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IAEA-TECDOC-2013

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Experiences of Regulatory Bodies and Owner/Operator Organizations in Developing Management Systems for New Nuclear Power Programmes

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International Atomic Energy Agency

EXPERIENCES OF REGULATORY BODIES AND OWNER/OPERATOR ORGANIZATIONS IN DEVELOPING MANAGEMENT SYSTEMS FOR NEW NUCLEAR POWER PROGRAMMES

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INTERNATIONAL ATOMIC ENERGY AGENCY
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FOREWORD

Launching a nuclear power programme is the decision of every country and constitutes a major undertaking requiring careful planning, preparation and investment in time, institutions, finances and human resources.

The IAEA has published a three phase comprehensive methodology for the development of a national infrastructure for nuclear power in IAEA Nuclear Energy Series No. NG-G-3.1 (Rev. 1), Milestones in the Development of a National Infrastructure for Nuclear Power. Known as the Milestones approach, it enables a Member State to understand the various aspects governments and key organizations need to consider for successful implementation of a nuclear power programme.

The IAEA's Milestones approach identifies 19 infrastructure issues that need to be addressed in each of the three phases. Infrastructure issue No. 3 (Management) emphasizes the need for management systems to be developed by three key organizations with a major role in developing the nuclear power programme: the nuclear energy programme implementing organization (NEPIO), the regulatory body and the owner/operator.

In Phase 1 and at the beginning of Phase 2, the NEPIO implements the majority of activities that will have an impact on the further development of the programme. Therefore, it is important to maintain the traceability of studies performed, surveys carried out and decisions taken, which can only be achieved through an appropriate management system with documented and agreed processes and procedural arrangements.

As stated in the Milestones approach, it is also the responsibility of the NEPIO to capitalize on the lessons identified at the end of Phase 1 and ensure adequate knowledge transfer to the organizations that will develop the programme from Phase 2.

In Phases 2 and 3 the regulatory body and the owner/operator develop and implement most of the activities in preparation for the construction of the nuclear power plant. The Milestones approach emphasizes that from the beginning these organizations develop management systems that are consistent with the main planned activities and recognize safety and security as a top priority.

This publication presents the experience of regulatory bodies and owner/operator organizations in advanced embarking countries that are planning and implementing management systems for their nuclear power programmes. The target users are decision makers and managers in NEPIOs, regulatory bodies and owner/operating organizations.

The IAEA is grateful to those who assisted in the drafting and review of this publication. The IAEA officer responsible for this publication was F. Bourdin of the Division of Nuclear Power.

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1. INTRODUCTION

1.1. BACKGROUND

Organizations involved in a new nuclear power programme are expected to establish and maintain management systems in line with the requirements of the IAEA Safety Standards Series No. GSR Part 2 (see Ref. [2]) to ensure consistency in practices and quality of the work undertaken. Those management systems are expected to reflect the activities to be implemented at different phases and need to be adjusted as the programme evolves.

The IAEA Milestones publication (see Ref. [1]) provides a logical framework for the implementation of a new nuclear power programme and explains the focus of key organizations in each phase. In addition, the IAEA database entitled 'Nuclear Infrastructure Competency Framework' can be used to identify key activities in each phase. Countries in Phase 2 are ready to take a decision or already decided and are preparing the infrastructure for a NPP. Phase 3 countries have their first NPP contract under negotiation or signed or have the first NPP under construction.

Deficiencies or the absence of management systems in organizations involved in nuclear power programmes were identified in several embarking countries through the IAEA Integrated Nuclear Infrastructure Review (INIR) missions as well as through other expert missions. The observations, for embarking countries in Phases 2 and 3, vary from a complete absence of management systems to situations where management systems are only partially implemented for some selected activities.

1.2. OBJECTIVE

The primary objective of this publication is to present the experiences of key organizations in different Member States engaged in implementing management systems in compliance with relevant international standards and national regulations to carry out their activities in a controlled and reproducible manner. The publication also provides insights on IAEA existing publications relevant to the topic.

1.3. SCOPE

This publication focuses on the development of integrated management systems (IMS) by selected Regulatory Body and Owner–Operator organizations, which are currently engaged in the process of developing their management systems or that have developed their management systems to support new nuclear power programmes.

1.4. STRUCTURE

Section 2 provides an introduction on the importance of management systems in the development of a nuclear power programme and project, and an overview of the IAEA publications relevant to developing a management system.

Section 3 provides a high-level summary of the lessons learned through the IAEA's peer review services and assistance provided to the Member States in support of the development of the management systems of key organizations involved in management, oversight, licensing, or inspection of nuclear power plants construction projects.

Section 4 provides an overview of experience of the contributing organizations in developing an integrated management system in the frame of a future or existing nuclear power plant project.

The Appendices provide a summary of the case studies considered in this publication, while the full case studies are available online as working material on the *NIDS Interactive Platform*.

2. IMPORTANCE OF MANAGEMENT SYSTEMS IN THE DEVELOPMENT OF A NUCLEAR POWER PROGRAMME

2.1. BENEFITS OF IMPLEMENTING MANAGEMENT SYSTEMS

A sustainable and successful management system gives assurance that nuclear safety, security, and safeguards matters are not dealt with in isolation. It integrates, *inter alia*, safety, security, safeguards, health, quality, economic and environmental issues to ensure that all the processes involved in carrying out the mission of the organization are planned, organized, led and controlled in a systematic documented way, and that decisions are taken with due consideration of all issues. The IAEA referenced publication (see Ref. [2]) provides details in these areas.

When organizations develop management systems in silos[1], this can lead to conflicting requirements, priorities and practices. An integrated management system aims to improve on this by combining all systems and processes into one complete framework, enabling an organization to work as a single unit with unified objectives. Establishing such framework improves efficiency ensuring a more comprehensive decision-making process.

Among the many reasons why integrated management systems are beneficial to organizations, the most noticeable are to:

- Focus on the organization's performance objectives;
- Enhance safety culture, security culture, leadership skills as well as safety–security interfaces;
- Promote safety as paramount over all else;
- Meet regulatory requirements, and other applicable laws;
- Promote an organizational culture and cross-functional engagement;
- Reduce risks, uncertainty, and inconsistencies by formalizing the organization's processes and interfaces while clarifying the roles and responsibilities;
- Improve internal and external communication;
- Facilitate systematic approach to getting work done;
- Help define competency requirements and a systematic approach to training;
- Drive continuous improvement.

An important aspect to keep in mind is that building a management system requires assessing the risks associated with the processes and activities of the organization (for example according to their maturity, complexity, or importance for safety). This will lead to the appropriate magnitude of controls, informed decision-making, measures, training, qualification, inspections, or detailed procedures commensurate with the risks identified. This approach is referred to as 'graded approach in the implementation of the management system'.

Overall, a management system is an efficient tool for an organization to support the effective and dependable achievement of its objectives. It also provides leaders and managers with a tool for promoting and deploying a safety culture across the organization. Finally, the management system can also be used to show transparency and openness for decision-makers and stakeholders involved in these activities.

[1] E.g., Quality Management System (QMS), Environmental Management System (EMS), Occupational Health and Safety Management System, etc.

2.2. IAEA REQUIREMENTS AND GUIDANCE

There is a broad set of IAEA publications that will help the key organizations develop their management systems. Below are some of the most relevant for a nuclear power programme.

Safety Requirements – General Safety

— Leadership and Management for Safety, IAEA Safety Standard Series N. GSR Part 2 (see Ref. [2])

Safety Guides – General Safety

— Organization, Management and Staffing of the Regulatory Body for Safety, IAEA Safety Standards Series No. GSG-12 (see Ref. [5]);
— Functions and Processes of the Regulatory Body for Safety, IAEA Safety Standards Series No. GSG-13 (see Ref. [6]);
— Application of the Management System for Facilities and Activities, IAEA Safety Standards Series No. GS-G-3-1 (see Ref. [7]);
— The Management System for Nuclear Installations, IAEA Safety Standards Series No. GS-G-3.5 (see Ref. [8].

Nuclear Energy Series Guide

— Development and Implementation of a Process Based Management System, IAEA Nuclear Energy Series No. NG-T-1.3 (see Ref. [9]).

IAEA TECDOC Series

— Use of a Graded Approach in the Application of the Management System Requirements for Facilities and Activities, IAEA TECDOC-1740 (see Ref. [10]).

2.3. PHASED DEVELOPMENT OF MANAGEMENT SYSTEMS

The activities undertaken by an organization change as the nuclear power programme moves forward from one phase to another.

TABLE 1 presents some typical activities identified with the support of the 'IAEA Nuclear Infrastructure Competency Framework' database for the Owner–Operator and for the Regulatory Body in Phases 2 and 3 of the Milestones Approach (see Ref. [1]). It reflects the changing nature of the activities over time.

As an example, the focus of the Owner–Operator in Phase 2 is on developing the organization, recruiting and training staff, developing the bidding process, or structuring the negotiations with a preferred technology provider, etc. Therefore, the core processes of the management system of the Owner–Operator for that phase are expected to reflect those activities.

As the programme moves to Phase 3, the Owner–Operator shifts its focus to reviewing the safety documentation provided by the technology provider, applying for the construction license and be ready to respond to Regulatory Body requests, oversee construction, etc. Therefore, the management system of the Owner–Operator (in particular, the core processes) is expected to change or to expand to reflect these new core activities.

The same dynamic is observed for the Regulatory Body where the focus is on recruiting and training, developing the management system, the licensing process and regulations and guides in Phase 2 and expands to reviewing license applications, issuing licenses, and inspecting construction and commissioning in Phase 3. It would be expected that the management system of the Regulatory Body also reflects these changes.

TABLE 1. SOME TYPICAL ACTIVITIES FOR THE OWNER-OPERATOR AND FOR THE REGULATORY BODY IN PHASES 2 AND 3

Organization	Phase 2 **Preparatory work for the construction of a nuclear power plant after a policy decision has been taken**	Phase 3 **Activities to implement the first nuclear power plant**
Owner–Operator	– Recruit and train staff; – Conduct environmental impact assessment; – Conduct site selection; – Apply for a site license; – Prepare bid/contract negotiations; – Develop a stakeholder involvement plan; – Develop and implement a management system – Contract with services providers.	– Negotiate and sign the NPP contract; – Review Preliminary Safety Analysis Report (PSAR) and other safety documentation provided by the Engineering, Procurement and Construction (EPC) contractor; – Apply for a construction license; – Supervise EPC contractor and supply chain during construction; – Apply for operating license; – Prepare the organization for commissioning and operation.
Regulatory Body	– Recruit and train staff; – Develop and implement a management system; – Issue regulations and guides; – Contract with Technical Support Organization (TSO).	– Review and assess licensing application documents; – Develop and implement a regulatory inspection programme for oversight of construction and commissioning; – Prepare for the operational phase.

3. LESSONS LEARNED FROM IAEA SERVICES

Three different services offered by the Agency have been considered hereafter, which all include a component on management systems:

— INIR missions: IAEA Integrated Nuclear Infrastructure Review (INIR) missions (see Ref. [11]) are designed to assist Member States in evaluating the status of development of their national infrastructure for nuclear power to achieve the milestone relevant to the phase subject to the mission. The INIR missions cover the 19 infrastructure issues described in the Milestones publication (see Ref. [1]) and the assessment is based on the analysis of the self-evaluation report prepared by the Member State, review of the supporting documents and interviews with key officials.

— IRRS missions: IAEA Integrated Regulatory Review Service (IRRS) (see Ref. [12]) helps host States strengthen and enhance the effectiveness of their regulatory infrastructure for nuclear, radiation, radioactive waste and transport safety. Module 4 of IRRS covers Regulatory Body's management system.

— Pre-OSART missions: Pre-Operational Safety Assessment Review Team (pre-OSART) missions are carried out during the construction and commissioning phase of a new nuclear power plant, with the objective to support the Owner–Operator in meeting high quality and safety standards in construction and commissioning and demonstrate readiness for operation.

3.1 INIR MISSIONS

INIR missions conducted in the past ten years observed on the topic of management systems (Infrastructure Issue No. 3) the following gaps:

— Most Phase 1 INIR missions identified the need for the NEPIO to improve its understanding of the IAEA safety standards in the area of management systems and develop plans and guidance to implement appropriate and phased management systems in the key organizations involved in the nuclear power programme;

— Most Phase 2 INIR missions observed that the organizations have initiated the development of management systems to cover the activities of Phase 2. However, in most cases they were not completed or not implemented effectively. The need to further develop management systems to cover Phase 3 in each of the key organizations, including the need to continue the development of a safety and security culture, was also identified.

3.2 IRRS MISSIONS

Feedback from the implementation of Module 4 over the period 2015–2019 (33 initial missions and 20 follow-up missions) shows that most of the Phase 2 and Phase 3 missions recommended or suggested that the Regulatory Body develop, implement and improve its integrated management system, in accordance with GSR Part 2 requirements (see Ref. [2]).

In Phase 2, typical recommendations or suggestions point out the need for the Regulatory Body to:

— Identify, develop, and document all key processes contributing to safety;

— Develop a safety policy;
— Assign the necessary resources for the development and implementation of the management system;
— Appoint an individual with responsibility and authority for the coordination of the development and implementation of the management system;
— Develop and improve safety culture.

In Phase 3, typical recommendations or suggestions indicate that the Regulatory Body needed to:

— Develop and implement processes for both self-assessment and independent assessment of the management system;
— Further improve descriptions of the graded approach to be used in different areas of activities;
— Consider having all policies integrated in the IMS and available to all staff;
— Apply continuous improvement to assessing leadership for safety and safety culture.

3.3 PRE-OSART MISSIONS

Following the three (3) pre-OSART missions conducted in new NPPs over the period 2016–2018, the *OSART Mission Highlights 2016–2018. Operational Safety Practices in Nuclear Power Plants* report available as 'Working Material' on the IAEA website identifies four (4) areas for improvement, namely:

1. Organization and management of commissioning: generic lacks were found in areas such as plant systems handover from commissioning to operation, competence of personnel for first core load, availability of adequate documentation in main control room, effectiveness of control activities before fuel loading, equipment ownership and commitment for staff protection during commissioning;
2. Implementation of the commissioning programme: in many cases, equipment was not appropriately protected during commissioning;
3. Control of plant configuration: design changes during construction and commissioning are not systematically reflected in operating or maintenance procedures and training;
4. Use of Operational Experience Feedback (OEF): it was observed that the OEF process did not prevent the same event to reoccur, in particular due to insufficient root cause and trend analysis and lack of experience of the personnel involved in the OEF process.

4. SUMMARY OF CASE STUDIES

4.1 OVERVIEW

4.1.1 Case study data collection and analysis

A template for individual case studies was developed with headings and guide questions (referred to as 'points of interest' in this document) to elicit consistent information. Expert counterparts were identified in four regulatory bodies and three Owner–Operators in four different countries, namely the Republic of Ghana, the Republic of Poland, the Republic of Türkiye, and the United Arab Emirates. The experts were requested to provide information using the template about their organizations' experiences in developing and implementing a management system.

The information gathered in the completed case study questionnaires was reviewed and analysed to identify common trends, differences and notable lessons in each area of the questionnaire.

All the management systems in the case studies considered are process based. A summary of the findings from the case studies is presented in the following Sections of this publication.

4.1.2 Status of nuclear power programmes in case study Member States

Each country that provided responses to the study is at a different Milestones phase in the development of their nuclear infrastructure. The status of the nuclear power programme and the respective organizations in each country is outlined below:

- REPUBLIC OF GHANA (Ghana):

  The Government of Ghana decided in 2012 to pursue a nuclear power programme for peaceful applications. Since then, four organizations have been established to implement the nuclear power programme, namely:

  — Ghana Nuclear Power Programme Organization (GNPPO): the NEPIO,
  — Nuclear Power Ghana (NPG): the potential Owner–Operator,
  — Nuclear Power Institute (NPI): the TSO, and
  — the Nuclear Regulatory Authority (NRA): the nuclear regulator.

