners in the regulatory process, working side by side with the regulatory body to explore potential solutions and perhaps even taking a role in the decision making. In doing so, the regulatory body gives up some control over the process in return for the potential for a better product and higher acceptance from interested parties. Collaboration is only appropriate where the regulatory body has not decided on a particular solution.

Prior to undertaking a collaboration process, the regulatory body must decide on the scope, objective, potential participants and a time scale for the collaboration. Many of the techniques used in dialogue are also appropriate for collaboration, including the use of a third party, neutral facilitator. The collaboration process may start with a small task group of representatives of the interested parties to produce draft discussion items for a larger group to then consider and develop into proposals.

4.6.5 Getting started with a communication programme

The regulatory body executive team should include a Chief Information Officer with the responsibility of ensuring that communications with all interested parties are effective. History has shown that not considering communications at a strategic level can have disastrous effects in times of crisis.

Senior management of the regulatory body must be committed to implementing an open and transparent communication programme. This implementation should be based on proactive

communications, a willingness to listen and genuine public participation in regulatory activities.

If regulatory responsibilities are divided between various organizations, effective arrangements need to be made to ensure that communication activities are coordinated to provide coherent information and to avoid contradictory information being disseminated.

As with any other specialty, communications is a field that requires specific knowledge, skills and attitudes developed through training and experience. The regulatory body should include trained communications experts who work in consultation with nuclear and radiation safety experts. This does not mean that all communication must be done by communication experts. Technical experts can be provided with training in communications, and some audiences will appreciate having technical experts explain regulatory body activities.

Before initiating any communication process, the regulatory body must identify the legal and regulatory requirements applicable to the disclosure of information and develop a communications strategy for interaction with its interested parties. It is critical to be clear about the role and functions of the regulatory body, its independence, and its strategy to interact with interested parties. Transparency and openness should form the basis for all communication and consultation activities.

To develop a comprehensive communication programme, five elements are needed:

— Clearly stated communications objectives;
— Identification of the various interested parties;
— Identification of the needs of the various interested parties;
— A communications plan for each interested party that includes goals, information development, communication mechanisms and schedules;
— An evaluation plan for continuous improvement.
— Figure 28 shows the flowchart of the process.

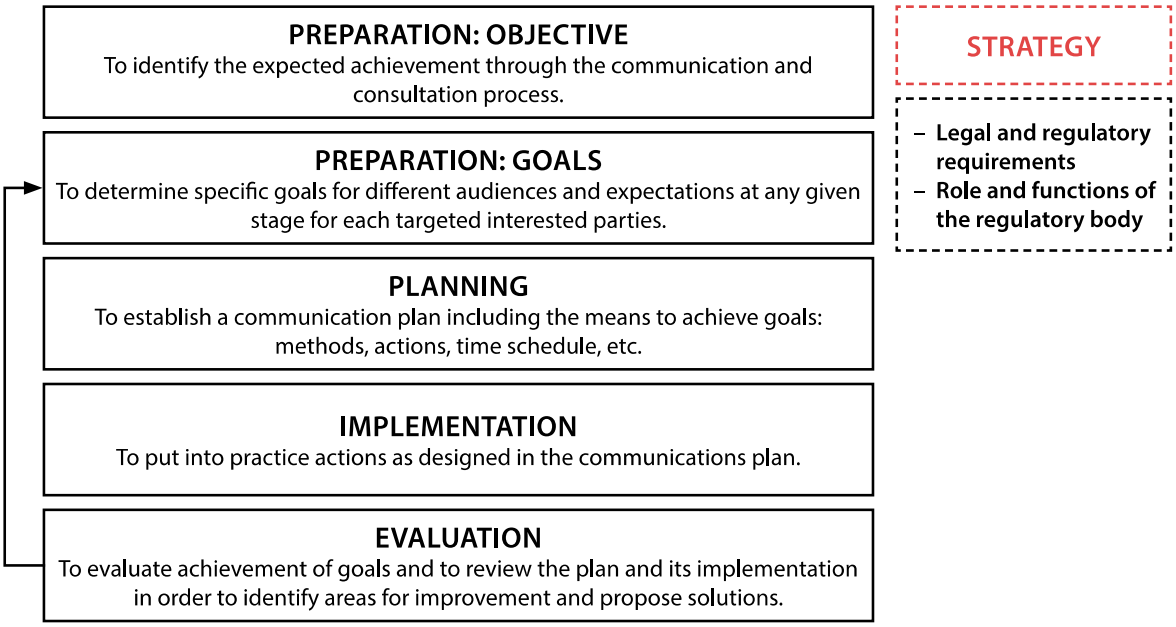


FIG. 28. Communication and consultation process.

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4.6.5.1 Preparation

The overall objective of the communication and consultation process should be established using rationales for independence, accountability, credibility and legitimacy, high quality in decision making and regulatory control stability. One objective of the communication plan is to increase public trust and confidence by keeping interested parties informed in a transparent and open manner on how safety requirements are established and enforced.

The goals of the plan should allow the regulatory body to, among other things:

- Disseminate information on safety to interested parties, including: information about abnormal occurrences and accidents; risks associated with nuclear installations; regulatory requirements; regulatory processes; and regulatory judgments and decisions;
- Involve interested parties in decision making;
- Improve cooperation and coordination with other authorities and governmental organizations;
- Improve cooperation with other Member States and with international organizations.

4.6.5.2 Planning

The communication process needs to be flexible enough so that specific communication plans can be tailored to specific interested parties and use a variety of communications tools, methodologies and subject matter expertise.

The regulatory body will require several communication plans for various purposes, such as specific regulatory projects, routine situations and incidents and emergencies. These communication plans must be coordinated to optimize the use of financial and human resources and to ensure coherence and consistency among plans.

Each communication plan should include the specific objectives and goals, appropriate timing to engage interested parties, the list of interested parties to be reached, their concerns, expectations and perspectives and channels and tools to communicate and consult with them. Responsibilities and prioritizations should be also addressed.

It is important when developing a communication plan to identify all possible groups that could be affected by or interested in the issue. These groups may have conflicting agendas, priorities, needs and expectations, all of which should be accounted for by the communication plan. Specific attention should be given to people residing in the vicinity of existing or potential installations. Should the composition and nature of these groups change over time, the communication plan may need to be amended.

Some interested parties will require only information, while others may expect or demand active participation and consultation. Some may merely want an opportunity to express their views. Others, particularly some non-governmental organizations, may be reluctant to participate fully in the consultation to preserve their independence and autonomy. All types should be considered when developing a communications plan.

4.6.5.3 Implementation

Implementation of a communication plan should be coordinated with senior management and communication staff of the regulatory body and with other governmental organizations if necessary. All persons involved should understand the purposes of the plan, their functions and responsibilities and how various organizations will interact. Necessary training for the proper plan implementation should be carried out. Regular meetings should review the plan's progress, identifying any difficulties with implementation and making any necessary adjustments. Communication plans should be flexible. For example, if an event of public interest or an accident occurs, the regulatory body may need to suspend implementation of a routine communication plan temporarily to deal with the immediate issue. Events may also necessitate amending a communication plan's schedule or key messages as the regulatory body's priorities change.

4.6.5.4 Evaluation

As with any programme, the regulatory body must periodically evaluate the effectiveness of the communication programme. Some evaluation methods include:

- Surveys and questionnaires for interested parties. These can be done on a random basis or systematically following interactions with the regulatory body;
- Research on public opinion can be a useful tool to identify gaps in communication or to determine the effectiveness of the regulatory body in communicating with the public. Reliable data can be collected using scientifically proven methods of research on public opinion;
- Face to face communication with a small group selected to represent pertinent points of view, although not as wide ranging as a public opinion poll, may provide valuable information for feedback to the communication programme;
- Identification of lessons learned from implementation of the programme;
- Peer reviews by communicators from other regulatory bodies or other organizations which have similar communication needs and programmes;
- Review of media coverage of nuclear issues can also be instructive in determining where communications have been unclear.

4.6.6 Regulatory body participation as an interested party

The regulatory body may also be asked to participate in an activity organized by another party, such as a licensee, a local government or a non-governmental organization. In these cases, the regulatory body must exercise caution so that it maintains its independence. The regulatory body should provide information related to its mandate and regulatory requirements, but must be careful when participating in any activity where it will eventually be required to make a regulatory decision. For example, if an applicant chooses to have a collaboration process with interested parties regarding site selection, the regulatory body may accept an invitation to provide information on its role and requirements for site selection, but should not participate in the collaboration process.

Experience has shown that the regulatory body can participate in activities organized by local governments to raise awareness of complex issues.

APPENDIX I. BACKGROUND INFORMATION ON THE CONVENTION ON NUCLEAR SAFETY (CNS)

I.1. HISTORY OF THE CNS

The CNS [6] was adopted on 17 June 1994 by a diplomatic conference convened by the IAEA Director General at its Headquarters from 14 to 17 June 1994. The CNS was opened for signature on 20 September 1994 during the 38th regular session of the IAEA General Conference and entered into force on 24 October 1996. As of November 2014, there were 77 Contracting Parties to the CNS and ten signatory countries which have not yet ratified the CNS. After 18 years of use, the CNS has reached a level of maturity, although a substantial revision is planned in light of the Fukushima Daiichi accident.

The Three Mile Island and Chernobyl accidents fundamentally changed the perception of nuclear safety in governments, regulatory bodies, NPP licensees and the public. The potential transboundary impacts of a nuclear accident led many governments to urge adoption an international legal instrument to codify basic measures that Member States should follow to ensure an appropriate level of safety at their nuclear installations. Immediately following the Chernobyl accident, a number of Member States called for negotiation of a nuclear safety convention. At that time there was insufficient political will to go forward and the initiative languished for several years.

In September 1991, the General Conference of the IAEA adopted a resolution requesting the Director General to establish an informal, open-ended working group to develop the text of a safety convention. The terms "informal" and "open-ended" meant that the convention text would be developed by a body comprised of safety experts rather than governmental representatives. The work of the expert group was not a formal diplomatic negotiation, but an extended technical and legal process conducted in nine meetings over a three year period. This approach permitted consultations on the text to be quite flexible.

The working document for the nuclear safety convention was the set of IAEA Safety Fundamentals, which reflected a consensus of technical experts developed over the previous years. The Safety Fundamentals at the time encompassed nuclear safety, radiation safety, waste management safety and transport safety[91]. The fundamental task of the working group was to convert the non-binding principles in these documents into provisions that Member States would be willing to accept under international nuclear law. This process obviously involved many compromises and reformulations.

In June 1994 a diplomatic conference was convened to enable accredited government representatives to produce the CNS. The month-long conference considered a wide range of controversial issues and on 17 June 1994 was able to adopt a consensus text.

Some delegations wanted to have the CNS including a provision that would have adopted IAEA Safety Standards as international law requirements. However, most delegations were not willing to give a binding legal effect to principles developed as voluntary guidelines. Delegates did agree that the CNS should recognize the value of IAEA Safety Standards in achieving safety:

[91] These Safety Fundamental have now been integrated in SF-1.

> "…recognizing that this CNS entails a commitment to the application of fundamental safety principles for nuclear installations rather than of detailed safety standards, and that there are internationally formulated safety guidelines which are updated from time to time and so can provide guidance on contemporary means of achieving a high level of safety" [6].

Paragraph (iv) of the preamble states the desire of the Contracting Parties to promote an effective nuclear safety culture. The Contracting Parties recognized the difficulties in introducing the concept as a specific international law obligation but felt the need to promote the concept in the CNS preamble.

Paragraph (v) recognizes that accidents at NPPs have the potential for transboundary impacts.

Paragraph (viii) describes the relationship of IAEA fundamental safety principles with the obligations contained in the CNS. Paragraph (viii) recognizes another important aspect of nuclear safety; namely, that technical and management approaches evolve over time. One of the concerns expressed in negotiating the CNS was how the instrument could codify standards or rules, but do so in a way that would enable them to adjust to change. The CNS acknowledges this issue by stating the view that practical implementation of the CNS can benefit from referring to the evolving body of internationally formulated standards.

Chapter 1, Objectives, definitions and scope of application, includes an article for each of the issues in the title. Article 1, Objectives of the CNS, identifies the following three objectives:

- To achieve and maintain a high level of nuclear safety worldwide through the enhancement of national measures and international cooperation including, where appropriate, safety related technical cooperation;
- To establish and maintain effective defences in nuclear installations against potential radiological hazards in order to protect individuals, society and the environment from harmful effects of ionizing radiation from such installations;
- To prevent accidents with radiological consequences and to mitigate such consequences should they occur.