  GNPPO was established to coordinate the development of national nuclear infrastructure based on the IAEA Milestones Approach. The former Nuclear Power Centre at the Ghana Atomic Energy Commission (GAEC) became in 2015 the Nuclear Power Institute, the main technical body of GNPPO. The Nuclear Regulatory Authority backed by the Nuclear Regulatory Authority Act No. 895 of 2015 was established in 2016. In 2018, the Cabinet approved the establishment of Nuclear Power Ghana (NPG) as the potential project organization. The core human resource of the NPG was recruited from NPI and the two hydroelectric power plant operators in the country: the Volta River Authority (VRA) and the Bui Power Authority (BPA), which were stakeholders of the GNPPO.

  Ghana hosted an IAEA Integrated Nuclear Infrastructure Review (INIR) mission in 2017. GNPPO has submitted a Comprehensive Report on the nuclear programme to

the Government in 2020, which marks the completion of Milestone 1 for Phase 1 activities. Some Phase 2 activities have begun.

- REPUBLIC OF POLAND (Poland):

  Poland presently operates the Maria Research Reactor at the National Centre for Nuclear Research. In the early 1980s, the construction of Żarnowiec Nuclear Power Plant was started in the today's Pomorskie Province but the unfinished project was abandoned in 1990. Efforts to renew Poland's nuclear power programme began in 2009. The Polish Government designated Polska Grupa Energetyczna (PGE) as the leading entity for construction of Poland's first nuclear power plant. PGE's wide experience in the completion of large investments as well as its stable economic standing and financial capability were decisive factors. In 2014, the Government engaged domestic business partners to support PGE in financing a joint venture known as PGE EJ 1. In March 2021, the State Treasury took over all the shares in the PGE EJ 1, now renamed PEJ, to ensure financing and development of the national programme.

  In 2020, the Government approved the revised Polish Nuclear Power Programme with the objective of constructing and commissioning 6 to 9 GWe of nuclear capacity based on proven, Generation III (+) pressurized water reactors, with the first unit scheduled to be commissioned in 2033.Within the Polish Nuclear Power Programme, the National Atomic Energy Agency (PAA) performs the role of nuclear regulator. PAA was established in 1982 in connection with the first efforts at a nuclear power program. PAA's activities are now regulated by the 29 November 2000 Atomic Law and the relevant secondary legislation.

  The Polish Nuclear Power Programme is in Phase 2 of the IAEA Milestones Approach.

- REPUBLIC OF TÜRKİYE (Türkiye):

  In 2010, the Government of Türkiye concluded with the Russian Federation an agreement for *Cooperation in Relation to the Construction and Operation of a Nuclear Power Plant at the Akkuyu Site in the Republic of Türkiye*. The facility at Akkuyu will consist of four AES2006 VVER-1200 units owned by Akkuyu Nükleer AŞ, a Russian-owned project company. The construction license for the first unit was issued in April 2018 and the lead unit is planned to be commissioned in 2023. Similar units exist at Novovoronezh NPP-2 in the Russian Federation.

  A second project following comparable lines is under consideration for the Sinop site on the coast of the Black Sea. In July 2018, the Government enacted a comprehensive nuclear law known as Decree Law No. 702, establishing a new independent Regulatory Body named Nükleer Düzenleme Kurumu (NDK) (Nuclear Regulatory Authority) to take over the regulatory responsibilities formerly carried out by the organization known as TAEK.

  Türkiye is in Phase 3 of the IAEA Milestones Approach.

- UNITED ARAB EMIRATES (UAE):

In April 2008, the UAE Government published its *Policy of the United Arab Emirates on the Evaluation and Potential Development of Peaceful Nuclear Energy* which set out the rationale and goals for a proposed nuclear energy programme. In 2009, by the passage of Law by Decree No. 6 of 2009, the Federal Authority for Nuclear Regulation (FANR) was established to be the Regulatory Body. The Emirates Nuclear Energy Corporation (ENEC) was established in 2009 under the Abu Dhabi law to be the entity responsible for the deployment and ownership of nuclear energy plants. In 2016, the Nawah Energy Company (Nawah) was established as a subsidiary of ENEC to be the operating organization. In December 2009, ENEC announced the selection of a consortium led by the Korea Electric Power Corporation (KEPCO) to design, build and assist in operation and maintenance of four 1400 MW APR–1400 units.

A construction license was issued in 2012 for the first two units at the Barakah site located on the coast west of Abu Dhabi, followed in 2014 by the construction license for Units 3 and 4. In February 2020, FANR issued to Nawah the operating license for Unit 1. Unit 1 reached 100% full power output to the electrical grid in December 2020.The UAE have therefore completed Phase 3 of the IAEA Milestones Approach.

4.2 REQUIREMENTS FOR A MANAGEMENT SYSTEM

4.2.1 Nature of the issue

The IAEA has published detailed safety requirements for management systems in its Safety Standard Series No. GSR Part 2 (see Ref. [2]) and its associated guides. Standards from other standards-making bodies such as the International Organization for Standardization (ISO) are widely used in business and commerce. A Regulatory Body or Owner–Operator organization may be obliged by law to implement a management system in accordance with a specific set of requirements. Alternatively, in the absence of a legal obligation, the organization may decide voluntarily to develop a management system following a particular standard. Examples taken from a parent company, peers at home and abroad, or other sources can influence the approach taken.

4.2.2 Points of interest

The main points of interest related to management system are the following:

- What legal or regulatory requirements on management system are applicable (if any)?
- What relevant IAEA Standards and other IAEA guidance are used?
- What other international standards are being considered to develop the management system (see Ref. [13])? Has a gap analysis been conducted to identify the complementary requirements from the relevant IAEA publication(s)?
- How did the organization decide to comply with any non-mandatory standards and on which basis they were selected e.g., industrial practice or recommendation from similar organizations, TSO, or technology vendor?
- Were elements of the management system inspired by other experienced Member States, a similar organization in another country, TSO, or technology vendors?
- What other source of industrial best practices were considered when developing the management system?

— If the organization is an affiliate of a parent company, to what extent does the management system derive from the parent (e.g., use of corporate standards, company's culture, interfaces)?

4.2.3 Review of the case study evidence

National legislation sets out the functions and responsibilities of the regulatory bodies in each of the case studies. However, in no case does the legislation oblige the Regulatory Body to implement a management system, nor does the law require adoption of a specific management system standard. Each Regulatory Body in the study decided to develop its management system as a means of fulfilling its mandate given by law and to enable it to carry out its regulatory functions and responsibilities in an effective and dependable way.

All the regulatory bodies in the case study selected safety requirements described in the IAEA Safety Standards Series No. GSR Part 2 (see Ref. [2]) as the primary standard for their management systems. Several regulators also adopted additional standards to complement the IAEA requirements. ISO 9001:2015 (see ref. [13]) for quality management systems, is the standard most mentioned, while others include ISO 45001:2018 (see Ref. [18]) for occupational health and safety, ISO 27001:2013 (see Ref. [19]) for information security, and ISO/IEC 17025:2017 (see Ref. [20]) for testing and calibration laboratories. FANR in the UAE has obtained formal ISO certification for its management systems, while NDK in Türkiye has expressed its intention to do so.

Each Regulatory Body learned from practices in other countries. NRA in Ghana studied examples of the management systems of several other national regulators. The National Atomic Energy Agency (PAA) in Poland learned of good practices for auditing of management systems from its counterparts in Slovakia and Switzerland. NDK in Türkiye is supported by a cooperative programme with the EU.

The operators, on the other hand, work in a different context and are subject to regulatory requirements. In the case of PEJ in Poland, the nuclear law in Poland obliges organizations which conduct activities involving nuclear energy to implement a management system. Nawah was also obliged by the terms of the UAE nuclear law, as well as the regulations issued by FANR, to implement an integrated management system.

In all cases the operators identified the IAEA safety requirements as described in GSR Part 2 (or the former standard GS-R-3) and associated guides as the primary reference. Some Owner–Operator organizations also adopted complementary standards including ISO 9001 (see Ref. [13]) and other standards in the ISO series.

All the Owner–Operator organizations considered external practices in the development of their management systems. The sources of examples included benchmarking studies, advice given by TSOs or technical advisors, and policy decisions to harmonize with a parent or daughter organization.

4.3 RESPONSIBILITIES FOR THE MANAGEMENT SYSTEM

4.3.1 Nature of the issue

The development, implementation, maintenance, and improvement of the elements of a management system involve people at all levels across the organization. GSR Part 2 – Requirement 3 (see Ref. [2]) states that "Senior management shall be responsible for

establishing, applying, sustaining and continuously improving a management system to ensure safety." Senior management plays a critical role in the implementation or improvement of a management system. Their support and visible participation will positively impact the success of the project and the achievement of its goals. Senior management may appoint a project manager who prepares the implementation plan and leads a development team whose members may include departmental representatives, process owners, process developers and management systems specialists (see Ref. [9]).

4.3.2 Points of interest

The main points of interest are the following:

- How and by whom is the development of the management system promoted and supported (e.g., leadership and management roles, mission, and vision)?
- What is the specific organizational structure and responsibilities (e.g., project manager, process owner) and sharing of responsibilities between in-house resources and external service provider(s), to coordinate the development of the management system?
- Who is assigned to develop elements of the management system and the criteria for their selection (e.g., position in the organization or knowledge of the work to be described)?
- How is assessment of the implementation and effectiveness of the management system organized?
- What services have been received (or planned) from the IAEA in support of the development of the management system?

4.3.3 Review of the case study evidence

All case study organizations report that a senior management representative (for example, Director General, President, Management Board, Executive Director, Chief Nuclear Officer) sponsored and supported the development of the management system. In most cases, these senior executives supervised a steering committee, or a project team made up of staff drawn from across the organization.

Most organizations appointed a project leader to direct and coordinate the activities of a team or working group composed of nominated process owners and other staff. NPG in Ghana, PAA and PEJ in Poland, NDK in Türkiye, and FANR and Nawah in the UAE also report on the establishment of a permanent organizational position or unit for ongoing coordination and support of the management system.

The role of 'Process Owner' is common to all organizations in the case study. However, the nature of the process owner roles and responsibilities varies in some cases. For instance, at FANR the process owners are senior staff members or section managers who are responsible for monitoring the process and ensuring the documentation is kept up to date. In contrast, in PEJ in Poland, process owners have a degree of executive authority for requesting the resources needed to perform the process, forming the desired relationships with key process stakeholders, and achievement of the process objectives and Key Performance Indicators (KPIs).

Arrangements for assessment of the effective implementation of management systems vary. In countries whose nuclear programmes are still in an early phase, these arrangements have yet to be fully developed. PAA in Poland already uses some practices on self-assessment

(questionnaire and process review) and conducts internal audits and management reviews. NRA in Ghana reported that they have appointed internal auditors and plan further development of self-assessment procedures. NDK in Türkiye referred to its plan for management self-assessments at least annually and highlighted the intended use of external certification audits. NDK has appointed and trained internal auditors, and the first internal audit is scheduled for early in 2021. In the UAE, where the nuclear programme is relatively advanced against the Milestones framework, FANR reported having procedures covering management system audits and management review and Nawah also has developed self-assessment procedures.

Several organizations (FANR, NDK, PEJ and Nawah) mentioned employing an external advisor or service provider to support the development of the management system. All case study organizations describe assistance from the IAEA in the development of their management system, including the use of IAEA safety requirements and guides, expert and peer review missions, workshops, and training.

4.4 MANAGEMENT SYSTEM PLANNING AND DEVELOPMENT

4.4.1 Nature of the issue

To implement a process based management system is to implement organizational change. Experience has shown that the adoption of a structured approach provides the best likelihood of success, efficiency, and long-term sustainability. The IAEA publication entitled *Development and Implementation of a Process Based Management Systems*, NE Series No. NG-T-1.3 (see Ref. [9]) provides guidance on the considerations to be taken into account in planning the development of a management system e.g., identifying the activities, schedule, timelines and milestones, and project resource requirements for development, rollout and implementation of the management system.

4.4.2 Points of interest

The main points of interest are the following:

- What was the time frame and the sequence of development of the management system for the key elements: policies, manual, processes, procedures, work instructions, etc?
- How did the activities in Phases 2 and 3 in the nuclear power programme determine the priority for development of the elements of the IMS?
- What were the main changes done or planned when moving from one phase to another (e.g., from Phase 2 to Phase 3 and from Phase 3 to operation) and the rationale?
- How is a risk-based approach used to develop the management system, what were the main risks identified and how these were managed?
- Is specific software used to develop and maintain the management system?
- How are stakeholders identified, categorized, and managed throughout the system development and execution?

4.4.3 Review of the case study evidence

The organizations making up the case study took (or plan to take, where development is ongoing) an average of about three years to develop and implement their management systems. The minimum time was just over one year, and the longest was six years. Some countries reported a change in direction part-way through their projects. Some organizations (FANR,

Nawah, NRA and NPG) started from scratch, while PAA built on an existing management system, NDK built on a legacy inherited from a predecessor organization, and PEJ was obliged to use the documentation of the parent organization directly in its management system or as guidelines for developing its own regulations.

All organizations report that the development of their management system was synced with the progress, actual and planned, of the nuclear power programme. The regulatory organizations for instance focused first on the elements needed to support activities in the initial phases such as site evaluation and construction licensing. The operator organizations prioritized bidding, vendor selection and construction management before commissioning and operation. A challenge faced by managers in regulatory and operator organizations alike is delivering the products and services needed in the current phase while managing in parallel the development of tools and methods for future phases.

Several organizations have reportedly adopted a formal approach to risk management. They have generally defined a method via a process or a procedure, which is sometimes part of a risk management policy. When risks are identified, possibly using the Failure Mode and Effect Analysis (FMEA) method, mitigation measures are defined and may include more stringent controls or staff training depending on the nature or severity of risk. Risk monitoring is facilitated by keeping a risk register and involving process owners.

Several organizations employed commercially available software tools, intranet, and electronic document management systems to support the management system. Specific software was used in a few cases: Nawah and FANR both use a system called ARIS (Architecture of Integrated Information Systems) for document and workflow management, while PAA employs software called NND Integrum for describing processes, internal audits and corrective actions.

All organizations report having developed to some degree a formal stakeholder management process. Some responses address external stakeholders in the business environment, while others refer to stakeholders in the development of the management system.

4.5 DOCUMENTATION OF THE MANAGEMENT SYSTEM

4.5.1 Nature of the issue

IAEA GSR Part 2 – Requirement 8 states, in common with other standards on related subjects, that “The management system shall be documented. The documentation of the management system shall be controlled, usable, readable, clearly identified and readily available at the point of use.” (see Ref. [2]).

It further specifies in paragraphs 4.16 to 4.20 the minimum content of the documentation of the management system and the documents and records control requirements.

4.5.2 Points of interest

The main points of interest related to the documentation of the management system are the following:

- What is the overall hierarchy of documents in the management system and have changes to this hierarchy been necessary?
- What policies has the organization developed for different components of the IMS (such as Safety, Quality, Environment, Health and Safety, Security and Economy)?

— How are processes identified and described in the management system? (see examples in Ref. [9])). How are the risks identified for each process monitored? What are the roles and responsibilities of process owners in the organization?
— What lower-level documents (for example procedures, work instructions and records) are prepared in the management system?
— What process is established to control the development, approval, issuance, and revision of management system documents?
— How are all personnel notified of changes, including new documents, in the management system and how do managers ensure that staff understand and implement these changes?
— What system has been established to manage archiving of records, including retention policies and information security?

4.5.3 Review of the case study evidence

All case study organizations reported having created a hierarchy of management system documents. In most cases the document hierarchy took the conventional form of a pyramid comprising three to five levels, with policy-type documents and manuals at the top, and processes, procedures, work instructions and records on the lower tiers. A notable exception is PEJ which presented a 8-level document hierarchy which includes such additional levels as company regulations, vision, mission and key values, and codes. Three of the seven organizations reported that changes to the document hierarchy were either planned or had been implemented to accommodate new document categories.

All organizations report having either planned for or having developed policies as part of their management system documentation. In some cases, the policies cover the standard topics of safety and quality. PEJ reported identifying initially the need for many policies but narrowed the list to three to comply with IAEA GSR Part 2 (see Ref. [2]) namely, leadership and management for safety, quality, and security.

There are also examples of policies from PAA, FANR and Nawah covering other topics such as:

— Ethics and Compliance Foundation Policies;
— Enterprise Risk Management Policy;
— Business Continuity and Crisis Management Policy;
— Research Policy;
— Personal Data Protection Policy.

The three standard categories of processes described in the IAEA publication entitled *Application of the Management System for Facilities and Activities*, IAEA Safety Standard Series No. GS-G-3.1 (see Ref. [7]) namely *management* processes, *core* (in some cases, *main*) processes, and *support* processes are used by all case study organizations. The regulatory bodies generally identified their core processes from the functions and responsibilities set out in their enabling legislation, with the relevant IAEA safety guides as a reference. The Owner–Operator organizations, perhaps less tightly prescribed by law, developed their core processes according to their business needs. A particular challenge noted by some Owner–Operator organizations arises from the fact that their activities vary considerably during the phases of development of an NPP, from planning and procurement to oversight of supply and construction, to commissioning, then operation. PEJ settled on the inclusion of both ‘active’ and ‘inactive’

processes in the management system to address the needs of different phases of the nuclear power programme.

The roles assigned to process owners show some variety. In all cases, the process owner is responsible for the development of process documents, monitoring process effectiveness, and analysis of non-conformances. However, some organizations give the process owners a role in coordinating work activities across functions. Further, PEJ gives the process owners a degree of executive authority for requesting the resources needed for the process, forming the desired relationships with stakeholders, and achievement of the process objectives and KPIs.

A formal risk management process is reported by all case study organizations as being either implemented or planned. Some organizations identify risks down to the level of individual processes. Notably, at PEJ, identification of risks associated with each process is based on FMEA methodology and updated periodically and the results are used to define the grade of the process and applicable controls.

All case study organizations have created lower-level documents to support their processes. All organizations use procedures to describe a sequence of actions that are followed to complete one or more process steps. These procedures in most cases follow standard templates in each organization for format and content. Some, but not all, organizations also employ a further lower tier of work instructions. FANR, for instance, creates work instructions at the departmental level to give further implementation details as needed to support procedures. In contrast, NDK reports that it writes procedures in sufficient detail that work instructions are generally unnecessary.

A process (or a procedure) for control of management system documents has been established at all case study organizations. In most cases, the process describes the format and content of different categories of documents, and the actions required for creation, approval, issuance, revision, and withdrawal of documents. Most organizations progress by assigning either the process owner or a team of knowledgeable persons to draft a new or revised document, followed by broader review and resolution of comments, and finally management approval and issuance. Some organizations (FANR, PEJ and NPG) report that the initiation of a new or revised document requires justification and approval before proceeding to drafting. Commonly, the head of organization or a senior executive approves the higher-level documents in the management system.

All organizations have implemented methods for making current approved documents available to staff for use and for withdrawing obsolete documents. Several organizations make use of an intranet, Microsoft SharePoint, or a shared server under the control of the responsible management system personnel to make available the current versions of management system documents to their staff and to remove obsolete documents from use. Staff are notified of changes by email or through meetings and, in some cases, training is provided for new documents.

An electronic document management system (EDMS) is either implemented or planned in all case study organizations, along with the corresponding procedures for archiving and retention of records. Several organizations, having the status of governmental or public bodies, are required to comply with government regulations for security and control of records, including confidential personnel and security records. Organizations that operate an EDMS typically control user access by granting restricted access rights to personnel.

4.6 INTEGRATION OF THE COMPONENTS

4.6.1 Nature of the issue

In the past, organizations commonly maintained separate management systems for areas such as quality, safety and environmental protection. IAEA GSR Part 2 – Requirement 6 states that "The management system shall integrate its elements, including safety, health, environmental, security, quality, human-and-organizational-factor, societal and economic elements, so that safety is not compromised" (see Ref. [2]). IAEA Safety Standards Series No. GS-G- 3.1 (see Ref. [7]) also states that an integrated management system can provide several benefits together with enhanced safety and business performance.

4.6.2 Points of interest

The main points of interest related to the integration of MS components are the following:

- How does the management system integrate all components, e.g., Safety, Quality, Environment, Health and Safety, Security and Economics?
- What mechanism was used to ensure integration e.g., for decision making?
- What examples exist (e.g., nonconformance) showing how potential impacts of changes/deviations are assessed against the various components before a decision is made?

4.6.3 Review of the case study evidence

All case study organizations report that their management systems are intended to integrate the necessary components. Specific integration mechanisms mentioned by several organizations comprise the following:

- Organization wide plans and budgets;
- Processes and other management system documents directing execution of actions in planned, systematic way consistently with goals and requirements;
- Projects (cross-functional teams);
- Review and assessment within the IMS;
- Ongoing monitoring and supervision by the management.

PAA for instance reports that integration and meeting all relevant requirements is a principle and objective of the management system. It is assumed that integration is supported by the '*red threads'* of cascading goals and planning, the process approach, and safety priority in each element and action within the system.

Some regulatory bodies also have responsibilities for national oversight of security and safeguards which have to be given due priority along with safety. FANR reports that this '3S' (security, safety and safeguards) integration is achieved through the relevant IMS processes.

The application of ISO standards which follow a common structure, such as ISO 9001 (see Ref. [13]) and ISO 45001 (see Ref. [18]) is used in some instances to push integration. NDK reports that it intends to integrate ISO requirements for quality and occupational health and safety in its management system, whose scope covers regulatory control activities regarding nuclear energy and ionizing radiation, and to have its management system formally certified.

Regarding integration of IMS elements in decision making, most organizations responded that this is governed by the relevant processes. PEJ indicates that it categorizes decisions at three levels in terms of program and projects, process, and corporate level with different people responsible at each level.

4.7 GRADED APPROACH

4.7.1 Nature of the issue

The IAEA GSR Part 2 – Requirement 7 requires that:

"**The management system shall be developed and applied using a graded approach.**"

4.15. In accordance with GSR Part 7, the criteria used to grade the development and application of the management system shall be documented and include:,

- The safety significance and complexity of the organization, operation of the facility or conduct of the activity;
- The hazards and the magnitude of the potential impacts (risks) associated with the safety, health, environmental, security, quality, and economic elements of each facility or activity;
- The possible consequences for safety if a failure or an unanticipated event occurs or if an activity is inadequately planned or improperly carried out." (see Ref. [2]).

4.7.2 Points of interest

With regard to a graded approach for development and implementation of management system one point was of particular interest:

- How was grading the implementation of the management system translated into practice (e.g., graded oversight based on importance), with possible reference to the examples in the IAEA Safety Standard Series No. GS-G-3.1 (see Ref. [7])?

4.7.3 Review of the case study evidence

All the case study organizations reported that they apply a graded approach in the development and implementation of their management systems. Several organizations, notably NRA, PAA, and Nawah, described the factors considered in grading elements of their management systems as including: the hazards and risks associated with the activity, the complexity of the activity, and the consequences of inadequate performance of the process or procedure. Some organizations did not describe detailed methods for grading.

Among the case study organizations, it was reported that the graded approach is reflected in factors such as the following:

- Responsibility for the review and approval of management system documents (FANR, NDK);
- Level of controls applied to MS documents;
- Frequency of reviews of MS elements;
- Frequency of audits (PEJ);
- Expectations for assessment, evaluation, and qualification of suppliers (PEJ);

— Frequency and rigour of regulatory oversight of the Owner-Operator activities (NRA, PAA);
— Significance levels assigned to condition reports based on safety consequences (Nawah)
— Tighter controls put in place for safety-related artefacts as well as those critical to the safe and reliable operation of the NPP (Nawah).

4.8 IMPLEMENTATION OF THE MANAGEMENT SYSTEM

4.8.1 Nature of the issue

To implement a management system is to implement organizational change. IAEA Safety Standard Series No. GS-G-3.1 advises that:

"Implementing the management system demands the collaborative efforts of managers, those performing the work and those assessing the work. For satisfactory implementation, planning and the deployment of adequate resources are necessary. All individuals should be trained to ensure that they understand the management processes that apply to the performance of their work" (see Ref. [7]).

4.8.2 Points of interest

The main points of interest related to the implementation of management system were the following:

— How did each organization roll out the new management system; what change management challenges were experienced and how they were addressed?
— How were staff made aware of the management system (e.g., mandatory on-boarding training, on-the-job training, refresher training)?
— How does each organization ensure that people follow the management system, its processes, and detailed documents?
— How are personnel from vendors and suppliers made aware of requirements that derive from the management system arrangements?

4.8.3 Review of the case study evidence

The rollout and implementation of the management system was treated by several case study organizations as an organizational change. Common to their approaches were: engagement of people at different levels in the organization, open communication about the changes in responsibilities and methods of working, and consistent support from senior management. Three organizations, FANR, Nawah and NDK, commented that the newness of their respective organizations helped the implementation of the management system. Contrastingly, PAA reported that its longer history hindered adoption of the changes associated with the new management system.

Training is the main way by which staff are made aware of the management system in all case study organizations. In some cases, staff involvement in the development of process and procedures was another way of building awareness. Training included onboarding training for new hires, periodic refresher training, and specific training as required to address changes, in some cases led by management system personnel or the process owners, along with information made available on company intranets. Notably, PEJ trained all department directors, process owners, and selected executive personnel on the ISO 9001 standard (see Ref. [13]) up to the

level of internal auditor. NDK carried out activities for the development of management systems with national and international organizations, and training given to personnel who have roles within the management system has been a part of these studies.

Most organizations report that supervisors are responsible for ensuring that people follow the management system. At PEJ, each member of the management system team monitors the performance of their designated processes and can take prompt corrective action through collaboration with executive management. Compliance is promoted by involvement of staff in development of the elements of the management system and is reinforced by having adequate procedures and instructions. Supervisory oversight of staff is supported by management system assessment tools such as risk assessment, non-conformance and corrective action, and internal and external audits.

Procurement of goods and services from external providers in most cases is carried out in accordance with established management system processes. Some organizations are required to follow public-sector procurement rules. Management system requirements for suppliers are specified in the procurement contracts in some cases. PEJ reports that it prepares manuals on quality, environmental protection, and occupational health and safety for subcontractors, the specific requirements of which follow a graded approach. Before the commencement of contract performance, the contractor personnel are trained in the manuals and the contractual requirements. In addition, a vendor supply chain oversight team supervises contractors through audits and work controls. FANR indicated that its technical support organizations were briefed on the procedures and work instructions they were expected to follow and were given access to the relevant documents through an EDMS.

4.9 VALUES AND ORGANIZATIONAL CULTURE

4.9.1 Nature of the issue

GSR Part 2 – Requirement 12 states that "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" (see Ref. [2]).

4.9.2 Points of interest

The main points of interest were the following:

— How was the organizational culture developed throughout the organization and promoted by leaders and managers?
— Did the culture help or hinder the management system development and vice versa?

4.9.3 Review of the case study evidence

Leaders' actions to foster a strong safety culture are reported by several case study organizations. Nawah, for instance, referred to a set of organizational values built into the management system, consisting of a*ccountability, teamwork, safety, integrity, trust* and, forming the words 'AT SITE'. Nawah leaders regularly promote these values and hold themselves and all staff accountable for them. At the PAA, the rules and directions referring to safety as well as appropriate values, attitudes, and behaviours are set in the Safety Policy and the MS Manual. The management of the PAA aims at Safety Culture becoming a universal phenomenon at all levels of the organization. FANR's management system manual sets out the corporate values, and promotes an integrated safety, security and safeguards ('3S') culture to

enable sound and reliable regulatory decisions. Some organizations are still developing their safety culture approach. In Ghana, NRA has started a programme to implement a culture that places high priority on nuclear safety and security. NPG's research and benchmarking has led to the development of a policy on safety culture as well as the inclusion of safety culture as an integral part of the Ghana nuclear leadership programme.

The development of the management system in several organizations was helped by the perception among staff of the importance of safety and security. This was particularly true in newly formed organizations like FANR, NDK, and Nawah, where awareness of the organization mandate and values helped people to adopt the management system. On the other hand, at PAA, which is a longer established organization, cultural aspects that hindered implementation included the autonomy of individual departments to continue their habitual ways of working, and staff being unaccustomed to current/timely updating of the written procedures.

4.10 MEASUREMENT, ASSESSMENT, AND IMPROVEMENT OF THE MANAGEMENT SYSTEM

4.10.1 Nature of the issue

GSR Part 2 – Requirements 13 and 14 state that "the effectiveness of the management system shall be measured, assessed, and improved to enhance safety performance, including minimizing the occurrence of problems relating to safety"; and that "senior management shall regularly commission assessments of leadership for safety and of safety culture in its own organization" (see Ref. [2]).

4.10.2 Points of interest

The main points of interest in the context of measurement, assessment and improvement of the management system were the following:

- How are non-conformances identified and managed?
- How are self-assessments of the management system and its components carried out?
- How does senior management use management system reviews?
- How are processes managed, measured, maintained, reviewed, and continuously improved (e.g., via process reviews)?
- What type of internal and external assessments (incl. audits, benchmarks and other) are in use?
- How are decisions made about modifications in the management system?
- How are people encouraged to contribute to the continuous improvement of the management system?
- What were/are the performance improvement expectations given or attained by implementing a management system?

4.10.3 Review of the case study evidence

Most case study organizations (FANR, NDK, PAA, PEJ and Nawah) report having procedures and standard quality tools to identify non-conformances, including internal/external audits, management reviews, self-assessment, and non-conformance reporting. FANR notes that staff members are encouraged to use the non-conformance system to identify opportunities for improvement. Identified non-conformances are screened for significance, and responsibilities

are assigned to the relevant person, such as the process owner, for corrective action and follow up. In several cases, an electronic system is used to register and track the status of non-conformance reports. At NRA and NPG, non-conformance management is reportedly a work in progress.

All case study organizations have implemented, or are planning, arrangements for self-assessment of the effective implementation of the management system. PAA conducts self-assessments based on the standards in Poland for public bodies and, additionally, the process owners review their processes in the framework of the MS review. At PEJ, process owners conduct self-assessments annually and as needed following a graded approach using checklists developed based on IAEA guidelines. Nawah has implemented a self-assessment regime comprising tools such as process maturity models, benchmarking, and formal IMS review, the latter being driven by regulatory requirements. FANR indicates that it conducts self-assessments following its procedure, considering a variety of inputs. Self-assessment is not yet fully developed as a process in some other cases.

Management system reviews follow a similar pattern in those case study organizations that report on them. A summary report is prepared based on a range of inputs including process self-assessments, internal audits, etc., which is presented to a meeting of senior management for discussion and confirmation of proposed improvement actions. Nawah reports that its IMS reviews generate positive energy among senior management about the value of the IMS for the organization.

Process owners (or unit managers in NDK) in most cases are responsible for monitoring the performance of their processes and initiating corrective actions. At PAA for instance, the process owners monitor defined measures for each process, the most important of which are included in the activity budget and are reported quarterly to top management. Issues are discussed and solved on an ongoing basis, with important issues on processes and their interactions decided at management meetings. PEJ has an interesting approach of focusing assessment on the interactions between processes where non-conformances most frequently occur. PEJ also tries to select internal auditors in such a way that the customer of a process audits their internal supplier. Cooperation between processes is also assessed and is subject to improvement actions.

Regarding methods of internal and external assessment of the management system, all case study organizations report using internal audits with internal auditors and audit procedures in place. A variety of other tools are employed, ranging from external certification audits, international IAEA peer reviews and expert advisory.

In all cases, changes (including improvements) to the management system can be initiated by a range of inputs including self-assessment, external assessment, experience feedback mechanisms, and staff suggestions. In most cases, changes are developed by process owners, and are reviewed by the IMS committee or in some cases by senior management when the change involves decisions on finance, human resources, or responsibilities, before being implemented in new or revised documents. PEJ is currently extending a change management approach implemented within the programme and project methodology to the entire organization at the corporate level.