Many delegations sought a broad scope of coverage to include research and test reactors, fuel cycle facilities, nuclear waste management and even military activities. It was finally decided that the primary focus should be on NPPs since they posed the greatest risk of major injury (including transboundary damage) and since a clearer consensus had been developed on fundamental safety elements for NPPs. The CNS does cover storage, handling and treatment facilities for radioactive materials that are on the same site and directly related to the operation of the NPP.

Article 6 was the most contentious provision in the CNS and deals with the issue that created the political pressure to negotiate the CNS; how to ensure the safety of NPPs constructed to earlier standards. Although this article covers all NPPs in operation at the time the CNS entered into force, its real focus was NPPs constructed without full application of current defence in depth principles. The primary debate was on what actions Contracting Parties should take regarding NPPs that lack modern safety features. The final text of the CNS does not provide any precise guidance on whether a particular NPP should be shut down. However, the presence of Article 6 means that Contracting Parties must include information on their reviews of existing NPPs in their national reports and must justify any decision to continue to operate NPPs that do not meet current safety standards.

The issue of confidentiality arose during the CNS negotiations. Many delegations stated that, unless national reports were made public and the review process was conducted openly, the CNS would not increase public confidence in the safety of NPPs. Other delegations stated that a public review process would be a disincentive for Contracting Parties to be candid about problems they might be experiencing. The final text of the CNS allows Contracting Parties to submit confidential reports and that the debates during the review of reports would be confidential. To date, no Contracting Party has submitted a confidential national report. The discussions in Member State groups and plenary debates continue to be confidential, with only the summary report under Article 25 made public.

Article 26 recognizes that all official UN languages are equal, with the provision that the Contracting Parties could adopt—under the rules of procedure—one or more working languages. In practice, most of the sessions have been conducted in English with some sessions having simultaneous Russian interpretation.

Under the rules of procedure, an oral report by a rapporteur from each country group is made at the final plenary meeting. These oral reports were to provide the basis for the written summary report stipulated in Article 25. Contracting Parties decided that the IAEA would keep, as permanent records, the notes the rapporteurs use to prepare these oral reports.

I.2. CNS REVIEW MEETINGS

I.2.1. 1st review meeting (12–23 April 1999)

The conduct of the 1st Review Meeting was itself a test to prove the validity of the CNS procedures. In general, it was concluded that the process was successful. It also became clear that the Contracting Parties reconfirmed their commitment to the objectives and obligations of the CNS and recognized the need to achieve a high level of safety in all NPPs in all Contracting Parties.

The Review Meeting was attended by 45 Contracting Parties. Except for three non-nuclear power countries, all Contracting Parties met their fundamental obligations to prepare national reports and to be represented at the meeting. These national reports, most of which were made public, represented a useful statement of the status of nuclear safety worldwide. They also provided a baseline for future assessment of whether levels of nuclear safety in any particular Member State, or generally, are being raised or are deteriorating.

The final summary report prepared by the President and agreed by consensus contains some observations on matters important to enhancing nuclear safety. Some of the most notable were:

- The legislative framework is well established in most Contracting Parties;
- Some Contracting Parties that started their nuclear programmes some decades ago have found that their legislation now needs updating;
- All Contracting Parties had established regulatory bodies. For some Contracting Parties, questions were raised as to the effective independence, administrative position and the human and financial resources of their regulatory bodies;
- Advantages and limitations of regulations of a detailed prescriptive nature as compared to less prescriptive, goal oriented approaches and the complementary use of risk based assessments were discussed.

I.2.2. 2nd Review Meeting (15-26 April 2002)

An organizational meeting conducted in September 2001 decided to make only very modest adjustments to the process used for the 1st Review Meeting. The conflict of interest problem raised at the 1st Review Meeting, where, in a few instances, country group chairs or rapporteurs took decisions concerning the safety record of their own country was corrected.

The President's report for the 2nd Review Meeting confirmed the general validity of the CNS process and the commitments of the Contracting Parties. It noted significant improvements since the 1st Review Meeting in the areas of legislation, regulatory independence, financial resources for regulatory bodies and NPP operators, implementation of safety improvements in NPPs built to earlier safety standards and emergency preparedness. The Review Meeting also identified areas for improvements including the new concepts of safety management and safety culture, NPP ageing and upgrading; maintaining competence and effectiveness of regulatory practices.

I.2.3. 3rd Review Meeting (11-22 April 2005)

The President's report for the 3rd Review Meeting concluded that most Contracting Parties have already achieved the objectives of the CNS and that it was necessary to shift towards more thematic subjects. Among issues that were discussed was the possible role of the CNS with regards to research reactors and a request was formulated to the IAEA Director General to convene meetings with Member States to discuss how best to assure the effective application of the *Code of Conduct on the Safety of Research Reactors*[92]. The 3rd Review Meeting also noted the positive contributions of international organizations and regulatory bodies to the international safety culture. It was noted that safety initiatives in international organizations such as the IAEA, as well as safety and peer review processes, have helped improve overall safety culture.

I.2.4. 4th Review Meeting (14-25 April 2008)

The President's report for the 4th Review Meeting identifies new thematic issues, including: independence of the regulatory body; safety management and safety culture; staffing and competence; probabilistic safety assessment; PSR; ageing management and life extension; emergency management; and new NPPs.

It was noted that in some Contracting Parties the independence of the regulatory body was not complete, despite the fact that the issue has been discussed since the 1st Review Meeting, and it was decided that it required further attention. It was noted that safety management, as promoted by *GS-R-3: Management System for Facilities and Activities* [29], had been put into practice in most Contracting Parties.

It was noted that many Contracting Parties have introduced in their national regulations the concept of PSR promoted by *NS-G-2.10: Periodic Safety Review of Nuclear Power Plants*. It was considered that PSR and ageing management were matters of concern needing technical cooperation among the Contracting Parties. Emergency management became a matter of extraordinary concern mainly in those Contracting Parties without NPPs but with NPPs close to their border.

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[92] Approved by the IAEA General Conference in 2004.

I.2.5. 5th Review Meeting (4-14 April 2011)

The 5th Review Meeting was held shortly after the Fukushima Daiichi accident (which started on 11 March 2011); since the preparation had started a year before, the schedule for the 5th Review Meeting was not changed and the Fukushima Daiichi accident was not formally considered. The Contracting Parties agreed to hold a 2nd Extraordinary Meeting in August 2012 to analyze the impact of the Fukushima Daiichi accident on the CNS and the existing Rules of Procedure and Guidelines. The President's report for the 5th Review Meeting refers to some new developments and concerns related to the regulatory framework, siting of new NPPs, Member States embarking in new nuclear programmes, emergency preparedness and response, operating experience and human and organizational factors. Two completely new subjects arose: cyber security and extreme manmade events such as plane crashes on NPPs.

Although the regulatory framework had considerably improved in all Contracting Parties there were still improvements needed on the independence of some regulatory bodies and a pressing need to increase the human and financial resources to properly cope with new activities. The belief that many Member States will start to build new NPPs raised the issue of their siting and the need to develop new siting requirements based on the IAEA Safety Standards. Managing operating experience feedback was also considered a major issue and both the IRS and the work by WANO and INPO on operating experience were recognized.

I.2.6. 6th Review Meeting (24 March-4 April, 2014)

In his opening remarks the President of the 6th Review Meeting stated his main objectives:

- To allow wide-ranging, animated high-quality discussions, with real commitment by all Contracting Parties, so that it is a true peer review where all learn from the others;
- To improve the mechanisms of the CNS and to strengthen its effectiveness;
- To discuss a common position on the lessons to be learned from the Fukushima Daiichi accident, with a clear statement at the end of the Review Meeting.

In his closing remarks, the President reminded participants that the Review Meeting had taken actions to improve the effectiveness of the CNS peer review process by approving changes to the Guideline documents that will improve consistency in reporting and enhance international cooperation. He also noted the concern of participants that although all Contracting Parties with operating NPPs produced a national report and participated in the Review Meeting, some other Contracting Parties had not.

A decision was taken to organize a diplomatic conference to examine a proposal by the Swiss representatives to amend Article 18 of the CNS. Article 18 requires Contracting Parties to ensure that the design and construction of NPPs, both existing and new, provide defence in depth protection, incorporate proven technologies and allow reliable and safe operation.

The President, representing the sentiments of the participants, was touched with the displacement of people and the land contamination caused by the Fukushima Daiichi accident and invited all regulatory bodies regulators to identify provisions to prevent and mitigate severe accidents with off-site consequences.

I.3. CNS EXTRAORDINARY MEETINGS

I.3.1. 1st Extraordinary Meeting

At the 4th Review Meeting Contracting Parties decided to hold an extraordinary meeting in conjunction with the Organizational Meeting for the 5th Review Meeting to discuss and agree on the changes to the Rules of Procedure and Guidelines.

Contracting Parties established the Working Party on National Reports, which, with IAEA assistance, produced a draft revised version of the Guidelines. This draft was discussed and modified by Contracting Parties and approved as INFCIRC/572/Rev.3. At the same time, for consistency, INFCIRC/571 Guidelines regarding the Review Process under the CNS was updated to INFCIRC/571/Rev.3, and INFCIRC/573 CNS Rules of Procedures and Financial Rules was updated to INFCIRC/573/Rev.3.

I.3.2. The 2nd Extraordinary Meeting

The 2nd Extraordinary Meeting of the CNS was held from 27 to 31 August 2012 to review and discuss lessons learned so far from the Fukushima Daiichi accident and to review the effectiveness of the provisions of the CNS. The Contracting Parties recognized that these objectives must be accomplished in addition to meeting the ongoing safety obligations for currently operating NPPs.

The Contracting Parties discussed six topical areas: (1) external events; (2) design issues; (3) severe accident management and on-site recovery; (4) national organizations; (5) emergency preparedness and response and post-accident off site management; and (6) international cooperation.

The Contracting Parties also addressed ways to enhance the effectiveness of the CNS. A working group open to all Contracting Parties was established with the task of reporting to the next Review Meeting on a list of actions to strengthen the CNS and on proposals to amend the CNS where necessary. Several relevant conclusions came from the Extraordinary Meeting, including:

- Contracting Parties have undertaken comprehensive reassessments of natural hazards, including earthquake and floods, to identify measures to improve nuclear safety based on the lessons learned from the Fukushima Daiichi accident. The Contracting Parties remain committed to take any follow-up and additional actions needed, to enhance the ability of NPPs to withstand natural hazards;
- Improvements to NPP design, procedures and processes have been implemented, are in progress or will appear in the future as further information and analysis emerge from the accident, which will take several years. Although Contracting Parties used various methods of review, these reviews all reached similar conclusions. Thus, many safety enhancements being implemented are common to many Contracting Parties;
- Contracting Parties agreed that on and off-site emergency preparedness and response should be enhanced to ensure the public is adequately protected from all events, including severe accidents. The displacement of people and the land contamination after the Fukushima Daiichi accident calls for all regulatory bodies to identify provisions to prevent, manage and mitigate the potential for severe accidents with off-site consequences;

— Contracting Parties encourage international cooperation through the IAEA and networks of regulators, operators and TSOs to share information on the lessons learned from the Fukushima Daiichi accident;
— Contracting Parties recognize it is important to share information, including predictive tools, on extreme natural hazards at NPPs and to update the relevant IAEA Safety Standards. In addition, communicating the outcome of these assessments in an open and transparent way to the public remains a high priority.

Proposals to further review the Guidelines and the CNS itself were discussed and accepted:

— Contracting Parties discussed the proposals formulated by 11 Contracting Parties[93] to further amend the Rules of Procedure and Guidelines to enhance the effectiveness of the review process and to make national reports more comprehensive;
— Initial proposals to amend the CNS were submitted by two Contracting Parties[94]. A set of 15 action oriented objectives for strengthening nuclear safety were considered, including use of IAEA Safety Standards, enhancement of transparency, enhancement of regulatory effectiveness and use of international peer review missions;
— The Contracting Parties decided to establish an effectiveness and transparency working group open to all Contracting Parties, with the task of reporting to the next Review Meeting on a list of actions to strengthen the CNS.