All case study organizations encourage staff to contribute to continuous improvement. Culturally, this is reflected in some organizations' 'open door policy' and support for a questioning attitude. Mechanisms include the ability of staff to raise non-conformance reports,

suggestion boxes, employee surveys and staff participation in internal audits. PAA and FANR report on the existing or planned use of electronic systems to gather suggestions. At PEJ, many staff are trained as internal auditors which enables them to develop an accurate perspective on the management system.

Among those organizations that described expectations for the performance improvements attained by implementing a management system (not all did so), the gains most expressed were in terms of enhanced compliance with legal and regulatory requirements, and consistent and effective delivery of the organization's mission. PEJ identified that different stakeholder groups, namely the Management Board, top management, process owners, and employees gain different benefits from the management system, summed up with the observation that "an effective IMS makes your job simpler and gives you predictable outcomes from the activities you perform".

4.11 LESSONS LEARNED FROM THE DEVELOPMENT AND IMPLEMENTATION OF THE MANAGEMENT SYSTEM

4.11.1 Nature of the issue

An integrated management system can provide an organization and its stakeholders with enhanced safety and business performance together with other benefits. However, the implementation of a process-based management system is a major organizational change, particularly in an existing organization which has established ways of working. The development and implementation of the management system is a complex endeavour which has to take into consideration organizational changes (see Ref. [7], paras 5.56–5.71).

4.11.2 Points of interest

The main points of interest were the following:

- What are the lessons learned from the development of your IMS, what went well, what could have been improved, what are the pitfalls to avoid?
- Does the management system support the strategic direction and goals of the organization?
- What were/will be the financial costs of developing your management system and the main items of expenditure?
- What additional suggestions based on your experience would you like to share with Member States before they develop their management system?

4.11.3 Review of the case study evidence

Several common themes emerged strongly from the responses in this part of the case study.

First, several case study participants observed that the implementation of an integrated management system is a large, complex undertaking. Adequate definition of the objectives, attaining leadership consensus, and sound planning were reported as important success factors.

Therefore, senior management engagement and support were identified as instrumental in the successful implementation of the management system in several cases. In other cases, the relative absence of senior leadership involvement reportedly weakened progress through unclear strategy, inadequate resources, and diversion of staff to work on other duties.

The employment of expert consultants or advisors, along with benchmarking the experience of other organizations by various means, were mentioned as helpful tactics by several organizations.

The context of a newly established organization was a factor that helped the development and implementation of the management system in several cases, namely Nawah, FANR and NDK. Working in a new organization makes the need for a management system obvious to everyone, and a new organization has no loyalty to old ways of working. Conversely, some longer-established organizations reported that resistance to change, based on a belief that the old methods worked, hindered the implementation of their management system. The need to conform to parent company requirements was also mentioned as a factor that hindered implementation in a few cases.

Engagement of people in all parts of the organization was identified in all cases as vital to gaining widespread awareness, belief in, and use of the management system among staff.

The following quotations from the case study responses illustrate the strength of views on this point:

- "There should be the understanding that the Management System is for everyone and not just the team developing the management system. Work needs to be done to consistently communicate and train all staff about the Management System";
- "Train and engage into the system as many people as possible (and manageable). Too few people engaged into the development of the system excessively lengthens the timeframe and leads to the delays and low effectiveness of the implementation of the system";
- "Involve as many employees as possible in the development of the processes";
- "Visible senior leadership commitment and meaningful engagement of all staff are essential to continued success";
- "Treat the implementation of the system not only as an organizational but also as a cultural change";
- "Publish and continually advocate and maintain IMS standards through various staff across different levels in the business".

Contrastingly, the lack of attendance of staff at awareness or training workshops, failure to understand or use the management system documentation, and interruptions by other duties were reported issues that hampered management system implementation.

The costs of implementation of the management system did not emerge in detail from the case studies, although clearly substantial expenditures of resources were involved in several cases. The main categories of costs identified were internal staff time for planning and development, training costs, consultants' fees, costs to purchase standards, costs of certification audits where applicable, and the costs of procuring and implementing electronic document and workflow management systems to support the IMS.

Finally, the management system was seen in all cases to have produced strategic and operational benefits for the organization. By encouraging adherence to systematic procedures and continual improvement, the management system reportedly supports the organization's consistent delivery of results and thereby enhance nuclear safety and security. Compliance with recognized standards such as IAEA GSR Part 2 (see Ref. [2]) is judged to inspire stakeholder trust, respect, and confidence in the organization's role. Internally, the management system helps to ensure resource availability and financial sustainability, while through the human

resource process and its linkage with other processes, it supports recruitment and training. As PEJ observed, “the formalized structure of the management system, despite its many faults visible in the world that is changing faster and faster now, is still the only solution for organizations dealing with nuclear energy.”

4.12 KEY MESSAGES

Key messages emerging from the case studies comprise the following:

— The Owner–Operator organisations developed their management systems in accordance with the national nuclear law and other legislation, regulations and guidance specified by the Regulatory Body and their business needs;

— The Regulatory Body’s management system is generally developed in accordance with the relevant IAEA publications to deliver the mandate set out in the national legislation;

— The management system evolves as the nuclear programme progresses from bidding and procurement through construction to operation and the oversight and inspection of these activities;

— Core processes need to be developed based on the needs in each phase of the nuclear programme, from procurement, licensing, construction, and vendor oversight, to commissioning and operation;

— Leadership of senior management is critical to facilitate change and support the development of the management system and its continuous improvement;

— Engagement of people in all parts of the organization was identified in all cases as vital to gaining widespread awareness, belief in, and use of the management system among staff;

— The management system drives safety culture across the whole organization. Values that promote safety culture and leadership for safety are embedded in the management system;

— Finally, the management system supports the organization’s consistent delivery of results and thereby enhances nuclear safety and security and inspires stakeholder trust, respect, and confidence in the organization’s role.

APPENDIX I

CASE STUDY – NUCLEAR POWER GHANA (NPG), REPUBLIC OF GHANA

I.1 INTRODUCTION

The Ghana Nuclear Power Programme Organization (GNPPO) (i.e., Ghana's NEPIO) was established in 2012 to coordinate the development of national nuclear infrastructure based on the IAEA Milestones Approach [1]. Nuclear Power Centre (NPC) was established in 2014 at the Ghana Atomic Energy Commission (GAEC) as nuclear technical support for GNPPO. The centre became in 2015 the Nuclear Power Institute (NPI). A roadmap for Nuclear Power Development was developed. The National Nuclear Regulatory Authority (NRA) backed by the National Nuclear Regulatory Authority Act(ACT 895 of 2015) was established in 2016. In 2017, the IAEA Integrated Nuclear Infrastructure Review (INIR) mission was conducted. The Cabinet's approval was given for the establishment of Nuclear Power Ghana (NPG), the potential operator, in 2018. The core human resource of the NPG was recruited from NPI, and the two hydropower operating organizations in the country, the Volta River Authority (VRA) and the Bui Power Authority (BPA).

Presently NPI is the only institution still functioning as the GNPPO with the medium-term goal of transforming into a technical and scientific support organization (TSO) for NPG, NRA, and other nuclear organizations. The Programme Comprehensive Report for Phase 1 activities was submitted to the Government in 2020. Some of the Phase 2 activities have begun.

The country has plans to build a 1000 MW plant as a start.

All the information about the IMS in this Appendix is based on the IMS of the NPG and is consistent with Phase 2 activities. However, part of the IMS of the NPG was inherited from the NPI. The NPG's IMS began with a gap analysis of the NPI's IMS. The recommendations from the gap analysis report were taken into consideration in developing the NPG's IMS. The IMS of NPG is a work in progress.

I.2 REQUIREMENTS

The NPG's IMS documentation has a 3-level categorization structure.

Parts of the Level 1 document include both legal and regulatory requirements:

- Ghana Atomic Energy Commission Act, 2000: Act 588;
- Ghana Nuclear Regulatory Authority Act, 2015: Act 895;
- Labour Act, 2003: Act 651;
- Environmental Protection Agency Act, 1994: Act 490;
- Public Procurement Act, 2003: Act 663;
- Radiation Protection Instrument LI 1559;
- Other applicable national laws.

The following IAEA standards were also considered:

- Leadership and Management for Safety, No. GSR Part 2 (see Ref. [2]);
- Application of the Management System for Facilities and Activities, No. GS-G 3.1(see Ref. [7]);

— Development and Implementation of a Process Based Management System, No. NG-T-1.3 (see Ref. [9]).

Although international standards ASME/NQA-1(see Ref. [17]) and ISO 9001 (see Ref. [13]) have been discussed, they have been earmarked for future consideration.

Apart from the processes developed from scratch and those inherited from NPI, aspects of procurement, HR and document management processes were inspired by the BPA and VRA organizational processes and procedures. Invariably, there were some best practices inherited from VRA, BPA, and GAEC.

I.3 RESPONSIBILITIES FOR THE IMS

NPG envisions itself to be a regional leader in the provision of affordable, reliable, and sustainable low-carbon emission energy. It, therefore, has a mission to build Ghana's nuclear power plants and produce affordable electricity in a safe and environmentally friendly manner.

The organizational structure of NPG has the board of governors, providing oversight responsibilities. The executive director directs the day-to-day business and reports directly to the board of governors. The various departments under the executive director are headed by managers.

The manager of the Project Management Department is in charge of the IMS and is directly responsible for the development and promotion of the IMS. There is an IMS Unit under the Project Management Department that coordinates the development of the IMS. It brings together personnel from other departments as needed to develop the various aspects of the IMS. Processes have process owners who oversee to the day-to-day running of the process and the process manager who liaises with the IMS Unit to manage the processes. The major stakeholders are the Owner (the Government of Ghana), NPI (TSO) and NRA (Regulator).

Communication is the main tool for promoting the management system. Involvement of all including the senior management, training programmes, workshops, conferences, posters, and letters are used to communicate and promote the IMS. An IT consultant aids the IMS Unit in mounting developed processes on a digital platform. In effect, those with direct responsibility for developing the IMS include the manager, the IMS development team, the support staff, process owners, process managers, and IT consultant.

Two types of assessments of IMS are to be carried out at NPG: self-assessment and independent assessment. Self-assessments are to be conducted by heads of departments and sections in collaboration with the IMS development team. Independent assessments will be conducted every three years. These will be done through peer evaluation and technical reviews.

Through the Peaceful Uses Initiative (PUI) support, NPG has benefited from IAEA expert review missions, technical meetings, and training programmes.

I.4 MANAGEMENT SYSTEM PLANNING AND DEVELOPMENT

The schedule for developing and implementing the NPG's IMS is consistent with the processes needed for the various phases (see Ref. [10]) and for those that are needed to enhance the immediate activities.

For the Phase 1 activities, before 2018, the focus was on knowledge and document management processes. Some processes were developed for siting activities and high-level documents were developed for the various infrastructure issues.

The development of the IMS began in 2018 through gap analysis, addressing issues in the previous NPI IMS, drawing plans for the development and implementation of Phase 2 processes and development of some of phase 2 high-level documents.

In 2019, the development of policies and manuals continued, support processes (especially those that facilitate knowledge management, documentation) and administrative processes were developed. A review mission was organized. Development of some procedures, templates, forms, and guidelines continued to 2020. Another review mission was organized. The plans for the development of the rest of the IMS were laid, and implementation of aspects of the IMS began.

The period from 2020 to 2023 is considered to be Phase 2 of the nuclear power programme. Therefore, the current focus of the NPG's IMS is Phase 2 key activities: site selection, assessment, and licensing; reactor technology assessment, grid infrastructure development, and IMS development. Thus, the core processes were narrowed to siting, licensing, engineering development, bid management, and IMS development.

In the next three to four years, Ghana nuclear power programme will move into Phase 3. The major changes for the NPG's IMS will include the following:

- Strengthening of the safety culture;
- Bid preparation, assessment, and approval;
- Licensing application and management;
- Intensify public education and information;
- Assessment and update of knowledge and document management process;
- Assessment of Quality Assurance processes;
- Development of processes related to supply chain management, construction management, etc.

To streamline the integration of the IMS processes and their implementation, NPG has plans to deploy a combination of internally developed software and proprietary one for process management. NPG identified the processes that were most critical to the current phase, and whose non-existence posed the greatest risk to the nuclear power project and prioritized the development of those processes. There is also a stakeholder engagement strategy for identification, analysis and matrix categorization and management of the various stakeholders.

Besides, a nuclear leadership programme is intended to be implemented. Programmes that will help foster a strong safety culture will be organized. Self-assessments and expert reviews, external assessments and audits will be conducted followed by the recommended improvement of the IMS.

I.5 DOCUMENTATION OF THE MANAGEMENT SYSTEM

NPG uses a three-level documentation structure for its IMS documentation, represented as a pyramid:

— The apex of the pyramid constitutes the Level 1 documents which are among the highest-level documents used for directives. The documents here are IMS Manual, Corporate Governance Manual, Policies, etc. They derive most of their inputs from legal and regulatory documents. These documents are mostly used by the executive director and the board of governors. They feed directly into the next level of documents by prescribing most of the requirements for the IMS and some of the policy documents;

— Level 2 documents are more than the first level documents. These documents describe the processes of the organization and provide specific details on the activities to be performed and the organizational unit responsible for performing them. Level 2 documents are mostly used by managers. There are currently about thirteen (13) documents at this level (8 processes and 5 process description sheets), which are used to meet the requirements prescribed in Level 1 documents;

— Level 3 documents form the base of the pyramid and are many. They are detailed instructions and guidance that enable processes to be carried out. They prescribe the specific details for the performance of tasks by individuals or by small functional groups or teams. Documents at this level include procedures, forms, templates, reports, and other evidence to show that the work activity has been completed. There are about 60 documents at this level presently (12 procedures, 1 guideline, 11 forms, 24 templates and 13 checklists).

As the programme progresses and the documents number increases especially at Levels 2 and 3, it is expected that such levels will be sub-divided into various sub-categories to facilitate documents management. There will be a separate database for managing documents that are exclusively outputs (e.g., reports, records, results, etc.). NPG has plans to develop separate policies for various areas. However, there are considerations on whether to organize all these policies into one NPG policies document. At present, there are five policy documents. These include NPG nuclear safety policy, strategic HR planning policy, information sensitivity policy, and computer and internet usage policies.

The process map of NPG has three categories of processes in line with the standard nuclear performance model:

— Management Processes: Direct and Manage the Organization, Manage Stakeholder Expectation, Assess and Improve Performance, Manage the Processes;
— Core Processes: Siting, Licensing, Engineering Development, and Project Management;
— Support Processes: Document Control, Human Resource Administration, Procurement and Contracting, Information Technology (IT), Human Resource Development, Financial Services, Legal Services, and Communications.

A document has been developed to identify the various processes at each phase of the programme. The process description sheet is the key document for process description and documentation. Procedures and instructions are then developed to help describe processes in detail. There is a plan in place to develop a central risk register for the processes.

In terms of document control, there are processes for planning document development, creating the documents, and reviewing and approving the documents. Consistency is achieved by ensuring that all the people involved follow the approved processes. There are templates to be used and checklists to be completed. All IMS documents are captured in the IMS document hierarchy.

The documents are colour coded in terms of the following: (1) existing documents, (2) document to be developed and (3) documents to be cancelled. Documents that have been cancelled are taken out of the archive and stored elsewhere. The electronic versions of the documents which are no longer in use have all the pages stamped 'CANCELLED'. In addition to document ID numbers, all documents are identified with security numbers to guide how documents can be released. There is a plan in place to use an electronic document management system.

I.6 INTEGRATION OF THE COMPONENTS

Presently, the integration of the components of the IMS is a challenge. It is believed this is because NPG is still at the early stages of the programme. There is also a lack of practical understanding of how the components can be integrated.

Most of NPG present responsibilities deal largely with document creation, procurement, recruiting, and siting. Document quality and information security are the primary components being integrated. All documents developed go through a systematic and rigorous review process to ensure quality. Documents developed are given security classification such that even reviewers are chosen based on security implications. For procurement, there are checks to ensure that there is always value for money.

When a decision in the IMS is to be made, it is checked against requirements (in the IMS manual) and policies to ensure there is no conflict. Changes go through the prescribed change management process including discussion with the employees and approval process.

I.7 IMPLEMENTATION OF THE MANAGEMENT SYSTEM

The entire management system is being developed stepwise with a focus on the supporting processes. A process is considered ready to be implemented if it has gone through the review process and all issues have been addressed. Any issues encountered are reported to the manager of the IMS unit.

From the onset, employees who are going to use a particular process are normally involved in developing the process. After the process has been developed, the Executive Director briefs the whole organization about it. Often, the employees who directly use the process are made aware of the process through various means of communication by the IMS unit. If needed, the employees receive training about the processes.

If an activity is done without following the processes in the IMS, such an activity is not approved until it goes through the due processes. The processes have a feedback mechanism that generates output to serve as indicators for verification. All processes have KPIs that can be used to assess the process. Processes interact with other processes by requesting inputs from or generating outputs to those processes.

I.8 VALUES AND ORGANIZATIONAL CULTURE

NPG had workshops, technical meetings, and did literature reviews to understand the concept of organizational culture. The importance of determining the baseline for the organizational culture in the various national organizations is understood and accepted. Therefore, NPG participated in assessing the organizational culture of selected institutions in the country. There is a safety policy developed to help promote a safety culture. NPG is also promoting the *Ghana Nuclear Leadership Programme*, with the safety culture being an integral part of this

programme. The tools and methodologies developed for organizational culture assessment will be modified and used in subsequent assessment of safety culture. The results of the previous assessment will be helpful as a baseline in performance measurement and improvement.

I.9 MEASUREMENT, ASSESSMENT, AND IMPROVEMENT

A gap analysis was done for the IMS documents NPG inherited. For the NPG's IMS being developed, expert reviews and follow-ups have been conducted yielding helpful opportunities for improvement. For aspects being implemented, users are encouraged to report issues to the project management department.

Resolution of the issues is done by graded approach. Most of the processes being implemented have fewer safety concerns. Therefore, the issues reported are managed by looking at their impact on the security and safeguard, efficiency, quality, resources, consistency, etc. In this case, security and safeguards are primary concerns. However, the order of consideration of the impact depends on the processes and activities. Processes for document management are given security consideration first whereas those processes that deal with financial management are considered based on efficient and judicious use of resources.

For the past expert review missions, the Executive Director was present when the reviewer's comments were discussed. The manager in charge of the IMS ensured that the Executive Director was given copies of all the information involving the expert review mission. The Executive Director provided the necessary logistics for the review process.

I.10 LESSONS LEARNED FROM THE DEVELOPMENT / IMPLEMENTATION OF THE MANAGEMENT SYSTEM

There are several opportunities for improvement for the NPG's IMS development. The implementation of the IMS is a challenge. This can be overcome by repeated training, reminders and insistence from the senior management and supervisors. IMS easily becomes a series of documentation that are shelved and are scarcely used. This can be improved by deploying an appropriate electronic platform for managing the processes. The concept of IMS needs to be understood through several training workshops. The IMS development is considered more as a fulfilment of a requirement and less as an instrument for fulfilling requirements. After the development of the IMS, training the employees becomes a challenge. This can be overcome by the top management providing the resources for training and facilitating the training process.

Conducting gap analysis at the earliest stage of the NPG's IMS development was extremely helpful. The use of the IAEA standards provided useful guidance. Feedback received from employees from the GNPPO, specifically NPI was also useful. Conduction of IAEA expert review at the early part of the IMS development provided useful recommendations that helped shape the IMS.

IMS development and implementation require resources and the top management needs to be ready to invest the resources in terms of human, time, and finances. Top management are advised to consider channelling resources into the development and implementation of IMS as a form of investment that will pay off later. A substantial amount of time will need to be dedicated to communicating the IMS to the employees, training them on how to implement it, supervising its implementation, and assessing it for the necessary improvement. It is important to give considerable attention to the prevalent organizational culture within the country when developing the IMS. For easier implementation, it is simpler to develop the processes along the common way people do things than to try to bring people to do things the new way. The IMS

coordinators will allow the immediate users of the processes to be the main developers of the processes. Such users of the processes will then become the process owners. As many employees as possible are to be involved in the development of the processes.

APPENDIX II

CASE STUDY – NUCLEAR REGULATORY AUTHORITY (NRA), REPUBLIC OF GHANA

II.1. INTRODUCTION

The Nuclear Regulatory Authority (NRA), established by law in August 2015, is a key stakeholder organization of the Ghana Nuclear Power Programme Organization (GNPPO), the Ghana's NEPIO, and is currently working on developing its human resource capacity and building a strong regulatory framework for the oversight of nuclear installations, throughout all stages of their lifetime.

The NRA became operational in January 2016. The NRA was constituted mostly with staff transferred from two institutes of the Ghana Atomic Energy Commission (GAEC), namely, the Radiation Protection Institute (RPI), and the National Nuclear Research Institute (NNRI). Before that, regulatory oversight was focused mainly on facilities and activities using radiological sources and devices. This was handled by the Radiation Protection Board (RPB), through the RPI. The Regulatory Controls Division of RPI carried out the technical aspects of these regulatory activities (authorization, inspection, enforcement, review and assessment and interaction with interested parties).

II.2. REQUIREMENTS

The Nuclear Regulatory Act 2015 defines the functions of the NRA; these functions correspond to the NRA's core processes.

There are no legally required standards for the management system of the NRA. However, the NRA aims at implementing IAEA GSR Part 2 requirements (see Ref. [2]) and relying on IAEA's referenced publications No. GS-G-3.1 (see Ref. [7]), No. GSG-12 (see Ref. [5]) and No. GSG-13 (see Ref. [6]) for guidance. The NRA also aims to comply with ISO 9001:2015 (see Ref. [13]) for Quality Management.

The management system of the NRA is being developed by building on some inherited practices (administrative and regulatory procedures) from the previous Regulatory Body (RPI/GAEC).

It was also inspired with ideas taken from regulatory bodies from countries such as Canada, Egypt, Morocco, Lithuania, Netherlands, Pakistan and Slovenia. Information from these countries were obtained from presentations at workshops and copies of some of their management system manuals made available to the NRA.

Through the GNPPO it is expected that the NRA would have more forums to discuss best practices with other member organizations, in order to learn from each other.

II.3. RESPONSIBILITIES FOR THE IMS

The following are indicative of roles assigned to various group within the NRA to develop the management system:

— The Management System Committee is made up of 7 members (with representation from each directorate) responsible for implementing the development plan for the management system;

— A Steering Committee has been formed to exercise oversight of the Management System at senior management level;
— There are quarterly meetings with management from all levels where the status of the management system is discussed, and decisions are made on the way forward.

Within the Management System Committee, roles have been assigned to different members. One person oversees coordinating the development of all core processes and another for the development of all support processes. The coordination of the development of management processes have been assigned to individual members of the Committee. Some members have also been assigned the role of providing input on policy development, strategizing for change management and effective staff engagement.

Ghana has benefitted from the IAEA's support through:

— IAEA expert missions: Integrated Management Systems (IMS) Project under the Atoms for Peace Initiative;
— RAF9061: Enhancing the Capacities of National Regulatory Bodies for Safety in AFRA Member States.

II.4. MANAGEMENT SYSTEM PLANNING AND DEVELOPMENT

The development of the management system follows the needs in each phase of the Milestones (see Ref. [1]) as shown in TABLE 2.

TABLE 2. TIMEFRAME AND STAGES OF IMPLEMENTATION OF THE IMS VS PHASES IN THE MILESTONES APPROACH

Phase	Topic
Phase 1	— General description of all processes — Development of organizational policies — Procedures under core processes mostly focused on radiological installations and for a research reactor
Phase 2	— Review of core processes — Creation of procedures and supporting documents for oversight of site evaluation, authorization of construction and oversight of construction of Nuclear Installations
Phase 3	— Review of core processes — Creation of procedures and supporting documents for the oversight of operating nuclear power plants

TABLE 3. shows past, current, and future activities relating to the development of the management system.

TABLE 3. MANAGEMENT SYSTEM DEVELOPMENT TIMELINE

No.	Activity	Period
1	Formation of the Management System Committee	March 2018
2	Identification and initial drafting of some key documents: — Draft Management System Manual — Document Control Guide — Information Security Policy — Process Description Template — Communication plan for the Management System	March 2018–August 2018
3	Committee's review of the key documents	September 2018–July 2019
4	Meeting with management on the Management System on progress	July 2019
5	Identification and classification of processes	July 2019
6	Drafting of some processes: — Process Development Process — Regulations and Guidelines Development Process — Nuclear Installations — Safeguards Reporting — Authorization — Review and Assessment — Inspection — Finance and Administration — Human Resources — Procurement — Transport Management	July 2019–December 2019
7	2nd Meeting with the management to resolve the identification of processes, process owners and process managers and introduce the identified management processes	February 2020
8	Revision of drafts and combining of common processes for Nuclear Installations (NI) and Radiological and Non-Ionising Installations (RNI) Core processes (NI and RNI) Support processes (finance and administration) Management processes Identification of needed policy statements	February 2020–November 2020
9	Gap analysis of the status of development of the management system by external consultants	November 2020–February 2021
10	Revision of the IMS implementation plan	March 2021

No.	Activity	Period
11	Development of safety policy statements	January 2021–March 2021
12	Developing process documentation for: — Process Management — Project Management — Document and Records Control — Development of Regulations and Guides — Emergency Preparedness and Response (EPR)	April 2021–February 2022
13	Developing process documentation and top level management system documents (with support from consultants)	January 2022–December 2022
14	First internal audit (with support from consultants)	(yet to be specified)
15	Management review (with support from consultants)	(yet to be specified)
16	ISO 9001 quality audit	(yet to be specified)
17	IRRS mission review	(yet to be specified)

II.5. DOCUMENTATION OF THE MANAGEMENT SYSTEM

Figure 1 shows the documentation hierarchy of the NRA documentation:

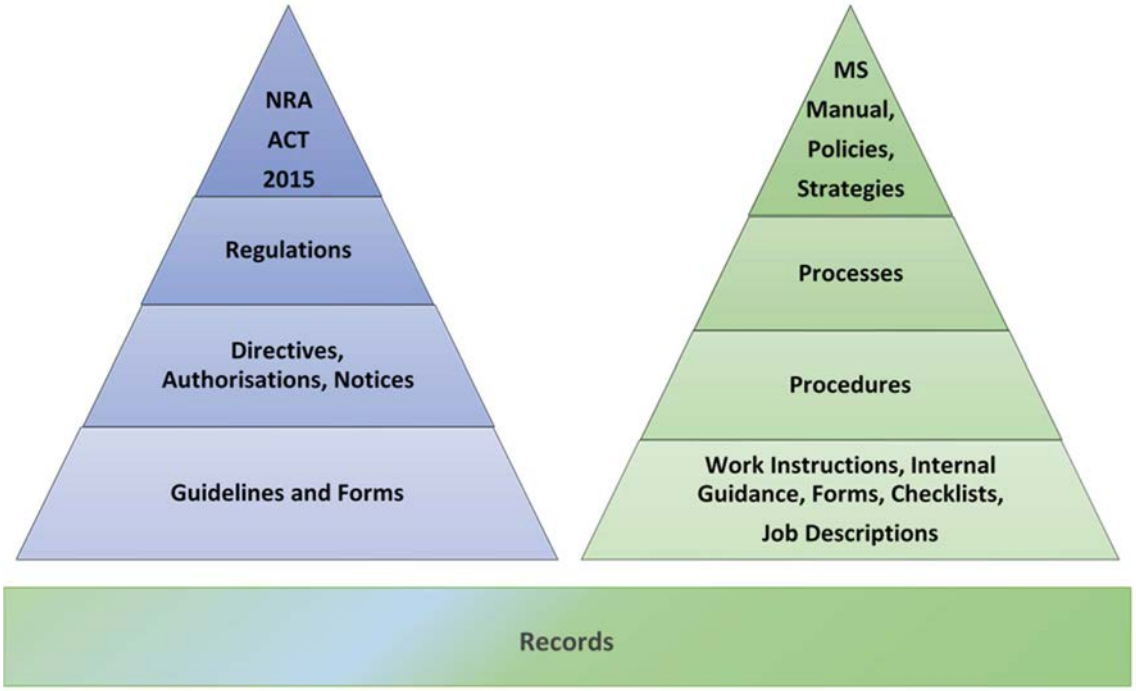

FIG.1. Document structure of the management system (Courtesy of NRA, Ghana)

The policies for all these components have not yet been fully developed. Senior management has tasked some staff with the needed competence to draft separate policies for Safety (also including occupational health and safety), Security and Quality.

Processes in the NRA are categorized as shown in Figure 2.

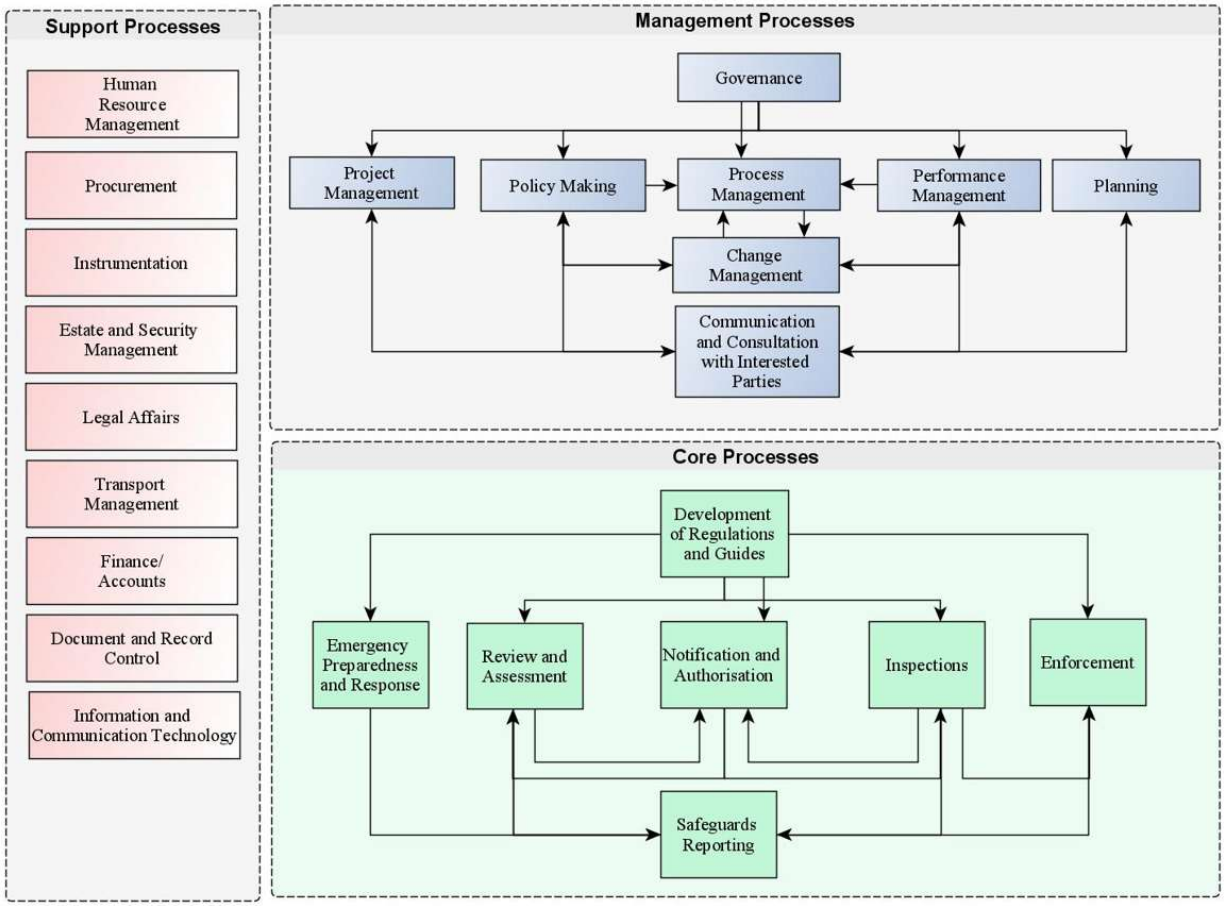

FIG. 2. Process map of the NRA (Courtesy of NRA, Ghana)

The Performance Management Process is planned to cover the conduct of self-assessments of processes, internal audits, management reviews, development of corrective actions and implementation of corrective actions.