[93] Australia, Canada, France, Germany, Republic of Korea, Russian Federation, Spain, Switzerland, UAE, UK and USA
[94] Russian Federation and Switzerland

APPENDIX II. BACKGROUND ON THE JOINT CONVENTION ON THE SAFETY OF SPENT FUEL MANAGEMENT AND ON THE SAFETY OF RADIOACTIVE WASTE MANAGEMENT (JOINT CONVENTION)

II.1. HISTORY OF THE JOINT CONVENTION

The history of management of spent nuclear fuel and highly active and long lived radioactive waste can be divided into three phases. In the 1950s, 60s and 70s, many Member States were promoting the use of nuclear energy and little attention was paid to the long term management of spent fuel and radioactive waste. By the 1980s, NPP licensees had accumulated large amounts of operational waste NPPs and there was a loss of interest in reprocessing spent fuel. This led to the second phase, where many Member States created specific national agencies to properly administer the accumulated spent fuel and highly radioactive wastes. The third phase is now being initiated to fully take advantage of new reprocessing technologies, the transmutation of the actinides and very long life fission products, the recycle of fissionable materials and a new generation of fast breeder reactors.

The Joint Convention [7] is the first international legal instrument to directly address the safety of spent fuel and radioactive waste, mainly high level long lived specific activity waste. It was adopted at a diplomatic conference convened by the IAEA at its headquarters from 1 to 5 September 1997. It was opened for signature at Vienna on 29 September 1997 during the 41st session of the IAEA General Conference and it entered into force on 18 June 2001. As of November 2014, there were 69 Contracting Parties to the Joint Convention.

II.2. JOINT CONVENTION REVIEW MEETINGS

II.2.1. 1st Review Meeting (3-14 November 2003)

The 1st Review Meeting was held at IAEA headquarters, with 33 Contracting Parties participating. The 1st Review Meeting gave the opportunity for Contracting Parties to present their national reports, including their response to the written questions, and respond to the questions put to them by other Contracting Parties. It was also an opportunity to understand the measures being taken by Contracting Parties to implement the obligations of the Joint Convention.

As expected, there was a wide spectrum of size and scope of spent nuclear fuel and radioactive wastes and related installations and activities in the national reports. Some Contracting Parties have major nuclear power programmes, while others were limited to just a small research reactor; there were Contracting Parties with large amounts of legacy radioactive wastes, some with large quantities of uranium mine tailings, and others with only hospital waste and disused sealed sources.

It was generally agreed that the review process worked well, but needed improvement. The national reports and the written questions were seen as a positive initiative that helped bring a focus to the safety of spent fuel and radioactive waste management activities. Contracting Parties had a good opportunity to understand how others were implementing the Joint Convention and to share good practices. To better identify and implement improvements, Contracting Parties established an open ended group to improve the review process.

Some of the conclusions and recommendations from the 1st Review Meeting include:

- Contracting Parties concluded that the Review Meeting, the peer review process, and the Joint Convention, in general, had already contributed significantly to the safety of spent fuel and radioactive waste management;
- Contracting Parties clearly demonstrated a strong commitment to the objectives of the Joint Convention and to implementing its obligations. Some Contracting Parties were more advanced than others in the implementation of their radioactive waste and spent fuel management programs;
- Contracting Parties agreed that for the safe and successful management of spent fuel and radioactive waste, there needed to be: a clear legal framework; a strong and independent regulatory body; competent licensees; clear lines of responsibility and accountability; public involvement in the decision making process; adequate financial provisions; and clear and integrated plans on how spent fuel and radioactive waste will be managed to ensure continued safety;
- Contracting Parties also concluded that all Contracting Parties were aware of their responsibilities and were taking measures to implement their obligations under the Joint Convention.

II.2.2. 2nd Review Meeting (15-24 May 2006)

The 2nd Review Meeting was held at IAEA headquarters with 41 Contracting Parties participating. The OECD/NEA was present as an observer.

Contracting Parties demonstrated their commitment to improving policies and practices particularly in the areas of: national strategies for spent fuel and radioactive waste management; engagement with interested parties and the public; and the control of disused sealed sources. The main issues on which progress was noted were as: legislative and regulatory framework; spent fuel and radioactive waste management; decommissioning NPPs; disused sealed sources; mining and milling tailings; naturally occurring radioactive materials; past practices; and international cooperation.

Some Contracting Parties reported on progress with siting of near-surface disposal facilities. A few Contracting Parties reported progress in the more complex subject of siting geological repositories. Several Contracting Parties mentioned the subject of regional repositories. Many Contracting Parties, especially those having old NPPs, have established funding schemes for decommissioning. The strategies in Contracting Parties vary from immediate decommissioning, starting within ten years after final shutdown, to delayed decommissioning, after a long safe enclosure phase.

The conclusions of the 2nd Review Meeting can be stated in the following three statements:

- Participants noted with satisfaction the increased number of Contracting Parties from the 1st Review Meeting. (from 33 to 41);
- Contracting Parties adopted an open and frank attitude, allowing fruitful discussions to take place even on difficult or controversial matters;
- Many Contracting Parties had initiated, or were initiating, new actions to improve the safe management of spent fuel and radioactive waste.

II.2.3. 3rd Review Meeting (11-20 May 2009)

The 3rd Review Meeting was held at IAEA headquarters with 45 Contracting Parties participating. The OECD/NEA and the European Bank for Reconstruction and Development were present as observers, as agreed at the Organizational Meeting.

Among the general observations Contracting Parties noticed that the 3rd Review Meeting showed that progress had been made in building and maintaining a reasonable legislative and regulatory framework. The 3rd Review Meeting was held at a time when many Member States were considering expansion of nuclear power and Contracting Parties promoted the strong recommendation that the safety of spent fuel and radioactive waste management be taken into account from the outset. Some of the highlights from the 3rd Review Meeting included:

- Many Contracting Parties have already developed, or are currently developing, spent fuel and waste management strategies based on comprehensive inventories, including spent fuel and waste arising from decommissioning NPPs. Some progress was also noted on geological disposal facilities and the subject of regional repositories was mentioned, with little progress noted;
- Preservation and transfer of knowledge, corporate memory and experience concerning the safety of spent fuel management and the safety of radioactive waste management were recognized as being of crucial importance for both licensees and regulatory bodies;
- Contracting Parties agreed that societal acceptance and stakeholder involvement were needed in taking decisions on the policy of radioactive waste management and spent fuel management and on the siting of facilities. Involving interested parties, including affected communities, from the beginning of the process was highly recommended;
- Many Contracting Parties saw the benefits and importance of enhancing international cooperation through the exchange of information, experiences and technology. Many Contracting Parties reported on their use of the IAEA Safety Standards and on their experiences with the IRRS.

The conclusions of the 3rd Review Meeting included:

- The participants in the 3rd Review Meeting noted the moderate increase in number of Contracting Parties. Contracting Parties suggested that efforts should be increased to improve participation;
- The review process is maturing and constructive exchanges and knowledge sharing took place in an open and frank manner;
- The 3rd Review Meeting showed that many Contracting Parties had initiated new actions or were enhancing existing actions to improve the safe management of spent fuel and radioactive waste. However, every Contracting Party has challenges requiring further action or continuing implementation of recently initiated activities.

II.2.4. 4th Review Meeting (14-23 May 2012)

The 4th Review Meeting was held at IAEA headquarters with 54 Contracting Parties participating, a notable increase from the 3rd Review Meeting. The OECD/NEA was present as observer, as agreed at the Organizational Meeting.

As the 4th Review Meeting was conducted more than a year after the Fukushima Daiichi accident, many Contracting Parties addressed the lessons learned from the accident, as

requested in advance by the President of the Review Meeting. Many Contracting Parties reported that they carried out an immediate initial analysis for their spent fuel and waste management facilities based on the scenarios that happened at Fukushima Daiichi NPP. In most cases, these initial analyses indicated that no risks had been identified that would warrant immediate action. More detailed assessments are planned or are being carried out to verify the validity of the initial results.

Some of the technical highlights from the 4th Review Meeting include:

- Contracting Parties reaffirmed the need for long term radioactive waste and spent fuel management strategies. It was noted that EU Member States are obliged to comply with the recently adopted Council Directive 2011/70/EURATOM establishing a framework for the responsible and safe management of spent fuel and radioactive waste. This Directive is aligned with the provisions of the Joint Convention;
- Contracting Parties reaffirmed the need for a well-established and secure funding system to ensure the safe management of spent fuel and radioactive waste, including decommissioning of facilities and the long term storage and disposal of waste. These funding systems must be established in such a way as to ensure they remain robust even in a financial crisis;
- Contracting Parties acknowledged that near surface disposal facilities are now mature and established technology, while geological repositories for spent fuel and high level waste remain a challenge for all Contracting Parties;
- Decommissioning NPPs is foreseen as a major future activity, with some Contracting Parties gaining experience in managing decommissioning projects and in managing decommissioning waste. There is no consensus on decommissioning methods, with some Contracting Parties preferring dismantling immediately following final shutdown, while others prefer safe storage for many years to allow decay.

The conclusions of the 4th Review Meeting include:

- Although the number of participating Contracting Parties increased, it was noted that nine Contracting Parties did not participate in the 4th Review Meeting, three participating Contracting Parties did not attend country group sessions and six Contracting Parties did not submit a National Report;
- Constructive exchanges and sharing of knowledge took place in an open and candid manner. However Contracting Parties recognize the need for the invigoration of the peer review process including an increase in willingness of Contracting Parties to challenge and comment on the presentations of other Contracting Parties;
- The exchange of information on actions taken by Contracting Parties to review safety and identify needs for improvement as a consequence of the Fukushima Daiichi accident was very valuable.

II.2.5. 5th Review Meeting (starts 11 May 2015)

It is expected that some of the 5th Review Meeting will focus on lessons learned from the Fukushima Daiichi accident. Topics will probably include the safety of fuel spent pools and the safe removal of spent fuel under the conditions created by the accident. Discussions are also expected lessons learned related with cleaning the NPPs, removing contaminated equipment, managing large quantities of contaminated water and handling waste coming from the outside for decontamination.

In addition, the 5th Review Meeting will include discussions on a wide variety of topics, including: the interface between safety and security; resolution of spent fuel management policy and strategy; funding for spent fuel management; and collaboration with the CNS.

APPENDIX III. INTERNATIONAL NUCLEAR SAFETY GROUP (INSAG)

III.1. HISTORY OF INSAG

After the Three Mile Island accident, it became clear to the IAEA that NPP safety was in need of reconsideration and enhancement. In response to its international duties, the IAEA took a number of steps to improve the situation, including the creation of INSAG in 1985. Originally named the International Nuclear Safety Advisory Group, INSAG included 13 safety experts from around the world and was tasked with reviewing the IAEA's activities in nuclear safety and advising the IAEA Director General on future directions.

In 2003, although the acronym remained the same, *Advisory* was removed from the name to indicate that INSAG serves the international community, not just the IAEA. Today, INSAG:

> "…is constituted under the auspices of the IAEA with the objective of providing authoritative advice and guidance on nuclear safety approaches, policies and principles for nuclear installations (defined as NPPs, fuel cycle facilities, research reactors and support facilities). In particular, INSAG provides recommendations and informed opinions on current and emerging nuclear safety issues, to the international nuclear community and public through the offices of the IAEA".

The number of members increased to 19 in 2013 from the original 13. To ensure the quality and reliability of reviews and advice the INSAG members were selected from a range of Member States and backgrounds including research, academia, industry and regulatory bodies.

INSAG maintains a webpage at the IAEA website where all INSAG documents can be found

III.2. EARLY INSAG WORK: INSAG-1 AND INSAG-7

In August 1986, the IAEA hosted a meeting of experts to review the causes, sequence of events and consequences of the Chernobyl accident and determine the steps that should be taken to enhance the safety of other RBMK reactors. The IAEA Director General invited INSAG to review the information presented at this meeting and in 1987 INSAG published its first report, *INSAG-1: Summary Report on the Post-accident Review Meeting on the Chernobyl Accident* [44]. Although INSAG identified design defects, the main emphasis in INSAG-1 was how operational mistakes were the major cause of the Chernobyl accident. In 1992, using new information that had emerged on the accident, INSAG published *INSAG-7: The Chernobyl Accident: Updating of INSAG-1* [45]. INSAG-7 confirmed that the cause of the accident was due to a lack of safety culture in design and operation at both the national and the NPP level.

III.3. INSAG AND THE DEVELOPMENT AND APPLICATION OF FUNDAMENTAL SAFETY PRINCIPLES

The Three Mile Island and Chernobyl accidents created a concern for the safety of current NPPs and the recognition that all NPPs needed to achieve and maintain a high level of safety. After the first analysis of the Chernobyl accident, INSAG turned its attention to the development of fundamental safety principles and on how to apply them to present and future NPPs.

III.3.1. Basic safety principles for NPPs: INSAG-3 and INSAG-12

In 1988 INSAG published *INSAG-3: Basic Safety Principles for Nuclear Power Plants* [58], outlining three overriding safety objectives and twelve fundamental safety principles. The three safety objectives considered general nuclear safety, radiation protection and technical nuclear safety.

There were three fundamental safety principles related to safety management, three fundamental safety principles on defence in depth and six technical fundamental safety principles. There were also seven specific principles on siting, design, manufacturing and construction, commissioning, operation, accident management and emergency preparedness.

During the 1990s substantial structural changes occurred in regulatory bodies and licensee organizations. These changes put emphasis on management and leadership, the need to manage change efficiently and the recognition of responsibilities and accountabilities. With this additional information, in 1999 INSAG published *INSAG-12: Basic Safety Principles for Nuclear Power Plants: INSAG 3 Rev. 1* [34], which included:

— More comprehensive treatment of safety culture and defence in depth concepts;
— Increased application of NPP operating experience, safety analyses and results from research programmes;
— Use of self-assessment and independent peer reviews at all levels of the licensee organization;
— Use of probabilistic safety assessment—also discussed in INSAG-6 [79]—to evaluate design changes, take operational decisions and develop risk informed nuclear safety regulations;
— Implementation of severe accident management to enhance accident prevention and mitigation.

The structure of INSAG-12 is the same that for INSAG-3. Operational excellence was added to the general technical principles and decommissioning to the specific principles. Quality assurance, self-assessment and peer review principles were also added.

Both INSAG-3 and INSAG-12 were produced with the participation of invited experts and IAEA staff, and both were widely distributed and used as basic references in many training courses and IAEA assistance missions. They created the bases for *SF-1: Fundamental Safety Principles* [21].

III.3.2. How to apply basic safety principles: INSAG-8

In 1995, INSAG published *INSAG-8: A Common Basis for Judging the Safety of Nuclear Power Plants Built to Earlier Standards* [80] to develop a common basis on which an acceptable level of safety of all operating NPPs built to earlier standards can be judged, and to provide a basis for deciding:

— Who has the responsibility for conducting an assessment;
— Which overall approach should be used in that assessment;
— What criteria should be used to decide what corrective actions are needed.

III.4. INSAG AND SAFETY CULTURE

INSAG-1 [44] indicated that a culture of safety would prevent most human errors in the use of nuclear power and INSAG-3 provided an early definition of safety culture:

> "Safety culture is that assembly of characteristics and attitudes in organizations and individuals which established that, as an overriding priority, nuclear plant safety issues receive the attention warranted by their significance" [58].

III.4.1. The safety culture concept: INSAG-4

INSAG fully developed the concept of safety culture in *INSAG-4: Safety Culture* [37], which related safety culture to organizations and individuals engaged in nuclear power activities. INSAG-4 was a milestone for the nuclear industry and highlighted that organizational and cultural issues were as important as engineering issues to NPP safety. Since the publication of INSAG-4, a number of IAEA Safety Standards have discussed leadership and management for safety and the concept of safety culture is highlighted in Fundamental Safety Principle 3:

> "Effective leadership and management for safety must be established and sustained in organizations concerned with, and facilities and activities that give rise to, radiation risks" [21].

III.4.2. Management of safety: INSAG-13

In 1999, INSAG published *INSAG-13: Management of Operational Safety in Nuclear Power Plants* [81]. It states that organizations having a strong safety culture will have an effective management system, which will lead to good safety performance. INSAG-13 details how an applicant for an operating licence for a NPP needs to describe the safety management organization and state the safety requirements for each operating mode, including normal operation, outages, malfunctions, plant modifications and accidents. The applicant must also describe how all safety related activities will be planned, implemented, controlled and supervised, and how the applicant with deal with corrective actions. The applicant must also describe how it will measure and assess its performance. INSAG-13 includes a questionnaire that can assist in determining the safety management status of a NPP.

III.4.3. Strengthening safety culture: INSAG-15

In 2002, the IAEA published *TECDOC-1329: Safety Culture in Nuclear Installations* [82], which defines three main stages in the development of safety culture:

Stage 1—Safety is based on rules and regulations—At this stage, safety is seen as a technical issue, where compliance with regulatory body imposed rules and regulations is considered adequate for safety. The licensee considers that meeting all safety rules is the prime objective and does not pay much attention to the behavior and attitudes of the operating staff.

Stage 2—Good safety performance is taken as an organizational goal—Good safety performance is considered the prime objective, as it also implies reliable NPP operation. There is some safety ownership within the management but a blame-free environment does not exist. The organization is willing to learn from external groups, especially new techniques and best practices.

Stage 3—Safety can always been improved—Safety is seen as a continuing process of improvement where everyone can contribute. There is a strong emphasis on communication, training, leadership and improving efficiency and effectiveness. There is also a clear understanding of the meaning of safety culture and its impact on NPP operation.

In 2002, INSAG expanded on INSAG-4 [37] and INSAG-13 [81] by publishing *INSAG-15: Key Practical Issues in Strengthening Safety Culture* [38], which assists licensees in getting to Stage 3, the desired state. INSAG-15 includes a questionnaire to assess personal contributions to the enhancement of safety culture within the NPP. There are questions for members of every level of the organization, from the board of directors to workers in the NPP.

III.5. INSAG AND SAFETY ASSESSMENT OF NPPS

III.5.1. The concept of defence in depth: INSAG-10

INSAG first considered the concept of defence in depth in INSAG-3, which included the following principle:

> "Principle: To compensate for potential human and mechanical failures, a defence in depth concept is implemented, centred on several levels of protection including successive barriers preventing the release of radioactive material to the environment. The concept includes protection of the barriers by averting damage to the NPP and to the barriers themselves. It includes further measures to protect the public and the environment from harm in case these barriers are not fully effective" [58].

In 1996, INSAG expanded on this definition in *INSAG-10: Defence in Depth in Nuclear Safety* [32], which summarizes: the historical development of the concept; the objectives, strategy, physical protective barriers and levels of protection; how the concept is implemented in practice; how it can serve to enhance the safety of currently operating NPPs and be applied to new construction.

INSAG-10 includes a table, reproduced in Table 39, which defines five levels of defence in depth.

TABLE 39. LEVELS OF DEFENCE IN DEPTH [32]

Level	Objective	Essential Means
1	Prevention of abnormal operation and failures	Conservative design and high quality in construction and operation
2	Control of abnormal operation and detection of failures	Control, limiting and protection systems and other surveillance features
3	Control of accidents within the design basis	Engineered safety features and accident procedures
4	Control of severe plant conditions, including prevention of accident progression and mitigation of the consequences of severe accidents	Complementary measures and accident management
5	Mitigation of radiological consequences of significant releases of radioactive materials	Off-site emergency response

For each level of defence, INSAG-10 provides additional insight, including how deterministic and probabilistic methods can be used to evaluate the safety of the NPP. INSAG-10 also describes how the concept can be applied to enhance the safety of currently operating NPPs and how it should be applied to new NPPs.

III.5.2. Probabilistic Safety Assessment: INSAG-6

In 1992, INSAG published *INSAG-6: Probabilistic Safety Assessment* [79], which reviews the general bases of probabilistic safety assessment (PSA), emphasizing its merits and limits, as well as the general lines of future development of the methodology and its applications.

In the early days of NPPs, there was not enough operating experience to estimate the probabilities of potential events producing NPP damage and releases of radioactivity. In 1975, the USNRC published the Rasmussen Report[95], which provided a new methodology that was applied to a selected PWR and a BWR sited in a theoretical location that represented the average characteristics of the 68 nuclear sites in the USA. The methodology was not immediately accepted in the USA, but was applied in Germany[96] to the prototype of a PWR of German design and later on to the prototype of a fast breeder reactor. Later, it was shown that the methodology predicted the initiating event that caused the Three Mile Island accident and PSA began to be used worldwide.

INSAG-6 analyzed the situation and concluded that PSA methodology had matured to a point where there was a broad basis of understanding and that PSAs were a valuable tool for identifying NPP weaknesses. INSAG noted that limitations and the range of uncertainties involved must be taken into account in the interpretation and use of results.

III.5.3. Integrated risk informed decision making: INSAG-25

The progress achieved in both the deterministic approach to safety and the probabilistic methodology has resulted in the use of both techniques to assess NPP safety. GSR Part 4 (Rev. 1) states:

> "The results of the safety assessment have to be used to make decisions in an integrated, risk informed approach, by means of which the results and insights from the deterministic and probabilistic assessments and any other requirements are combined in making decisions on safety matters in relation to the facility or activity" [30].

In 2011, INSAG published *INSAG-25: A Framework for an Integrated Risk Informed Decision Making Process* [83] to promote a common understanding of how the concept of risk can be used in making safety decisions relating to NPPs.

INSAG-25 identifies the framework, safety principles and key elements for an effective integration and addresses a number of the Fundamental Safety Principles. It describes the interrelationship between the key elements, the integration of their inputs and lists the need for documentation, communication and follow-up on the implementation of the decisions, including performance monitoring and corrective action.

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[95] Rasmussen, N.C. et al. *Reactor Safety Study: An Assessment of Accident Risks in US Commercial Nuclear Power Plants*, WAH-1400 (NUREG-75/014). USNRC. Washington D.C. 1975.

[96] Bundesminister für Forschung und Technologie. *Deutsche Risikosude Kernkraftwerke: Phase B*. GRS. Cologne, 1989.

III.6. INSAG AND THE NATURE, FUNCTIONS AND CHARACTERISTICS OF THE REGULATORY BODY

III.6.1. Making independent regulatory decisions: INSAG-17

Although IAEA Safety Standards had addressed the legal status, organization and staffing of the regulatory body, INSAG recognized that the independence of the regulatory body to make decisions related to safety had not received sufficient attention. In 2003, INSAG published *INSAG-17: Independence in Regulatory Decision Making* [61] to promote a common understanding among legislators and other political decision makers, regulatory bodies and licensees of the concept of independence in regulatory decision making and how to achieve it.

INSAG-17 noted that a regulatory body cannot be absolutely independent in all respects from the rest of government and must function within a system of laws and under budget constraints, just as other governmental organizations must. Therefore, effective independence of the regulatory body must come from the laws creating the regulatory body and in the selection of the senior officials of the regulatory body. INSAG-17 suggests that the regulatory body should more resemble the judicial branch (the courts of law) than the executive branch of government.

INSAG-17 divides the long list of activities within the regulatory body into three major functions:

- To develop and enact a set of appropriate, comprehensive and sound regulations;
- To verify compliance with such regulations;
- In the event of a departure from licensing conditions, malpractice or wrongdoing by those persons/organizations under regulatory oversight, to enforce the established regulations by imposing the appropriate corrective measures.

In responding to those functions there must be an effective separation between the functions of the regulatory body and those of any other body or organization concerned with the promotion or utilization of nuclear energy.

The law may protect the body from external influences, but not from internal deficiencies. INSAG-17 includes a number of recommendations to cope with these internal deficiencies.

III.6.2. Licensing the first NPP: INSAG-26

To assist Member States embarking on a nuclear power programme, INSAG published *INSAG-26: Licensing the First Nuclear Power Plant* [67], which provides a high level, yet practical guide for decision makers.

INSAG-26 discusses the importance of starting with a strong legal framework that establishes fundamental principles and defines the responsibilities of the operating organization and the regulatory body. Both organizations must implement a formal and sustainable training process. INSAG-26 recommends the use of the IAEA Safety Standards on training and knowledge management, as well as active participation in the Global Nuclear Safety Framework.

INSAG-26 discusses the ‘reference NPP’ concept, whereby the Member State’s first NPP would have essentially the same design and safety features as a NPP that is already licensed

by an experienced regulator. INSAG-26 goes on to state that nevertheless, every new regulatory body must develop its own set of national regulations and must begin to build its competence at an early stage in the process.

INSAG-26 includes an appendix summarizing 14 characteristics of a fully mature and effective regulatory body. A new regulatory body can use this appendix as a self-assessment tool to determine where improvements need to be made.

III.7. INSAG AND DEALING WITH INTERESTED PARTIES

III.7.1. Interested parties[97]: INSAG-20

INSAG-20: Stakeholder Involvement in Nuclear Issues [73] , published in 2006, has four main purposes:

- To advocate open, transparent, factual, timely, informative and easily understandable multilateral communications among members of society and those who are operating or regulating nuclear installations or developing a nuclear project;
- To establish that substantive interested party communications contribute to the safe operation of nuclear installations;
- To present the major attributes of an effective communication programme;
- To discuss ways and means for the efficient and rational involvement of interested parties in the consideration of nuclear issues.