An Internal Audit procedure already exists only within the scope of assessing the Finance and Accounting. It is yet to be expanded to cover all processes.

Templates were designed for processes and procedures. Each process identifies the procedures, supporting documents and records associated with them.

The following items are covered in each process description:

— Scope of the process;
— Purpose;
— Key activities/process steps;
— Key stakeholders;

— Major inputs and responsible people;
— Major outputs and responsible people;
— Key performance indicators (KPIs);
— Risk and mitigation measures;
— References (requirements, interfacing processes, other related documents);
— A flowchart (which indicates the process steps. subprocesses/procedures, inputs, outputs, and responsible people).

Process owners have been assigned for each process. They have been given the responsibility for developing processes and related key performance indicators, assessing processes, and continually improving the processes.

Process managers have been assigned the role of overseeing the execution of processes, periodic reporting on process KPIs to the process owners. They may also support the process owners to document the processes.

The two roles of process owner and process manager could however be played by one person. The separation of roles is envisaged to help implement different variants of the same process where different role players are involved, especially using different process managers for the same process as is the case with core processes being implemented by different directorates in the NRA (Nuclear Installations and Radiological and Non-ionizing Installations).

There is a new process for document and records control that is being developed to ensure a harmonization of all documents and records, in line with the management system requirements. This process aims to control the development, review, approval, issuance, distribution, and discontinuation of documents. An internal guidance on documentation has been drafted to support this process; this guidance document was based on the IAEA Safety Standards publication No. GS-G 3.1 (see Ref. [7]).

Figure 3 shows the cycle for the development and revision of documents in the NRA.

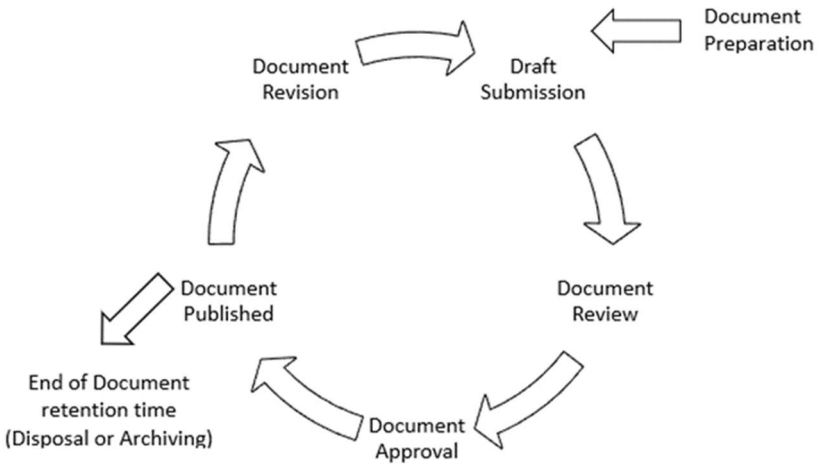

FIG. 3. Document lifecycle (Courtesy of NRA, Ghana)

II.6. INTEGRATION OF THE COMPONENTS

Policies are to be developed to ensure that all these components are addressed in meeting the NRA's objectives.

The NRA is currently pursuing a project to identify all requirements applicable from IAEA standards, legal requirements, and adopted standards related to these components. This would help ensure that a holistic approach can be applied to meet all requirements.

There are plans to implement Enterprise Risk Management, based on ISO 31000:2018 ('Risk Management – Guidelines') ISO within the NRA. This will identify the risks to each of the management system components. This would also enable the NRA to come up with an integrated solution to make sure that all risks relating to safety, security, health, quality, environmental, societal and economic objectives are mitigated.

II.7. GRADED APPROACH

The graded approach is applied in the core processes based on the radiation risk of facilities. Greater controls are applied where greater risk is involved. The controls applied are through procedures in the form of frequency of oversight, rigour (as evidenced in the protocols), levels of qualification/experience of staff involved in the activity (e.g., inspection, review and assessment).

II.8. IMPLEMENTATION OF THE MANAGEMENT SYSTEM

The intent is that the new development plan would be reviewed and approved by the Steering Committee before it is introduced to all staff of the NRA. A process for the management of change is also being developed to support the embedding of the changes within the NRA.

Awareness of the management system is to be done through trainings, seminars, and regular communication about the management system.

The following measures help ensure compliance with processes:

- Including role players in process development;
- Ensuring that there are detailed guidance, forms, templates, and checklists that facilitate the performance of activities.

Plans are also in place to ensure the following:

- Reporting on adherence to the process as part of assessment;
- Educating staff on the how to execute the process and the need to comply with the procedures involved.

New documents and revisions to all general documents are announced to all staff through email. The document and records control process ensures that all staff that needs to have access to a document are identified and receive the document. Training on new documentation is planned to follow the approval of the documentation.

II.9. VALUES AND ORGANIZATIONAL CULTURE

The NRA aims to develop an organizational culture that is focused on safety and security. Senior management has tasked a team to work on a Safety and Security Culture Programme to

bring out the various actions needed to implement an organizational culture that is places a high priority to Nuclear Safety and Security.

II.10. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

Currently, avenues for improvements in the NRA are identified from: periodic (quarterly and annual) reports on performance, direct communication with managers, staff meetings and internal audits (financial).

The internal audit process is currently focused on the Finance/Accounting Process but is going to be expanded to cover all processes.

The Performance Management Process is developed to address the self-assessment of processes, internal audits, management review, development of corrective actions and implementation of corrective actions.

It is expected that management system reviews would be conducted at least once yearly. The NRA has planned a training on the conduct of management system reviews, and this would be followed up with the first actual management system review. It would be a forum whereby all results of assessments are evaluated against the identified requirements.

All staff would be educated on who they can report non-conformances to and there would be a reporting mechanism to send feedback to all process owners.

II.11. LESSONS LEARNED FROM THE DEVELOPMENT AND IMPLEMENTATION OF THE MANAGEMENT SYSTEM

The following lessons were learned from the development of the IMS:

- There needs to be early awareness creation on the importance of the management system so that all staff attach the necessary importance to its development;
- There needs to be a good understanding of what realistic timelines for developing the management system look like;
- Developing a clear decision making/conflict resolution mechanism is key to resolve differences of opinion in the development of the management system.

The management system encourages a strict adherence to procedures, assessment, and continual improvement in carrying out regulatory duties. This is expected to reflect in improvements in nuclear safety and security in Ghana, inspire public trust in the NRA as a regulator and allow to effectively measure performance.

Until now, developing the management system has relied on internal resources. An additional budget is envisaged to cover the following needs:

- Enterprise software for document and workflow management;
- Training and communication tools for promoting the management system internally;
- Logistics for meetings (both virtual and physical).

APPENDIX III

CASE STUDY – FEDERAL AUTHORITY NUCLEAR REGULATION (FANR), UNITED ARAB EMIRATES

III.1. INTRODUCTION

In 2008, the UAE Government published the *Policy of the United Arab Emirates on the Evaluation and Potential Development of Peaceful Nuclear Energy* which set out the rationale and goals for a proposed nuclear energy programme. The Federal Authority for Nuclear Regulation (FANR) was established as the Regulatory Body by the passage of Law by Decree No. 6 of 2009.

The Emirates Nuclear Energy Corporation (ENEC) was established in 2009 to be the entity responsible for the deployment and ownership of nuclear energy plants. In 2016, the Nawah Energy Company (Nawah) was formed as a joint venture between ENEC and the Korea Electric Power Corporation (KEPCO) to be the operating organization.

In December 2009, ENEC announced the selection of a consortium led by KEPCO to design, build and assist in operation and maintenance of four 1400 MW APR-1400 units. A construction license was issued in 2012 for the first two units at the Barakah site located on the coast west of Abu Dhabi, followed in 2014 by the construction license for Units 3 and 4. In February 2020, FANR issued the operating license for Unit 1 to Nawah. Unit 1 reached 100% power output to the electrical grid in December 2020.

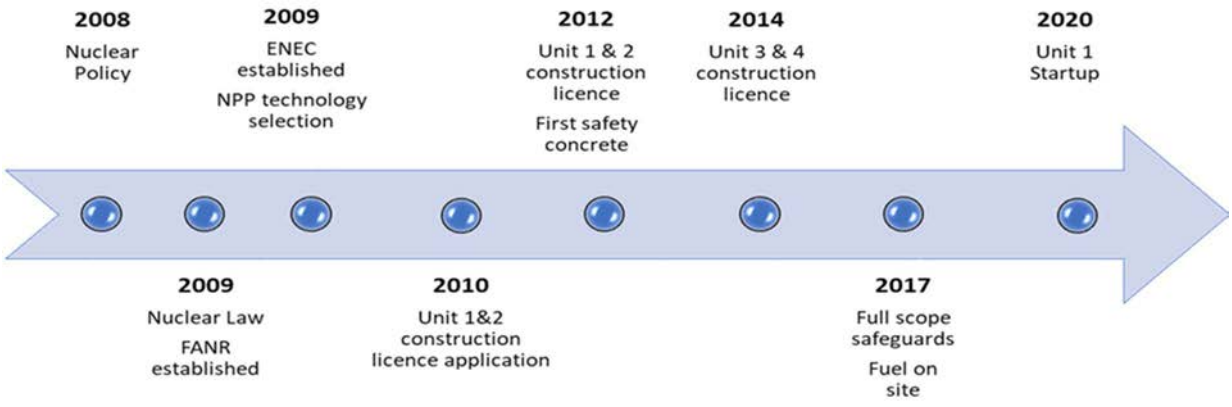

FIG. 4. Timeline for development of the UAE Peaceful Nuclear Energy Programme

III.2. REQUIREMENTS

The United Arab Emirates' Law by Decree No. 6 of 2009 *Concerning the Peaceful Uses of Nuclear Energy* (Hereafter, the 'Nuclear Law') sets out FANR's functions and responsibilities and was the primary reference for development of its management system. During the development of the management system, FANR also considered the IAEA standards that were current at the time, namely the IAEA Safety Standard Series publications Nos. GS-R-1, GS-R-2 and GS-R-3, respectively superseded by GSR Part 1 (see Ref. [21]), GSR Part 7 (see ref. [22]) and GSR Part 2 (see Ref. [2]), as well as the associated guides.

FANR also took account of the ISO standards referred to below and acquired certifications against these standards from 2018 onward. The ISO standards were non-mandatory and were

adopted by FANR to enhance its reputation for safety and quality and to promote good practice in addition to benchmark findings with similar Federal and regulatory entities:

- ISO 27001:2013 on Information Security Management Systems (see Ref. [19]);
- ISO/IEC 17025:2017 on Competence of Testing and Calibration Laboratories (see Ref. [20]);
- ISO 9001:2015 on Quality Management Systems (see Ref. [13]);
- ISO 45001:2018 on Occupational Health and Safety Management Systems (see Ref. [18]);
- ISO 14001:2015 on Environmental Management Systems (see Ref. [15]);
- ISO 30401:2018 on Knowledge Management Systems (see Ref. [23]);
- ISO 22320:2018 Guidelines for Emergency Management Systems (see Ref. [24]);
- ISO 10015:2019 Guidelines for Competence Management and People Development (see Ref. [26]);
- ISO 22301 on Business Continuity Management Systems (see Ref. [25]).

III.3. RESPONSIBILITIES FOR THE INTEGRATED MANAGEMENT SYSTEM

The Director General (DG) of FANR has ultimate responsibility for ensuring that the integrated management system (IMS) is established, implemented, assessed and improved. The Deputy DGs and department directors are responsible to provide active and visible support and leadership to the employees in accordance with the organization vision, mission, and core values; to communicate roles and responsibilities to the staff and set out how these roles will be accomplished within the framework of the IMS; and to implement, maintain, assess and continually improve the IMS.

FANR established the Integrated Management System Steering Committee to manage the development and implementation of the IMS. The Committee is chaired by the Deputy DGs on a rotating basis. Its members comprise the department directors and the process owners.

FANR has appointed a permanent Quality Management Section under the Corporate Development Department. The Quality Management Section is responsible for managing the development and revision framework of the IMS documents.

IMS document owners are responsible for the development, implementation and update of IMS documents. IMS document owners are selected based on their knowledge and understanding of the assigned process and its integration within the IMS. The Quality Management Manager ensures the compliance of the developed IMS documents to existing formal templates and applied management standards.

In addition, FANR employs internal management system auditors comprised of FANR staff in the Corporate Development Department.

Services received from the IAEA in relation to the IMS have included the use of the Safety Standards and Guides, peer reviews during the 2011 IRRS mission and the 2015 follow-up mission, an expert mission involving people from other regulatory bodies presenting examples of their approaches, and scientific visits through which FANR staff studied other organizations' practices.

III.4. MANAGEMENT SYSTEM PLANNING AND DEVELOPMENT

The IMS manual, the process model and the main processes and procedures were developed following the establishment of FANR during Milestones Phase 2 of the UAE programme. FANR employed an expert consultant to facilitate the creation of the IMS manual and the process model.

The IMS development was prioritized to establish the regulatory infrastructure in line with the implementation of the nuclear power project. Among the first developments were the process for issuing regulations and guides, followed by the licensing process. Processes and procedures needed in later phases were developed subsequently.

The main elements of the FANR IMS have stayed stable through the subsequent phases of the nuclear power project. Notable changes include the development of specific procedures and work instructions as the NPP implementation progressed through construction, commissioning, and operation. The FANR emergency preparedness organization and the associated procedures was a significant development during the latter part of Phase 3.

FANR implemented the management process '*MP.8 Manage National and International Stakeholder Engagement, Cooperation and Interactions Process'* to ensure effective and efficient relationship management with FANR's national and international stakeholders including the UAE Government, the IAEA, international nuclear regulators and other relevant stakeholders.

III.5. DOCUMENTATION OF THE MANAGEMENT SYSTEM

Figure 5 shows FANR's IMS documents structure.

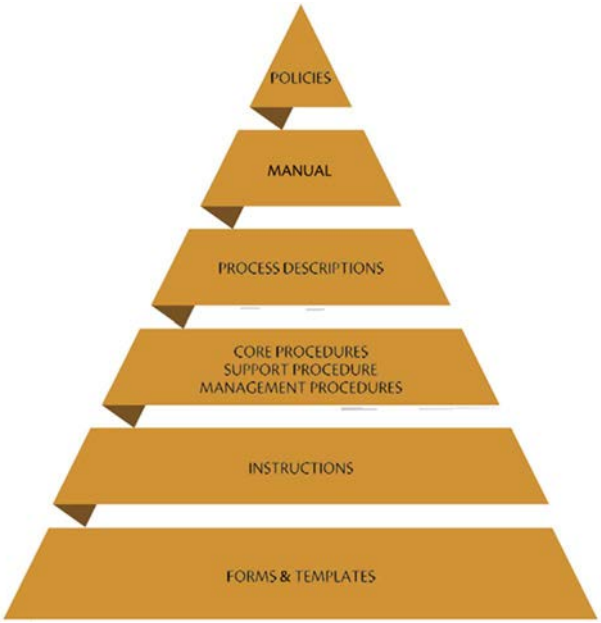

FIG. 5. FANR IMS documents hierarchy

The IMS document structure originally comprised three levels, namely (1) the IMS manual, (2) processes, and (3) procedures and work instructions. The additional levels were added later to recognize the existence of policies, and to separately identify procedures, work instructions, and forms and templates.