Apart from considering that it is a civil right that interested parties be informed of and be able to participate in essential national matters such as using nuclear energy, INSAG-20 also concludes that interested party involvement makes regulatory bodies aware that their actions are under public scrutiny. Likewise, interested party involvement compels licensees to be aware that NPP operations are under public scrutiny. This public scrutiny reinforces the sense of responsibility for nuclear safety.

INSAG-20 includes a list of examples of nuclear issues for interested parties. Among others, it includes:

- National debates on the incorporation of nuclear energy in the national energy plan; the economic and social justification of introducing nuclear energy is a key issue;
- Decision to build a new NPP or fuel cycle installation; the social and environmental impact around the site needs to be explored by the affected population;
- Decision to build a high level waste repository; international experience has clearly proven that such a repository needs the approval of the affected population;
- Establishment and execution of emergency plans; the population living in the potentially affected areas needs to know the details of the emergency plan and the means and ways to participate effectively, if necessary;
- Transport of spent fuel and high level radioactive material; transport creates a linear risk along the transport path of great concern to the affected populations;
- Nuclear security is a matter of public concern; communicating detailed information on security related issues must obviously be restricted, but knowing that security is

[97] The term *interested party* has replaced *stakeholder*

seriously considered by government, regulatory bodies and licensees improves social acceptance.

INSAG-20 concludes that the active involvement of interested parties in nuclear issues can provide a substantial improvement in safety and can enhance the general acceptability of the decisions made.

III.8. INSAG AND SAFE OPERATION

III.8.1. Managing change in the nuclear industry: INSAG-18

By the end of the 1990s, changes such as deregulation of electricity markets, privatization and an increased focus on competitiveness were taking place in many Member States with nuclear power programmes. These changes had the possibility of affecting operational safety that, in 2003, prompted INSAG to publish *INSAG-18: Managing Change in the Nuclear Industry: The Effects on Safety* [84].

INSAG-18 is directed at members of boards of directors and senior executives who: are responsible for the overall safety of an installation; make decisions for change; implement these decisions. It is also written for senior regulators who, on behalf of the public, ensure that boards of directors and executives meet their responsibilities for safety.

INSAG-18 includes some practical steps to cope with changes, noting that:

> " …when major changes are planned, not only the systems for assuring the safety of engineering modifications but also organizational systems should be rigorously and independently scrutinized. The boards of operating companies must remain aware that they have the responsibility for safe operations and that both they and the regulators must be convinced that safety considerations have been given priority commensurate with their significance during any process of major change" [84].

III.8.2. Maintaining NPP design integrity: INSAG-19

At the same time as changes were occurring in electricity markets, the safety and operational performance of currently operating NPPs showed improvement, prompting many owners to reconsider the operating life time of current NPPs. In 2003, INSAG published *INSAG-19: Maintaining the Design Integrity of Nuclear Installations throughout their Operating Life* [35].

INSAG-19 is a continuation of INSAG-18 [84] specifically dedicated to engineering changes over the long life of the NPP. These changes can arise from:

- Physical ageing of the NPP's SSCs;
- Obsolescence that inevitably occurs in many of its hardware and software elements;
- Feedback from operating experience and from research or unexpected design issues arising during its life;
- Changing engineering or regulatory standards;
- Changes in performance expected from the NPP;
- Changes in the organization or practices of the operating company.

INSAG-19 discusses the need for the licensee to have a complete and satisfactory knowledge at all times of the design of the NPP. Such knowledge must include the as-built design and all modifications or additions introduced in the NPP. INSAG-19 recommends that a design authority be established with the responsibility of ensuring that the knowledge base is established, has been preserved and is expanded with experience. The design authority is also responsible for ensuring that the knowledge of the design that is needed for the safe operation and maintenance of the NPP is available to the licensee.

III.9. INSAG AND THE GLOBAL SAFETY FRAMEWORK

III.9.1. Strengthening the global nuclear safety framework: INSAG-21

In 2006, INSAG published *INSAG-21: Strengthening the Global Nuclear Safety Regime*[98] [3] to review the framework and recommend improvements. INSAG-21 concluded that the effectiveness of the framework could be improved by:

- Enhanced use of the CNS review meetings for open and critical peer review and a source for learning about the best safety practices of others;
- Enhanced use of the IAEA Safety Standards for the harmonization of national safety regulations;
- Enhanced exchange of operating experience for improving operating and regulatory practices;
- Multinational cooperation in the safety review of new NPP designs.

III.9.2. National nuclear safety infrastructure: INSAG-22

In 2008, INSAG published *INSAG-22: Nuclear Safety Infrastructure for a National Power Programme supported by the IAEA Fundamental Safety Principles* [63], at a time when there was optimism on the future development of nuclear power programmes worldwide. INSAG-22 was intended to complement the extensive guidance given in IAEA publications *Considerations to Launch a Nuclear Power Programme* (2007) [85] and *Milestones in the Development of a National Infrastructure for Nuclear Power* (2007) [1].

INSAG-22 describes the elements of the nuclear safety infrastructure, the time frame needed for its development and the responsibilities of the key interested parties. Using previous INSAG reports as guidance, INSAG-22 discusses the five phases of the NPP lifetime:

- Phase I: the infrastructure necessary before taking the decision to launch a nuclear power programme;
- Phase 2: the infrastructure necessary to conduct the preparatory work for the deployment of a NPP after a policy decision has been taken;
- Phase 3: the infrastructure necessary to select the site and to construct the first NPP;
- Phase 4: the infrastructure necessary to commission and operate the first NPP;
- Phase 5: the infrastructure necessary to decommission and dismantle the NPP and to manage the spent nuclear fuel and radioactive waste.

[98] As mentioned in Chapter 2, the word *framework* is now used in place of *regime*.

III.9.3. Improving operating experience feedback: INSAG-23

INSAG-21 states that:

> "The international operating experience feedback systems available today are not adequate to meet the needs of the ever-increasing number of nuclear interested parties. There is an acute need to improve the mechanisms that are in place for sharing international operating experience, as well as to develop newer, simpler processes to expand on these overtaxed mechanisms" [3].

To follow up on this statement, in 2008 INSAG published *INSAG-23: Improving the International System for Operating Experience Feedback* [4], which states that reports and collecting data are meaningful only when there is a direct coupling to risk reduction and the enhancement of operating safety.

INSAG-23 discusses the IRS jointly operated by the IAEA and OECD/NEA. In particular, INSAG recommends that the IRS include a mechanism for submitting questions and receiving answers so users better understand the reported information and feedback reporting that provides information on measures that the recipients have taken in response to IRS reports. INSAG believes that a high level advisory group or an equivalent mechanism could guide and coordinate the work being done in different international organizations and thereby improve the IRS.

APPENDIX IV. INTERNATIONAL INSTITUTIONS AND STANDARDS MAKING BODIES

There is a long list of international, supranational and national governmental agencies and organizations, standards associations and dedicated groups and forums concerned with the safety and security of NPPs, fuel cycle installations, radiation sources and activities involving ionizing radiation. In performing their functions, these institutions maintain long term cooperation with the IAEA through agreements and memoranda of understanding and are considered part of the global safety framework.

Some of the more relevant government and industry institutions involved in developing nuclear regulation, safety standards and codes, technology and excellence in NPP operation include:

- **OECD/NEA**: Nuclear Energy Agency of the Organisation for Economic Co-operation and Development;
- **EURATOM/EU**: Signatories and Members of the EURATOM Treaty, and European Union;
- **WANO**: World Association of Nuclear Operators;
- **INPO**: Institute of Nuclear Power Operations;
- **ISO**: International Standardization Organization;
- **IEC**: International Electrotechnical Commission;
- **ASME**: American Association of Mechanical Engineers;
- **IEEE**: Institute of Electric and Electronics Engineers.

IV.1. OECD/NEA

The OECD/NEA is an international body dedicated to the peaceful use of nuclear science and technology.

The OECD/NEA undertakes its work through seven committees:

- Committee on the Safety of Nuclear Installations (CSNI);
- Committee on Nuclear Regulatory Activities (CNRA);
- Committee of Radiation Protection and Public Health (CRPPH);
- Radioactive Waste Management Committee (RWMC);
- Nuclear Science Committee (NSC);
- Committee for Technical and Economic Studies on Nuclear Energy Development and the Fuel Cycle, known as the Nuclear Development Committee (NDC), and
- Nuclear Law Committee (NLC).

These committees are forums for interchanging knowledge and experience, providing mutual help among member countries, developing joint research programmes, publishing technical documents, validating computer codes, maintaining a nuclear data bank and organizing conferences, symposia and seminars. Each committee has statutory activities that are conducted by standing or temporary working groups of experts. The work of all OECD/NEA committees is important, however the work of the CSNI and CNRA are most relevant here.

IV.1.1. Committee on the Safety of Nuclear Installations (CSNI)

CNSI currently conducts its activities through seven standing[99] working groups and a variable number of subgroups, senior expert groups and task groups. Apart from a standing working group for managing the current programme, the main issues currently explored are: nuclear risk assessments; managing of accidents; integrity and ageing of components and structures covering metal components, concrete structures and the effects of seismicity; and fuel and fuel cycle safety. There is a senior expert group on safety research opportunities and two task groups on external events and electrical systems in the light of the Fukushima Daiichi accident.

In 1980, the CSNI created the International Reporting System (IRS). An invitation was sent to member countries to freely submit the anomalies and operation incidents observed in the increasing number of NPPs in operation. During the first three years some 1,200 reports were presented and made available to experts. In due course, the work of IRS was transferred to the CNRA.

IV.1.2. Committee on Nuclear Regulatory Activities (CNRA)

In the 1970s the number of operating NPPs increased considerably, prompting a group of countries to propose the creation of a Subcommittee on Licensing to consider safety evaluation and inspection issues of NPPs. The relevance and need of the Subcommittee increased considerably and transformed into the current CNRA.

The members of CNRA are senior representatives of the regulatory bodies with NPPs in operation. The main objective is the interchange of experiences in: safety evaluation; NPP inspection; operating experience analysis and feedback; application of research results to safety evaluation; and the harmonization of safety principles, objectives and practices. CNRA has established standing working groups on: inspection practices; operating experience; public information; and regulation of new reactors. The CNRA works closely with CSNI.

IV.1.3. The OECD/NEA Data Bank

The OECD/NEA Data Bank is a continuously improving, well-tested, verified and fully documented suite of computer programmes on nuclear energy applications, with currently more than 2 000 documented packages. As part of the cooperation arrangement with the IAEA, the OECD/NEA provides computer programs in the OECD/NEA Data Bank to all IAEA Member States.

The OECD/NEA Data Bank includes many computer programmes for the design and operation of NPPs, including applications such as:

- Data bases and analytical tools for static and dynamic reactor calculations;
- Heat transfer and hydrodynamics (can also be coupled with neutronics for excursion simulations and safety analysis);
- Radiation transport for shield design, gamma heating and dosimetry;
- Structural analysis and stress distributions;

[99] Standing does not mean permanent. The groups exist until an issue is resolved. A new group is created when a new concern arises.

— Fuel depletion for fuel management,
— Cost analysis and NPP economics;
— Environmental impact of nuclear activities, and,
— Mathematics and computing system routines.

IV.1.4. OECD/NEA cooperation agreements with the IAEA

Staff members of each organization are present in relevant activities of the other, including IAEA staff participating in OECD/NEA Standing Working Groups meetings and OECD/NEA staff participating in IAEA Safety Standards Committees. OECD/NEA is also represented on INSAG. In addition, the IAEA and OECD/NEA collaborate on the IRS and the International Nuclear and Radiological Event Scale.

IV.1.5. The International Nuclear and Radiological Event Scale (INES)

In 1990 the IAEA and the OECD/NEA jointly launched INES and recommended Member States use it for rating the severity of events at NPPs with the aim to communicate their safety significance to the public. Later INES was expanded on two occasions: to apply for events associated with all installations associated with civil nuclear industries and to apply for events associated with transport, storage and use of radioactive materials and radioactive sources too.

Events are rated on the scale at seven levels: Levels 1–3 are called "incidents" and Levels 4–7 "accidents". The scale is designed so that the severity of an event is about ten times greater for each increase in level on the scale. Events without safety significance are rated Below Scale / Level 0 (see Figure 29). Event that are not related to the nuclear or radiation safety are not rated on the scale.