FANR structured its IMS processes as recommended in IAEA Safety Guide No. GS-G-3.1 (see Ref. [7]) namely core processes, support processes, and management processes. The IMS process map is shown in Figure 6.

The core processes were identified based on FANR's functions and responsibilities set out in the UAE Nuclear Law and the IAEA safety requirements. The necessary management processes and support processes were identified by the FANR IMS Committee with the support of an expert consultant, considering the relevant IAEA safety guides.

Each FANR process is described in a flow chart illustrating the sequence of activities with a brief description of each step highlighting what needs to be done and who is responsible. Links with other processes are shown on the process charts. Cross functional responsibilities are presented through a RACI ('responsible – accountable – consulted – informed') responsibility matrix. The process descriptions typically fill one page. This graphical presentation aids understanding in training, assessment, and the performance of work.

Procedures are identified in the process charts where needed to give more detailed instructions on how to carry out specific steps.

Work instructions give further implementation details as needed to support procedures. Work instructions are created, controlled, and approved at the departmental level with the approval of the quality manager.

The *MP6 Development and Revision of IMS Documents Procedure* contains guidance on the format and content of the various types of IMS documents. The procedure also describes the process for review and approval of a new or revised document.

The management process documents *MP.9 Risk Management Process* and the *Risk Management Policy* are the basis for reviewing and identifying risks as part of the procedure development requirement and included in the final IMS document. The Quality Management Section monitors the internal entity wide risk register with assigned focal points from the Departments (FANR Champions).

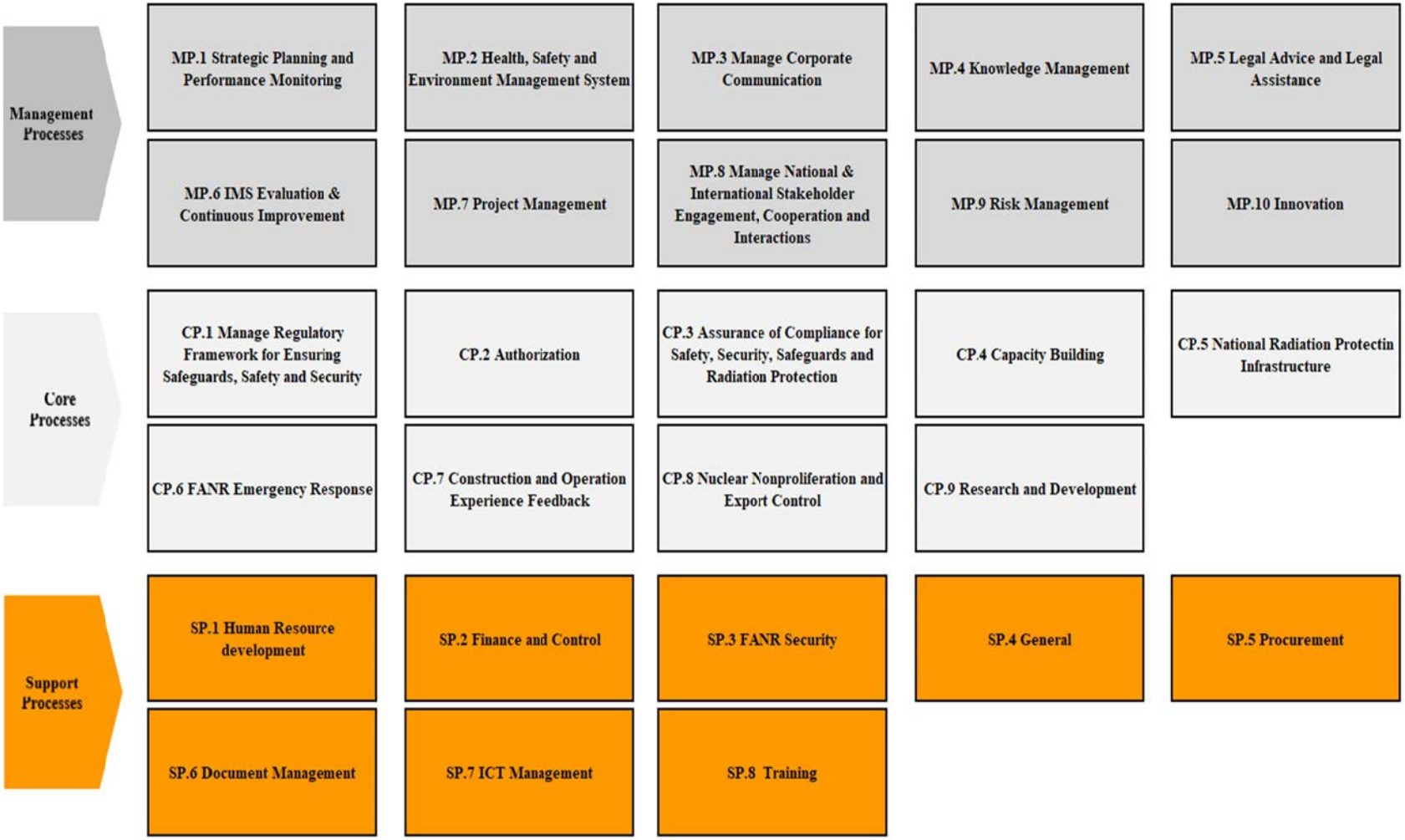

FIG. 6. FANR IMS process map

FANR uses a ‘clickable map’ on its intranet to present to staff the current versions of management system documents. The Management Systems Coordinator from the Quality Management Section is responsible for the maintenance of the ‘clickable map’ to ensure that it links to approved documents and that obsolete documents are withdrawn. The Architecture of Integrated Information Systems (ARIS) platform also includes interactive access to the process and procedure models. Further, all external and internal IMS audits, the IMS Committee and management review meeting minutes, awareness material, and IMS documents are available through the Quality Management page.

FANR maintains an Electronic Document Management System (EDMS) to manage records. The EDMS provides organized electronic storage, indexing, archiving, search, retrieval, and distribution of documents. Any paper records are scanned and indexed in the EDMS. FANR designates retention periods for different categories of records according to the policies of the national archive authority.

Information security is managed according to rules established in cooperation with the national security authorities. Each document is given a standard classification such as ‘*public*’, ‘*official use only*’, or other security classification. Access to documents and records of various classifications is granted through the EDMS to personnel who have the appropriate level of authorization.

III.6. INTEGRATION OF THE COMPONENTS

FANR’s IMS integrates the elements of safety, radiation safety, security and safeguards to ensure that regulatory decisions are taken with due regard for the mandate given by the nuclear law. Other aspects of managing the authority, such as economics and human resources, are also integrated into the management system through the processes for planning and budgeting. The ISO standards adhered to also pushed integration through common standard clauses (e.g. ‘Annex SL’).

Regulatory decision-making such as issuing a regulation or granting a license is controlled by the relevant process which ensures consideration of all necessary elements. Decisions on issues such as budgets and allocation of resources are made by senior management in accordance with the relevant processes. Management Review Meetings are conducted twice a year with the attendance of the Director General, Deputy Directors General, and the Directors to review any evident gaps to the management system standards compliance, and to discuss proposed and agreed actions.

III.7. GRADED APPROACH

An example of the graded approach in FANR’s IMS is the level of control applied to preparation and approval of different documents in the management system. Important documents such as processes and procedures are subject to formal review by the IMS Committee and approval by the DG. Contrastingly, work instructions are created, controlled, and approved at the departmental level with the review and endorsement of the Quality Management Manager.

III.8. IMPLEMENTATION OF THE MANAGEMENT SYSTEM

The IMS Manual sets out the Director General’s expectation that all FANR staff members will follow the IMS. Department Directors are responsible to communicate to the staff how their roles and responsibilities are to be accomplished within the framework of the IMS and supervise the performance of work.

An introduction to the management system is included in onboarding training for new employees and in general refresher awareness sessions. Soft copies of training material are available to staff in the Quality Management portal and to be included in the eLearning portal.

External providers, such as the technical support organizations who supported the review and assessment of license applications, received briefings on the procedures and work instructions applicable to their work and were given access to documents through secure electronic document folders.

III.9. VALUES AND ORGANIZATIONAL CULTURE

FANR's management system fosters a '*3S'* culture to create awareness among staff of the importance of safety, security, and safeguards in FANR's work and to enable them to make sound regulatory decisions.

The '*3S'* culture promotes a questioning attitude and two-way communication to ensure that all factors that might impact upon safety, security and safeguards are considered. These attitudes and behaviours support the implementation and improvement of the management system in line with the Integrated Management System Manual and Policy.

III.10. MEASUREMENT, ASSESSMENT AND IMPROVEMENT OF THE MANAGEMENT SYSTEM

FANR established a *Management Systems Audits Nonconformance Management and Management Review Meetings* procedure under which external and internal audits are conducted to identify nonconformities or areas for improvement.

FANR auditors carry out risk-based internal audits under the direction of the Board Audit Committee. FANR is subject to external audits by the State Auditor of the UAE Government. FANR has also hosted external and internal management systems certification audits as well as IAEA peer review missions to review and provide feedback on its IMS.

In addition, FANR fosters among staff a questioning attitude about the functioning of the management system. Any staff member may raise a non-conformance report through the Quality Management portal. The non-conformance report is screened for significance and responsibilities are assigned to the relevant persons for corrective actions. Staff are also encouraged to provide ideas for improvement to the Director General through a 'suggestion box' or through the innovation management system 'Thoughts'.

Self-assessment takes into consideration the results of internal/external audits, and input from operating experience and from stakeholders, performance measures, and surveys, as well as independent assessments and peer reviews. Consolidated findings are discussed in the Management Review Meetings to address gaps, confirm corrective actions and recommendations.

As part of the annual planning for management system development, process owners identify processes and procedures for review with the IMS Committee. The IMS Committee reviews proposed modifications to the IMS manual, processes and procedures before approval by the DG.

III.11. LESSONS LEARNED FROM THE DEVELOPMENT AND IMPLEMENTATION OF THE MANAGEMENT SYSTEM

Considering all the above, the implementation of an IMS at FANR proved to be a sound decision which greatly supported its successes.

Factors that went well included:

- The decision to implement the IMS early in the life of the organization, so that staff quickly accepted it as 'the FANR way';
- The use of a knowledgeable consultant in the initial stages to facilitate agreement among staff on the format and the content of key elements of the IMS such as the manual and the process model;
- The use of a relatively simple process structure and a graded approach avoided unnecessary complexity and helped to expedite the work.

FANR's strategic goals were enabled by the implementation of the IMS. The establishment of effective processes and the internal alignment among staff enabled FANR to publish needed regulations and to issue licenses on a time scale in keeping with the launch of the UAE nuclear programme.

The performance expectation in implementing the IMS was to support achievement of the mandate given by the nuclear law in an effective and efficient way. In addition, a more consistent approach is practiced to ensure meeting quality, health and safety environment requirements, business continuity, information security and knowledge management objectives/performance in line with the ISO certification requirements.

FANR's experience shows that embarking on the implementation of a process-based management system in accordance with the IAEA standards is a strategic decision that can pay dividends for any Regulatory Body in terms of the effectiveness and efficiency of its work. However, the implementation of the management system is a journey, not a destination. Visible senior leadership commitment and meaningful engagement of all staff are essential to continued success.

APPENDIX IV

CASE STUDY – NAWAH ENERGY COMPANY, UNITED ARAB EMIRATES

IV.1. INTRODUCTION

The United Arab Emirates (UAE) is a new-to-nuclear country and in 2009 its leaders established a peaceful nuclear energy program that is in line with UAE strategic energy objectives and goals of the country. Construction consists of four simultaneous Advanced Pressurized Reactors (APR-1400) within one site, making the project the largest of its type in the world at the time of construction. Once all four units are operational, the Barakah Nuclear Power Plant will provide a baseload of 5600 MW of clean electricity to the country for a minimum of 60 years with potential for extension. Once complete, electricity generation through nuclear will provide power for approximately 25 percent of the country' electricity demand.

The Emirates Nuclear Energy Corporation (ENEC) was established in 2009 under Abu Dhabi law to be the entity responsible for the deployment and ownership of nuclear energy plants. In 2016, the Nawah Energy Company (Nawah) was established as a subsidiary of ENEC to be the operating organization.

To facilitate the journey from construction through commissioning to operations, ENEC first developed a management system to comply with the UAE construction requirements and regulations for obtaining the construction license from the UAE regulator, the Federal Authority for Nuclear Regulation (FANR).

Subsequently, Nawah developed a management system to comply with nuclear operating requirements and regulations for obtaining the Barakah Nuclear Power Plant operating license.

The two systems integrate in several ways, maintaining their strategic alignment as well as mutual exclusivity where needed to satisfy both construction and operating mandates together. Both systems, working together, satisfied FANR regulation in the establishment, implementation, assessment, and continuous improvement of a management system, and applicable laws, national and international standards, and industry best practices.

This case study will focus on the headlining components of the Nawah Integrated Management System (NIMS), highlighting how it was built, its content and how it, together with the ENEC Management System, represents the collaborative and structured nature of the project, from inception to decommissioning that is enhancing overall safety and quality across the organizations.

Key components of the Nawah IMS are represented in Figure 7.

FIG. 7. The Nawah Integrated Management System

IV.2. REQUIREMENTS

References used to establish the Nawah IMS included those from FANR and the United Arab Emirates Federal Laws Concerning Peaceful Uses of Nuclear Energy (2009). Several other non-regulatory and industry references were utilised as well as desk research, industry best practices were learned through the benchmarking and site visits of other power plants, interviews with nuclear industry professionals as well as similar non-nuclear organizations (e.g. airline), review of other management systems, excellence roadmaps, governance models, critical assessment internal performance and needs, staff surveys, establishment of focused working groups and executive leadership forums.

The primary reason for Nawah to implement a management system for nuclear operations is to comply with the UAE regulatory requirements for the operating license. This puts the appropriate emphasis on enhancing safety and quality within the Nawah organization for operations.

IV.3. RESPONSIBILITIES FOR THE INTEGRATED MANAGEMENT SYSTEM

The Nawah IMS is promoted primarily by a dedicated unit titled the Nawah Integrated Management System (NIMS). This unit was established to maintain and drive improvements in the system for the benefit of the wider organization. The NIMS team currently resides within the Plant Support organization within the Chief Nuclear Office.

IV.4. MANAGEMENT SYSTEM PLANNING AND DEVELOPMENT

Planning the IMS design began in November 2013 and the work was completed in December 2014. At this time ENEC had already established its management system and obtained the construction license. The planning start for the Nawah IMS for operations was based on a schedule that included such significant milestones as construction, commissioning and plant operations. At the timeline in place in 2014, the Nawah IMS would have been ready for regulatory scrutiny 22 months in advance of the Operating License Application milestone.

At the same time, a department was established that would own the implementation, assessment, management, measurement, and continuous improvement of the management system. This group would also be the key liaison between the ENEC and Nawah management systems. Post-project, the Project Manager transitioned as lead for the NIMS department (plus four staff) for a smoother continuity of effort.

Several stakeholders were considered that included nuclear industry associations (e.g., WANO, INPO), nuclear advisory groups (e.g., the Committee for Nuclear Power, the Nuclear Safety Review Board), FANR, the International Advisory Board, ENEC and the Nawah Board of Directors, selected ENEC leaders and staff, Nawah Chief Executive Officer (CEO) and Chief Nuclear Officer (CNO), licensing staff and management system working and steering committees.

IV.5. DOCUMENTATION OF THE MANAGEMENT SYSTEM

The Nawah IMS underpins the controlled documentation structure that enables the cascading of obligations and activities. This consists of a hierarchy beginning with organizational policies, manuals (e.g. processes and programs), procedures, references and records. Most documentation was provided through the prime contractor, KEPCO with further supplementary documents written by internal and third-party contractor staff.

The Nawah Integrated Process Model (NIPM) shown in Figure 8 categorizes all Nawah processes within the IMS, and its core documentation used to obtain and maintain the Nawah Operating License. Every process and program complies with either the UAE regulatory or statutory requirement or organizational need.