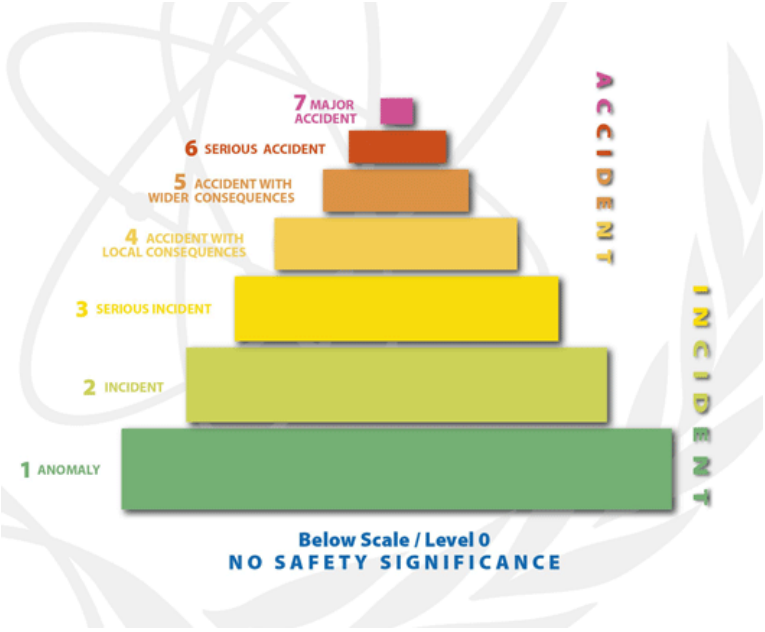


FIG. 29. The International Nuclear and Radiological Event Scale.

INES rates nuclear and radiological events by considering three areas of impact:

— People and the Environment considers the radiation doses to people or the amount of radioactive material released into the environment.
— Radiological Barriers and Control considers events where the primary barriers to prevent a large release are significantly damaged or events where the primary barriers are intact but there is a major spillage of radioactive materials or significant increase in the dose rate.
— Defence-in-Depth considers events without any direct impact on people or the environment, but for which the range of measures put in place to prevent accidents did not function as intended.

The Three Mile Island accident was rated INES Level 4, the Chernobyl accident and the Fukushima Daiichi accident were rated INES Level 7.

Further details on INES can be found in INES Manual [86]. Guidelines and good practices for effective use of INES for event communication can be found in [87].

IV.2. THE EUROPEAN UNION AND THE EURATOM TREATY

On 28 March 1957, by the Treaty of Rome, six European countries[100] created the European Atomic Energy Community (EURATOM) and the European Economic Community, now the European Community (EC). Although the EC Treaty has been significantly amended since 1957, the EURATOM Treaty is essentially unchanged.

Article 1 of the EURATOM Treaty sets out the purpose:

> "By this Treaty the HIGH CONTRACTING PARTIES establish among themselves a EUROPEAN ATOMIC ENERGY COMMUNITY (EURATOM). It shall be the task of the Community to contribute to the raising of the standard of living in the Member States and to the development of relations with the other countries by creating the conditions necessary for the speedy establishment and growth of nuclear industries" [88].

The Treaty includes:

— Title II: Provisions for the encouragement of progress in the field of nuclear energy;
— Title III: Provisions governing the institutions;
— Title IV: Financial conditions;
— Title V: General provisions;
— Title VI: Provisions related to the initial period.

IV.2.1. Health and safety in the EURATOM Treaty

Chapter 2 of Title II addresses health and safety. The chapter is developed in articles 30 to 39 and deals exclusively with protection from ionizing radiation. The EURATOM Treaty was silent on nuclear safety issues and the Contracting Parties considered nuclear safety was an exclusive national competence.

[100] Belgium, France, Germany, Holland, Italy and Luxemburg.

IV.2.1.1. The European Union enlargement the first safety case: The creation of WENRA

A key turning point on EURATOM´s concern for nuclear safety came with the Chernobyl accident. The accident brought to light serious flaws in the safety culture and technology in the RBMK reactor types. Analysis of the Soviet designed VVER reactor types also revealed serious deficiencies. Soviet VVER reactors were in operation or under construction in Bulgaria, Czechoslovakia, East Germany, Hungary and Lithuania. The concern for the safety of these NPPs and potential radiological effects on Western Europe peaked when the EC began considering enlargement to include some of these countries.

The NPPs in the candidate countries were divided into three categories: NPPs of western design (Krsko in Slovenia); Soviet designed NPPs which can be upgraded to meet international safety standards (VVER-440-213 model), and Soviet designed NPPs which cannot be upgraded at a reasonable cost (VVER-440-230 model). The EU repeatedly stated that the third category of NPPs operating in candidate countries should be closed at the earliest practical date. This applied to Bohunice V-1 in Slovakia, Ignalina units 1 and 2 in Lithuania and Kozloduy units 1 to 4 in Bulgaria. The national authorities in those countries accepted the proposal. The NPPs then under construction or operation in the former East Germany were all closed down following the German reunification.

It was recognized that the decision to close down NPPs should be based on technical studies referencing a complete and satisfactory set of nuclear safety standards which could apply across the EU. Each Member State with operating NPPs had nuclear safety standards, but the EU did not have the statutory authority to take safety decisions even within its Member States.

On 4 February 1999 the heads of regulatory bodies of western European countries with NPPs[101] created WENRA with the objectives of: developing a common approach to nuclear safety and regulation; providing the EU with an independent capability to examine nuclear safety and regulation in candidate countries; and evaluating and achieving a common approach to arising nuclear safety and regulatory issues.

In October 2000 WENRA issued a report titled *WENRA Report on Nuclear Safety in Candidate Countries to the EU* [89]. The general conclusions in this report served as the basis for the EU decision to require the shutdown of Bohunice-V in Slovakia, Ignalina 1 and 2 in Lithuania and Kozloduy 1 to 4 in Bulgaria as a condition for those countries becoming members of the EU.

In March 2003, WENRA invited the heads of the regulatory bodies of the seven EU candidate countries with NPPs[102] to join WENRA.

IV.2.2. The European Commission Nuclear Package: The creation of ENSREG

The enlargement of the EU in 2004 and concerns on nuclear safety from the Chernobyl accident prompted the European Commission to consider, in November 2002, what is known as the nuclear package, which included proposals for two new EURATOM Directives[103]:

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[101] Belgium, Finland, France, Germany, Italy, Netherlands, Spain, Sweden, Switzerland and United Kingdom.
[102] Bulgaria, Czech Republic, Hungary, Lithuania, Romania, Slovakia, and Slovenia.
[103] EURATOM Directives are pieces of European nuclear legislation.

- The Nuclear Safety Directive, setting out the basic obligations and general principles for the safety of nuclear installations;
- The Waste Directive, setting out the basic obligations and general principles for the safe management of spent nuclear fuel and radioactive waste.

The two proposals were formally adopted by the European Commission in January 2003.

The EURATOM Treaty does not give the European Commission the power to regulate nuclear safety. However, in December 2002, the European Court of Justice—while considering the matter of whether the EURATOM could become a Contracting Party to the CNS—ruled[104] that EURATOM does have competence in the establishment of a legislative and regulatory framework to govern the safety of nuclear installations. This ruling opened to path to greater harmonization of nuclear safety in the EU.

In 2007, the EU established the European Nuclear Safety Regulators Group (ENSREG) to contribute to the achievement of EURATOM objectives in the field of nuclear safety.

The Nuclear Safety Directive was approved in 2009 and required implementation by Member States by 22 July 2011. The Nuclear Safety Directive includes 11 articles and refers to the IAEA Fundamental Safety Principles SF-1 [21]:

> "Member States should assess, where appropriate, the relevant fundamental safety principles set by the IAEA [IAEA SF-1] which should constitute a framework of practices that Member States should have regard to when implementing this Directive".

The Nuclear Safety Directive indirectly refers to the IAEA IRRS:

> "The international peer reviews should be regarded as an opportunity to exchange professional experience and to share lessons learned and good practices in an open and cooperative spirit through advice by peers rather than control or judgment".

The Nuclear Safety Directive also introduces the concept of PSR into the safety framework:

> "Member States shall at least every 10 years arrange for periodic self-assessments of their national framework and competent regulatory authorities and invite an international peer review of relevant segments of their national framework and/or authorities with the aim of continuously improving nuclear safety. Outcomes of any peer review shall be reported to the Member States and the Commission, when available".

IV.2.3. The stress tests after the Fukushima Daiichi accident

As a result of the Fukushima Daiichi accident, the EU launched a targeted reassessment of the safety margins of NPPs called the "Stress Tests" [62]. All 14 EU countries that operate NPPs, plus Croatia, Switzerland and Ukraine, participated in the Stress Tests and peer review process.

[104] Commission of the European Communities v Council of the European Union. Judgement of the Court of Justice in Case C-29/99.

The Stress Tests reports contain indications on the potential areas of legislative improvement, mainly in the areas of safety procedures and frameworks, roles and resources of regulatory bodies, openness and transparency, monitoring and verification. On this basis, a proposal to amend the Nuclear Safety Directive has been developed.

IV.2.4. International agreements under the EURATOM Treaty

EURATOM has the authority to enter into international agreements and the most known is the Agreement on Safeguards.

In 2013, EURATOM and the IAEA signed a MoU for a partnership to strengthen and structure their cooperation in the area of nuclear safety. Some of the areas considered for cooperation include:

- Nuclear safety matters: Develop nuclear safety standards, regulatory framework and installation safety;
- Peer reviews: Provision of IRRS and OSART plus safety review missions to nuclear installations requested by EURATOM Member States;
- Assistance to Member States: Support to EURATOM Member States, on request, in further development of comprehensive risk and safety assessment and related peer reviews and those introducing a nuclear power programme or further developing nuclear power use;
- Emergency preparedness: Arrangements for emergency preparedness and response in accordance with EPR-JPLAN.

IV.3. INSTITUTE FOR NUCLEAR POWER OPERATIONS (INPO) AND THE WORLD ASSOCIATION OF NUCLEAR OPERATORS (WANO)

INPO and WANO are two organizations aimed at improving the safety and reliability of NPPs. INPO was created in the USA as a nuclear industry response to the Three Mile Island accident and WANO as a worldwide reaction to the Chernobyl accident. Both INPO and WANO are learning from the Fukushima-Daiichi accident.

IV.3.1. INPO

The presidential report to the Three Mile Island accident, called the Kemeny Report [57][105], was made public in October 1979 and concluded that:

> "To prevent nuclear accidents as serious as Three Mile Island, fundamental changes will be necessary in the organization, procedures, and practices—and above all—in the attitudes of the USNRC and, to the extent that the institutions we investigated are typical, of the nuclear industry".

The Kemeny Report made specific recommendations for licensees and their suppliers on the training of operating personnel, the technical assessment of NPPs, worker and public health and safety, emergency planning and response and the public's right to information. The US

[105] Professor John G. Kemeny of Dartmouth College was the chairman of the commission requested by President Carter to analyze the Three Mile Island accident. The investigating commission included the chairman, ten experts from academia and industry, and one housewife resident in the nearby town of Middletown, Pennsylvania.

nuclear power industry took early strong measures, which resulted in the creation of INPO, a non-governmental corporation owned by the US electrical utilities with NPPs. Currently it has 27 members, 25 international partners and 26 supplier participants. INPO's mission is:

> "To promote the highest levels of safety and reliability—to promote excellence—in the operation of commercial NPPs".

INPO is a self-regulatory body that enhances safety through comprehensive and rigorous peer reviews to operating NPPs, a set of performance indicators, analysis of events and dissemination of lessons learned, benchmarking against international best practices and providing for the training of operating personnel. INPO activities have resulted in considerable improvement in the safety and reliability of US NPPs.

IV.3.2. WANO

WANO was part of the nuclear industry response to the Chernobyl accident. Both the Kemeny Report and INSAG reports on Chernobyl found the same root causes: the lack of safety culture in the regulatory bodies, in the management of the NPP and in the training of operating personnel; the human factor. WANO is patterned after INPO, with the mission:

> "To maximize the safety and reliability of NPPs worldwide by working together to assess, benchmark and improve performance through mutual support, exchange of information and emulation of best practices".

WANO held its inaugural meeting in Moscow in 1989. WANO operates four regional centres in Atlanta, Moscow, Paris and Tokyo, maintains a coordinating centre in London and links 115 operators of NPPs in 34 countries. Today WANO also involves reactor designers and vendors so there is better feedback of construction and operation experience.

IV.3.3. INPO and WANO nuclear safety programmes

WANO and INPO maintain four major programs of interest: peer reviews; analysis and feedback of operating experience; professional education and training; and technical support and exchange. The four activities have many common points in both organizations, but also some differences.

IV.3.3.1. Peer reviews

Peer reviews are at the heart of INPO´s and WANO's programmes. Teams of approximately 15 to 20 highly qualified, experienced individuals conduct periodic evaluations of operating NPPs, focusing on NPP safety and reliability. The scope of the evaluation includes the functional and cross-functional performance areas shown in Table 40. The performance of operations and training personnel during simulator exercises is included as a key part of each evaluation.

TABLE 40. FUNCTIONAL AND CROSS-FUNCTIONAL PERFORMANCE AREAS GENERALLY INCLUDED IN WANO AND INPO PEER REVIEWS

Functional	**Cross-functional**
Operations	Safety culture
Maintenance	Operational focus

Engineering	Configuration management
Radiological protection	Equipment reliability/Work management
Chemistry	Performance improvement
Training	Organizational effectiveness

Formal reports identifying strengths and areas for improvement are provided to the NPP. The NPP responses to the identified areas for improvement, along with their commitments to specific corrective action, are included in the final review report. Subsequent evaluations and other WANO or INPO follow-up visits specifically review the effectiveness of corrective actions taken.

In the case of INPO a numerical assessment was developed and each US NPP is rated from 1 to 5. Categories 1 and 2 are considered excellent NPPs: they show strong leadership, are self-critical, do not tolerate complacency, are operationally focused, have exceptional equipment performance and effectively use training to improve performance. Categories 3 and 4 are adequate, but show some deficiencies with considerable room for improvement. Category 5 is unacceptable and requires considerable improvement in most areas.

An early priority of WANO was fostering interchange visits between operating staff of Soviet design NPPs and NPPs of western design. WANO used the term NPP twinning to describe this cooperation. Learning from INPO, WANO then created a peer review programme similar to INPO. By the end of 2009, every commercial NPP in the world had been peer reviewed at least once. This led to establish the requirement that peer reviews should be conducted every three years and a full WANO peer review should be conducted at each NPP at least every six years.

When large nuclear power programmes were started, mainly in China and other Asian countries, WANO introduced pre-startup peer reviews to evaluate how the transfer of responsibilities from construction to operation is organized. WANO provides all new NPPs with a pre-startup review before initial criticality. A team of specialists has been assembled to manage these reviews, which are increasing at a significant pace, particularly in Asia. The WANO pre-startup peer review team office opened in Hong Kong so the team could be based in the region where the greatest number of pre-startup reviews will be conducted in the next few years.

The WANO analysis of the Fukushima Daiichi accident identified gaps in the WANO system and changes have already been introduced to improve the system. The scope of the peer reviews has expanded to include accident prevention and mitigation. Full WANO peer reviews will be conducted every four years, with follow-up visits every two years.

IV.3.3.2. Operating experience and feedback

Since its creation, INPO has been very active in collecting, analyzing and distributing operating experience among its members and international partners. NPPs are required to share operating experiences with INPO, which analyzes and communicates the information to the industry through a variety of methods and products. In addition, INPO analyzes operational data to detect trends in industry performance and communicates the results to industry.

INPO operates and maintains extensive computer databases accessible to members and partners from a secure website, also used by WANO, as the primary mean for communicating and exchanging operating experience. Member NPPs support the event analysis program by providing INPO or WANO with detailed and timely operating experience information. The normal yearly rate of entries every year is about 30 to 40 per NPP. A key to this success is the timeliness of reporting. NPPs typically report events in less than 50 days after the occurrence of a reportable event. Events are screened, coded, and analyzed for significance and those with generic applicability are disseminated to the industry in one or more of the following forms:

- Significant Operating Experience Reports[106] (SOERs) identify the principal contributors to significant events or trends in types of events and provide recommendations. Member NPPs are required to evaluate and take appropriate action on recommendations provided in SOERs. During peer reviews, WANO and INPO teams follow up on the effectiveness of each NPP's actions in response to SOER recommendations. Topics of SOERs in recent years include loss of grid, reactivity management, reactor core designs, electrical transformers, unplanned radiation exposures, rigging/lifting of heavy loads and two SOERs on the Fukushima Daiichi accident [90] [91];
- Significant Event Reports (SERs) are advisory documents containing in-depth analyses of significant events to identify the lessons learned for the benefit of other NPPs. Member NPPs are expected to review the lessons learned and take action, as applicable, to reduce the likelihood of similar incidents;
- Just-in-Time (JIT) reports include briefing summaries on problems experienced and lessons learned during recurring activities and are intended to help and prepare personnel to perform specific tasks conducted successfully in other NPPs;
- Topical Reports review events and other data over a period of years to summarize performance trends and causes and suggest actions. Subjects of recent topical reports include fuel reliability, foreign material intrusion, intake cooling blockage, large motor failures and contractor personnel performance. NPPs use these reports to assess their performance and identify improvements.

WANO also has an Operating Experience programme for WANO members to openly share their operating experience for the benefit of other members. A WANO Event Report procedure requires NPP managers to analyze any significant deviation from the expected functioning of the NPP and send a report to the corresponding WANO centre.

WANO also produces Hot Topic reports, which provide summaries and highlights of adverse performance trends or specific events. These concise reports provide tools such as assessment guides. WANO issues CEO Updates describing important events and trends that utility chief executive officers are encouraged to discuss with their nuclear executives and oversight organization.

IV.3.3.3. Professional education and training

INPO has always devoted attention to the training and qualification of NPP personnel and was instrumental in the creation of the US National Academy for Nuclear Training in 1985. An INPO executive serves as the Academy's executive director. The Academy objective is to

[106] These reports have limited distribution.

develop and apply high standards in training and qualification and to promote professionalism of NPP personnel. Through INPO, the Academy conducts seminars and courses and provides training and training materials for NPP personnel.

The Academy has established guidelines for the conduct of training and qualification activities. The guidelines put emphasis on the training and qualification responsibilities of line managers, the training manager and personnel in training. It also describes how training and qualification are to be administered. Training has two very distinct phases: initial training for new candidates and continuous training for incumbents.

The line manager is responsible for maintaining a complete and satisfactory training and qualification programme from personnel selection and development to full qualification of every person involved in the operation of the NPP. The training manager is responsible for applying a systematic approach to training, introducing internal and external operating experience into the training process, measuring training effectiveness, managing training resources and enhancing professional development and career planning for training personnel. Persons in training must actively participate in required training, identifying deficiencies in the training and, in the case of incumbents, provide examples of operating experience.

The US nuclear industry has created the independent National Nuclear Accrediting Board to ensure that the training programmes at each NPP meet INPO's high standards. The accreditation process is designed to identify strengths and weaknesses in training programs and to point out needed improvements. The evaluation is based on a full training self-assessment provided by the NPP, an accreditation visit conducted by an INPO-led team of six to eight experts and a meeting of the Board with the NPP director, line managers and other NPP staff. The Board examines the quality of NPP training programmes and if training programs meet accreditation standards, the Board awards or renews accreditation. If significant problems are identified, the Board may defer accreditation, place accredited programs on probation, or withdraw accreditation. The Academy has established the list[107] of objectives for accreditation shown in Table 41. The accreditation of training programmes must be renewed every four years.

The following training programmes must be submitted for accreditation:

- Shift managers;
- Senior reactor operators;
- Reactor operators;
- Non-licensed operators;
- Continuing training for licensed personnel;
- Shift technical advisors;
- Instrument and control technicians and supervisors;
- Electrical maintenance personnel and supervisors;
- Mechanical maintenance personnel and supervisors;
- Chemistry technicians;
- Radiological protection technicians;

[107] NATIONAL ACADEMY FOR NUCLEAR TRAINING. The Objectives and Criteria for Accreditation of Training in the Nuclear Power Industry. Academy Document 02-001, December 2003

— Engineering support personnel.

The Academy accreditation process is independent, however the USNRC has endorsed the process as a means for satisfying regulatory training requirements.

TABLE 41 OBJECTIVES FOR ACCREDITATION OF TRAINING IN THE NUCLEAR POWER INDUSTRY[108]

Objective 1	Training for performance improvement	Training is used as a strategic tool to provide highly skilled and knowledgeable personnel for safe, reliable operation and to support performance improvement.
Objective 2	Management of training processes and resources	Management is committed to and accountable for developing and sustaining training programmes that meet NPP needs. Resources and an infrastructure of training processes are applied consistent with these needs to support training programme sustainability.
Objective 3	Initial training and qualification	The initial training uses a systematic approach to training to provide personnel with the necessary knowledge and skills to independently perform their job assignments.
Objective 4	Continuing training	Continuing training uses a systematic approach to training to refresh and improve the application of knowledge and job related skills and to meet management expectations for personnel and NPP performance.
Objective 5	Conduct of training and trainee evaluation	Training is conducted using methods and settings that support trainee attainment of job related knowledge and skills. Achievement of learning is confirmed with reliable and valid evaluation methods.
Objective 6	Training effectiveness evaluation	Evaluation methods are used systematically to assess training effectiveness and modify training to improve personnel and NPP performance.

WANO has not developed any training accreditation procedures. Only two Member countries have so far established training accreditation systems patterned after the INPO led system. The Kooberg NPP in South Africa established a training accreditation process similar to INPO and EDF Energy has maintained the training accreditation process established by British Energy for its UK NPPs.

IV.3.3.4. Technical support and exchange

INPO and WANO will provide technical support to NPPs that require assistance in a specific problem, as well as for broader management and organizational issues. A policy of graduated engagement is established when a given NPP performance trends indicate conditions that could detract from safe and reliable NPP operation. If the decline becomes significant the NPP is placed under the supervision of a Focus Oversight Board that will conduct scheduled periodic reviews.

[108] Taken from ACAD 2-001

Both INPO and WANO offer technical support missions, conducted by a team of peers, based on the needs of the NPP.

Performance indicators are measurable parameters that help quantify the performance and safety of an NPP. WANO and INPO have created a number of performance indicators that allow NPPs to assess their performance against international benchmarks. Table 42 lists some of these performance indicators. WANO has many other performance indicators that are available only to member NPPs.

TABLE 42 SOME OF THE PERFORMANCE INDICATORS USED BY WANO TO MEASURE SAFETY AND RELIABILITY OF NPPS[109]

Unplanned Automatic Scrams per 7,000 Hours Critical	Number of automatic shutdowns for 7000 hours of operation (about a year in a normal situation). Each automatic shutdown creates thermal and hydraulic transients that effects NPP systems and requires removal of decay heat. A lower number is better.
Industrial Safety Accident Rate	Number of accidents among employees that results in loss of work time, restricted work, or fatalities per 200 000 work hours and 1 000 000 work hours. A lower number is better.
Collective Radiation Exposure	The total radiation dose received per reactor unit, measured in Person-Sieverts This monitors the effectiveness of the personnel radiation protection system. A lower number is better.
Unit Capability Factor	Percentage of the maximum energy generation that a NPP is capable of supplying to the electrical grid, limited only by factors within the control of NPP management. The factor measures effective NPP programmes and practices to minimize unplanned energy losses and to optimize planned outages. A higher number is better.
Unplanned Capability Loss Factor	Percentage of maximum energy generation that a NPP is not capable of supplying to the electrical grid because of unplanned energy losses, such as unplanned shutdowns or outage extensions. A low value indicates important plant equipment is well maintained and there are few outage extensions.
Forced Loss Rate	Percentage of energy generation during non-outage periods that the NPP is not capable of supplying to the electrical grid because of unplanned energy losses, such as unplanned shutdowns or load reductions. A low value indicates important SSCs are well maintained and reliably operated.

IV.3.4. WANO cooperation activities with the IAEA

The IAEA first signed a MoU with WANO in 1999. In 2013, a new MoU was signed to increase cooperation between the two organizations following the Fukushima Daiichi accident. The objective of the new MoU is:

> "To work more closely together to support the safe and reliable operation of NPPs worldwide, and to enhance information exchange on operating experience and other relevant areas".

[109] Taken from WANO Performance Indicators 2012

IV.4. SAFETY RELEVANCE OF INTERNATIONAL STANDARDS MAKING BODIES

From the definitions for standard shown in Table 43, it is inferred that nuclear standards are public documents constructed by experts and approved by registered organizations with the aim of ensuring reliability and safety of nuclear products and services. An international standard is a standard produced and adopted by an international accredited organization and made available to anybody requesting it. Standards by themselves are not mandatory unless referenced in legislation or introduced into a legal contract.

TABLE 43 DEFINITION FOR STANDARD[110]

International Organization for Standardization	A standard is a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose.
International Electrotechnical Commission	A standard is a document, established by consensus and approved by a recognized body that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.
The Institute of Electric and Electronic Engineers	Standards are published documents that establish specifications and procedures designed to maximize the reliability of the materials, products, methods, and/or services people use every day.

Most Member States with operating NPPs have a national standard organization to cover nuclear applications. In addition to the IAEA, there are other international organizations that also develop standards for various technologies, including nuclear standards.

IV.4.1. International Organization for Standardization (ISO)

ISO was created in 1946 as an initiative of the United Nations to facilitate the international coordination and unification of industrial standards. Its membership currently comprises the national standards bodies of 86 countries, covering over 95% of the world's industry and every area of technology. The ISO has a Central Secretariat in Geneva and Technical Secretariats located in 29 countries.

ISO conducts its work through technical committees, which usually create sub-committees and working groups to cover specific topics. At any given time, some 100.000 experts from all over the world are engaged in ISO activities.

There are two ways of producing ISO standards:

- A new standard is proposed by experts; or,
- National standards organizations require that a given subject is harmonized and presented as an ISO standard.

In both cases it is expected that the individual countries will endorse the ISO standard superseding any national standard.

[110] These definitions are taken from the organizations' websites.

IV.4.1.1. ISO activities on nuclear energy standards

The ISO development of nuclear energy standards is conducted within Technical Committee 85 (Nuclear Energy ISO/TC 85) created in 1957. Most countries with developed nuclear technology participate in the activities of Nuclear Energy ISO/TC 85. The programme of work is divided into four subcommittees.

Subcommittee 1 maintains 33 standards in the area of terminology, definitions, units and symbols and created ISO 361:1975, the ionizing radiation warning symbol. SC 1 also published ISO 921:1997, a vocabulary of nuclear terms in English, French and Russian later extended to radiological protection, nuclear fuel cycle and dosimetry for radiation processing. SC 1 also maintains 28 standards issued with the ASTM[111] mainly on materials used in radiation dosimetry.

The subcommittee on radiation protection includes more than 100 standards covering all aspects of radiation uses in industry, medicine and irradiation; it also covers all aspects of radiation protection, including radioactive sources, external and internal dosimetry and radioactive contaminants.

The subcommittee on fissile materials and nuclear fuel cycle has published close to 50 standards on the analysis of the chemical and physical properties and isotopic composition of nuclear materials, such as $U0_2$, UF_6 and Pu, non-destructive methods for the determination of transuranic elements in solid waste, packaging and transport as well as performance requirements to avoid criticality.

The subcommittee on reactor technology has issued many standards, some of which are discussed below.

IV.4.1.2. Relationship between ISO and IAEA

At a seminar on the selection and implementation of safety standards for NPPs, jointly sponsored by the IAEA and ISO in 1980, there was general agreement that the ISO standards were complementary to the IAEA codes and guides. It was also concluded that ISO produced technical standards with emphasis on industrial and contractual aspects, while the IAEA standards were more regulatory in nature. This led the IAEA and ISO to sign a formal MoU in 1981.

The MoU stated:

> "The ISO recognizes the responsibilities of the IAEA… in particular with regard to the establishment of standards of safety for the protection of health… which are primarily addressed to national regulatory bodies".

and:

> "The IAEA recognizes the responsibilities of the ISO as a specialized international institution for matters of standardization, having as its objectives the facilitation of international exchange of goods and services [...]".

[111] American Society for Testing Materials, and now ASTM International is mainly concerned with all types of materials, including materials for nuclear SSCs. It is another example of an initially US standards organization becoming recognized worldwide.

ISO/TC 85 representatives participate in the IAEA Safety Standards Committees and IAEA Staff attend meetings of ISO/TC 85 and its subcommittees.

By the mid-1990s ISO had produced its ISO 9000 series of quality standards on design [92], production [93] and inspection [94] of industrial systems and components. At the time, the IAEA had developed its Code of Practice for Quality Assurance of Nuclear Power Plants and a number of Safety Guides [95]. The IAEA requirements were mainly used to establish nuclear safety requirements at the interface between the regulatory body and the NPP, while the ISO 9000 series standards have progressively been used to implement the quality assurance requirements at the interface between the NPP and its suppliers. In 2000, the IAEA published TECDOC-1182 [96], which provides a comparison between the IAEA and ISO requirements and provides guidance on how IAEA requirements should be transmitted to suppliers so all three parties are satisfied.

IV.4.1.3. International Electrotechnical Commission (IEC)

The IEC is the world's leading organization that prepares and publishes international standards for all electrical, electronic and related technologies. It was founded in 1906 to provide a platform for companies, industries and governments to meet, discuss and develop worldwide standards on all types and forms of electro technology applications.

All IEC standards are based on consensus and represent the needs of key interested parties of every member country participating in IEC work. Every member country, no matter how large or small, has one vote and a say in what goes into an IEC standard. Over 10 000 experts from industry, commerce, government, test and research laboratories, academia and consumer groups from 82 member countries—representing about 80% of the world population and 95% of the electricity generated—participate in IEC standardization work.

When ISO was created in 1946, the IEC was affiliated to ISO and, while preserving its autonomy, has served since then as the de facto electrical division of ISO. ISO, IEC and the International Telecommunication Union work together with joint committees that ensure international standards combine all relevant knowledge.

The IEC Standardization Management Board is responsible for the overall management of the IEC's standardization activities using technical committees, technical advisory committees and strategic groups. The technical committees may create subcommittees. In total there are 175 committees and subcommittees.

Technical committee IEC/TC45 deals with nuclear instrumentation. It has two subcommittees: IEC/SC45A on I&C for nuclear facilities; and IEC/SC45B on radiation monitoring instrumentation. There are also eight active working groups. Subcommittee IEC/SC45A maintains a portfolio of more than 60 standards.

IV.4.1.4. Relationships between the International Electrotechnical Commission and IAEA

The IAEA and IEC signed an agreement in 1981 to ensure coordination between the two organizations, with the IAEA responsible for developing safety principles and requirements and IEC/SC45A responsible for developing detailed standards implementing those safety principles and requirements. IEC/SC45A representatives are invited to participate in the IAEA technical groups on I&C and review proposed document drafts and IAEA representatives are invited to participate in the IEC/SC45 meetings.

As a result of this collaboration more than 30 IEC/SC45A standards have been developed, including eight in the domain of digital technology, to implement IAEA Safety Guide NS-G-1.3 [97] on I&C Systems Important to Safety in NPPs.

IV.4.2. American Society of Mechanical Engineers (ASME)

The invention of the steam engine in the late 18th century brought an emergent development of boilers to provide the steam necessary to generate mechanical energy for manufacturing and transportation. To increase steam engine efficiency, the temperature of the steam was augmented followed by a raise in the pressure within the boiler. Safety was not a major concern until thousands of boiler explosions had occurred in Europe and North America, some of which resulted in many deaths. The ASME, created in 1880, clearly understood that the design and operation of boilers needed to be standardized to improve safety, increase reliability and reduce cost. The first edition of the ASME Boiler and Pressure Vessel Code (BPVC) was developed in 1914 and was 114 pages. The 2013 version of the BPVC includes 28 books and 14.000 pages,

ASME has produced nearly 600 codes and standards covering many technical areas, including nuclear technology. Within ASME, the Council on Standards and Certification reports to the ASME Board of Governors. Under this Council, there are five standards developing supervisory boards that manage over 70 consensus committees with 4700 volunteer members and four advisory boards. The supervisory boards are responsible for pressure technology, nuclear installations, safety codes and standards, standardization and performance test codes and conformity assessment. The supervisory boards in turn have standards committees, each responsible for an area of standards development. The advisory boards deal with strategic initiatives, energy and environmental standards, hearings and appeals and council operations.

A request for a code or standard may come from an individual, a committee, a professional organization, a government agency, an industry group, a public interest group, or from an ASME division or section. First, the request is referred to the appropriate supervisory board for consideration. The board assigns the request to an existing committee or determines that a new standards committee must be formed. Once a committee has concluded that there is enough interest and need, the standards development process begins.

ASME standards have played a vital role in supporting the nuclear industry since its inception. Its widely-adopted BPVC Section III, Rules for Construction of Nuclear Facility Components, celebrated 50 years in 2013. Likewise, Section XI, Rules for Inservice Inspection of Nuclear Power Plant Components, is also widely used. Presently, half of the world's NPPs incorporate all or portions of ASME nuclear codes and standards in their construction, operation, and maintenance. Sixty nations generally recognize and apply the BPVC, while 30 of the 44 nuclear nations purchase their nuclear components to specifications contained within ASME's nuclear codes and standards.

IV.4.3. Institute of Electric and Electronic Engineers (IEEE)

IEEE, an association dedicated to fostering technological innovation and excellence for the benefit of humanity, is the world's largest technical professional society. Its core purpose is to foster technological innovation and excellence for the benefit of humanity. Its vision is:

> "IEEE will be essential to the global technical community and to technical professionals everywhere, and be universally recognized for the contributions of technology and of technical professionals in improving global conditions".

IV.4.3.1. Creation and development of IEEE

In 1884, a small group of individuals in the new electrical professions formed the American Institute of Electrical Engineers (AIEE). As electric power spread, enhanced by innovations, long distance electricity transmission and large scale power plants, the AIEE became increasingly focused on electrical power and led the growth of the electrical engineering profession. In 1912, the Institute of Radio Engineers (IRE) was formed—using the AIEE as a model—and devoted its activities to radio and electronics. Membership in both societies grew, and in 1963, in recognition of their similar activities, merged to become the IEEE. Today, the IEEE includes 38 Societies and ten technical Councils and has more than 1500 standards and projects under development, including more than 100 standards, guides and recommendations for NPPs.

IV.4.4. Common IEC/IEEE activities on NPPs

In 2008 the IEC and the IEEE created the IEC/IEEE 62582 series of standards: Nuclear Power Plants-Instrumentation and Control Important to Safety - Electrical Equipment Condition Monitoring Methods. IEC/IEEE 62582 establishes, for the first time, a worldwide common standard of a series of condition monitoring techniques that can be selected and applied to establish the actual condition of new or installed equipment.

ABBREVIATIONS

ALARA	As Low As Reasonably Achievable
EURATOM	European Atomic Energy Community
FAO	Food and Agriculture Organization of the United Nations
GSR	General Safety Requirements
I&C	Instrumentation and Control
IACRNE	Inter-Agency Committee on Radiological and Nuclear Emergencies
IAEA	International Atomic Energy Agency
IEC	The IAEA Incident and Emergency Centre
INPO	Institute of Nuclear Power Operations
INSAG	International Nuclear Safety Group
MoU	Memorandum of Understanding
NPP	Nuclear Power Plant
OECD	Organisation for Economic Co-operation and Development
PSA	Probabilistic Safety Assessment
PSR	Periodic Safety Review
SARCoN	Systematic Assessment of Regulatory Competence Needs
SAT	Systematic Approach to Training
SSCs	Structures, systems, and components
SSR	Specific Safety Requirements
TSO	Technical Support Organization
WANO	World Association of Nuclear Operators
WHO	World Health Organization
WMO	World Meteorological Organization

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CONTRIBUTORS TO DRAFTING AND REVIEW

Alonso, A.	Consultant, Spain
Andersson, K.	Karita Research, Sweden
Asfaw, K. E.	International Atomic Energy Agency
Britten, I.	Consultant, United Kingdom
Delves, D.	International Atomic Energy Agency
Gil Martin, J.	International Atomic Energy Agency
Kraft, Florien	Autorité de Sûreté Nucléaire, France
Lacey, D.	International Atomic Energy Agency
McDermott, C	Consultant, Canada
Moracho-Ramirez, M.J.	International Atomic Energy Agency
Nestoroska Madjunarova, S.	International Atomic Energy Agency
Nicic, A.	International Atomic Energy Agency
Polyakov, A.	International Atomic Energy Agency
Prohaska, G	International Atomic Energy Agency
Reiman, L.	Radiation and Nuclear Safety Authority, Finland
Sammadar, S.	International Atomic Energy Agency
Schwarz, G.	Consultant, Canada
Shokr, A.	International Atomic Energy Agency
Svab, M.	International Atomic Energy Agency
Ulses, A. P	International Atomic Energy Agency
Wells, P.	International Atomic Energy Agency
Vatov, S. Y.	International Atomic Energy Agency
Zimmermann, M.R.	International Atomic Energy Agency