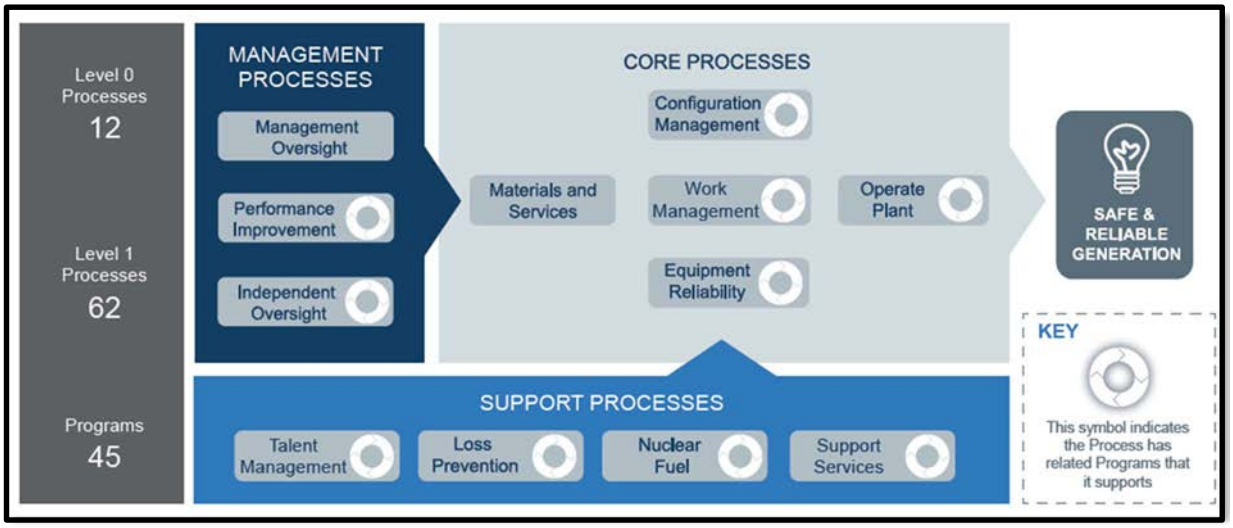

FIG. 8. The Nawah integrated process model

All processes and programs use procedures to implement and/or support them. Processes and procedures that are required in NIMS may exist in ENEC, Nawah or even a third-party entity, yet Nawah retains responsibility for them. In essence, no document resides outside the IMS as demonstrated by a detailed business architecture behind the NIPM model.

To drive accountability, each process and program has a suitably qualified owner defined through procedures and maintained as a documented record. Owners have primary responsibility for achieving process objectives. They coordinate the various work activities at all levels across the organization. They evaluate overall process operation to evaluate potential improvements. They design and manage the process end-to end to ensure optimal performance is achieved. As per the UAE regulations, Process Owners are responsible for ensuring the process is both effective and efficient, that appropriate performance measures are put in place and related risks are properly mitigated.

Document control is facilitated by a Procedure Change Request and document maintenance procedures and a digital document management system (Documentum platform) for the creation, development, review, approval, publishing, and storage. This applies to documents across management systems where for example, ENEC owns a procedure and Nawah contributes to its continuous improvement as a key stakeholder, and visa-versa. Process and Procedure sharing can create more complexity across organizations, but the reward is observed in the collaborative development and improvement of both management systems together.

Documents are classified as either ‘public resource’ (PR), ‘for office use only’ (FOUO), ‘business sensitive information’ (BSI), ‘secret’ or ‘top secret’. Each document category defines the audience who may access them. Digital record retention periods are defined by procedure

and by the author of the document. Paper records are also maintained on an as-needed basis. Retention can range up to the life of the plant based on defined need.

IV.6. INTEGRATION OF THE COMPONENTS

Central to the NIMS is the '5P' operating model that represents the core of the Nawah business process architecture. The 5P brings together *People, Plant, Programs, Processes and Procedures*.

Fundamentally, the operating model is about meeting all regulations, requirements, and stakeholder expectations. It is based on recognized and proven industry best practices and provides a basis for compliance with regulatory requirements and a model for achieving and sustaining high standards of performance as safety is built into everything Nawah does:

- **People** who perform work in the plant are engaged and qualified professionals who act in an error-free manner and have a constructive questioning attitude;
- The **Plant** is designed with robust features that ensure safe and reliable operation. Safety is managed effectively throughout the life of the plant;
- The **Programs**, **Processes** and **Procedures** provide accountabilities and methods that produce consistent and predictable results, prevent errors, and comply with applicable regulatory requirements.

The 5P operating model is enabled by all other components of the NIMS including but not limited to accountability expectations, company values and the Nawah Health and Safety Culture. The mechanism used to integrate these components is the IMS policy and network of connected documents, people and plant. This system, working together lays the foundation for effective change management planning, impact assessments and informed decision-making in all parts of the Nawah organization. Any deviations from current state can be detected by the NIMS, assessed, and properly actioned to maintain operating license compliance and, organizational effectiveness and quality.

IV.7. GRADED APPROACH

Nawah uses a structured approach through analysis, documentation, verification, resource allocation and other controls necessary to determine how management system requirements are deployed. With the paramount goal of increasing safety, consideration is given to the significance, complexity and the severity of any potential risk to safety. To this end, Nawah has implemented an *Enterprise Risk Management* framework that allows to manage risks in a consistent manner using a graded approach. This also applies in the Nawah processes and programs where tighter controls are put in place for safety-related artefacts as well as those critical to the safe and reliable operation of the Barakah Nuclear Power Plant.

IV.8. IMPLEMENTATION OF THE MANAGEMENT SYSTEM

Once the design project was complete, work was handed over to the NIMS unit to execute its implementation. Effort began with messages from senior management that continued at regular intervals and forums. Challenges were highlighted as risks with the headlining challenge being to educate staff about how to work under a process-based management system. Continuous and regular communications were sent to the defined stakeholder groups informing them of changes, general awareness, new documents (e.g. policies, programs and processes) up-and-

coming training, workshops, and events. These factors were successful in embed a new normal in the organization.

Once implemented, this influenced several other systems across the organization such as the document management system, risk and opportunity management application, corrective action program, self-assessment schedule, Quality Assurance Audit Plan, and change management procedures. It is through staff using the combination of these systems, that compliance and cross-functional work integration improved.

IV.9. VALUES AND ORGANIZATIONAL CULTURE

The Nawah and ENEC organizational values are shared and built directly into the management systems. The corporate culture is exemplified by the values of a*ccountability, teamwork, safety, integrity, trust and excellence* forming the words 'AT SITE'. These values were embedded before the NIMS was developed and helped shape its implementation. Having corporate values to fall back on when accountability, teamwork and interest started to fall, provided a solid argument to get stakeholder back on track and focus on IMS implementation. The IMS in turn would soon be the vehicle to promote and further advocate Nawah's values across the organization. Organizational cultures typically take years to build before benefits are realized. Given the high multi-cultural mix of nationalities at Nawah (more than 60 countries represented), implementing a common set of behaviours, was paramount in harmonizing an ideal culture, rather than an espoused one.

AT SITE is promoted regularly by organizational leaders who hold themselves and all staff accountable in living by them. They are discussed often as well as at the conclusion of every meeting as an 'AT SITE Moment' where examples from the plant are discussed in terms of value demonstration. This consistent focus on values has ingrained common behaviours in staff, with the goal of contributing to improved human performance and strive for excellence.

IV.10. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

Constant measurement and assessment have become a regular practice within the NIMS team, together with quality assurance and internal audits, nuclear oversight inspections and performance improvement reviews. In maintaining focus on improvements, a regime of self-assessments, process maturity model analysis, benchmarking, and a formal regulatory-requirement IMS review were put in place. This consisted of leveraging the findings from reviews by other units, implementing scheduled self-assessments twice per year as well as encouraging other organizational units to do the same and conducting a deep-dive assessment of the NIMS every two years.

The product of these reviews yielded several non-conformances that were managed through the corrective action program through to resolution. Findings from review were made available to senior management for their reference and action as needed. It was found that the IMS Review produced the greatest value given its depth of analysis that generated a positive energy among company leaders and stakeholders on the strategic and tactical value that the NIMS brought to the organization.

IV.11. LESSONS LEARNED FROM THE DEVELOPMENT AND IMPLEMENTATION OF THE MANAGEMENT SYSTEM

The NIMS was developed and implemented through extensive research of industry working practices. Various lessons were learned with key points listed below.

The following practices and attitudes have proven to be beneficial:

- A combination of waterfall and agile project planning together enabled a systematic way of achieving goals by putting higher intensity on immediate-term milestones, not unlike a graded approach;
- Open and honest team collaboration was helpful as all team members were focused on rollout including regular engagement and encouragement from the senior leadership team;
- Working sessions on specific milestones and products were conducted to ensure the knowledge and experience of the cross-functional group was captured;
- Clear and concise charter documents were developed for the working group and the steering committee to make clear scope and accountability;
- An initial meeting frequency and high-level agenda was established early and advocated regularly through the team with report-outs to senior leadership;
- Lessons learned workshops were held at the end of each project phase to ensure specifics were properly and adequately captured;
- The project team maintained a good relationship with vendor senior partners as well as working group staff, promoting a positive approach and effective and collaborative working ethos.

Some difficulties arose here and there due to misunderstandings in a multicultural context, insufficient engagement of staff:

- In the beginning of the project, vendor scope and variation were fluid and changed several times. This can be kept under control through contract documentation and advocacy;
- Staff attendance was low at some awareness sessions. This was expected in the beginning as the NIMS was unfamiliar was lost many times to competing work demands. Continued support from the 2014 senior leadership team eventually improved attendance;
- Some working staff did not attend meetings making obtaining different function perspectives difficult. As for the point above, this changed as IMS development progressed;
- Differing interpretation of the prime contract regarding management system expectations varied between the prime contractor, Nawah leadership, licensing staff and the IMS development team. Greater and properly translated (e.g. from Korean to English) clarification could have been more of a focus with the South Korean prime contractor;
- There was a slow start due to confusion with different stakeholder perspectives. This is typically the case at the beginning of a large project and while more time on planning may have helped, this was improved with the published of scope documents and outcomes of workshops with senior leaders;
- Not enough time was spent in Plan phase as some staff wanted results quickly. More time in clarifying needs through detailed situational and environmental assessments and journey mapping may have saved time on resolving challenges later.

The following best practices are worth highlighting:

- Being consistent with meeting timing, agenda and level of energy were all important traits to build and maintain effectiveness in the project;

— Bringing pre-prepared, specific, and detailed tasks to the meeting provided focus for attendees to problem solve teamwork and enabled decisions that are more efficient;
— Benchmarking of other systems was valuable to define a minimum standard and springboard for improvements;
— Publish and continually advocate and maintain IMS standards through various staff across different levels in the business. This effectively made IMS champions, so they made market the IMS in their own expertise and perspective within their teams and reach people in a way they understand;
— Develop and regularly distribute checkpoint reports on schedule set an expectation of systematic reporting so leaders and project sponsors would know exactly when and what to expect in status updates;
— Key is to never stop advocating for IMS value and criticality in building and sustaining the Nawah Health and Safety Culture. Using any means possible to communicate the message of the IMS, examples included visual marketing posters, flyers, booklets, printed policies, awareness sessions, live Q&A sessions, continuous improvement workshops, focus group working sessions and presentations at all-staff meetings;
— Speaking and sharing knowledge at international industry forums also helps in prompting management system effectiveness across the industry. This can bring recognition and validation to the implemented system, generate questions and enthusiasm in others who may be embarking on a similar journey.

CONCLUSION

Building a management system in a new-to-nuclear country that complies with all relevant UAE regulatory and statutory requirements from nothing was expected to be a challenge, made more complex as we continue to ensure that the ENEC MS and NIMS are well integrated, meeting mutually exclusive requirements and achieving shared goals.

A management system, going by whatever name suits, be it Corporate Governance Model, Operating System, Management Model, Excellence Model or otherwise, can unite staff together under one larger purpose and be the roadmap for the organization in achieving its goals. Whether to cover phases of plant construction, commissioning, or operations, implementing a way that brings together in a coherent manner all the requirements for managing and monitoring a business in a planned and systematic way, is an affirmative step forward to ensuring the organization safely achieves its objectives.

APPENDIX V

CASE STUDY – NATIONAL ATOMIC ENERGY AGENCY (PAA), REPUBLIC OF POLAND

V.1. INTRODUCTION

In 2009, the Polish Government decided to launch a nuclear power programme to help diversify the country's energy resources and limit their impact on the environment.

The Polish Nuclear Power Programme (PNPP) was adopted by the Council of Ministers on 28 January 2014. In October 2020, the Government adopted a resolution to update the Programme. Actual/revised PNPP assumes building of six units, with total installed capacity from 6 to 9 gigawatts (GWe) based on proven, large scale, generation III (+) pressurized water reactors by the year 2043.

Role of nuclear regulator within the PNPP is performed by the National Atomic Energy Agency (Państwowa Agencja Atomistyki (PAA)). PAA was established in 1982 in connection with the previous efforts to introduce nuclear power program. PAA's activities are regulated by the Act of Parliament of 29 November 2000 (Atomic Law) and the relevant secondary legislation. The President of the PAA is the central governmental administration body, whose core activities include:

- Exercising regulatory control and supervision over activities leading to actual or potential ionizing radiation exposure of people and natural environment (these currently includes over six thousand ionising radiation users, radioactive waste repository and the Research Reactor Maria);
- Assessment of the national radiation situation and providing relevant information to appropriate authorities and to the public;
- Preparing drafts of legal acts on the matters provided for in the Atomic Law and consulting them with other state authorities.

The integrated management system (IMS) of PAA covers all activities of PAA and was established based on existing management system. Implementation of the MS started in the first phase of the PNPP and was intensified within the second phase. The priorities for development of MS in the second phase were based on the recommendations of the IRRS mission 2013 and included: development and implementation of MS documentation, process approach and communication channels. The program on enhancement of safety culture was conducted in parallel.

At the final stage of the second phase, the process map is being verified, adequate processes amended, and projects launched to prepare for licensing and oversight of NPP construction. The MS is being continually developed based on the mechanism implemented within i.e. internal audit, self-assessment, and review as well as best practices and expertise from IAEA, the Nuclear Energy Agency (NEA) as well as other organizations and regulatory bodies.

V.2. REQUIREMENTS

The PAA's management system and related processes are regulated by number of legal acts binding all governmental administration offices in Poland. Furthermore, the guidelines accompanying the Act on Public Finances set so called 'managerial control standards' which are reference for many elements of the MS.

In addition to above requirements, the PAA strategic goal is to implement the process based integrated management system (IMS) in compliance with the IAEA GSR Part 2 requirements (see Ref. [2]). The PAA is using also other adequate IAEA standards and guidelines and other international standards. For the internal audit programme PAA has used the ISO 19011:2018 (see Ref. [27]) considered as good practice learned directly from the Slovak and Swiss Regulatory Bodies.

V.3. RESPONSIBILITIES FOR THE IMS

The development and implementation of the management system was initiated and has been supervised and supported by the Director General and the President of the PAA.

The ownership of the main processes belongs mainly to the directors and in some cases to the specialists. The owners of sub-processes are mainly Heads of Units or specialists.

In 2016, within the establishment of the project entitled *Implementation of the Integrated Management System*, the project team was created and a coordinator for IMS implementation was appointed. The members of senior management formed the Steering Committee, and the Director of the President's Office supported and carried out direct supervision over the project.

The project team consisted of representatives of all organizational units (seven people). The end of the year 2019 is considered as the completion of the project.

The current structure of roles for the MS is summarized in TABLE 4.

TABLE 4. ROLES AND RESPONSIBILITIES FOR THE MANAGEMENT SYSTEM

Position or function	**Main roles and responsibilities within the MS**
Top management: President, Vice President, Director General	— Supervision and support (incl. promotion and communication); — Approval of plans, key MS documents, reports, etc.
Directors of units	— Consultation/approval/ownership of MS documents; — Review of IMS; — Supervision and improvement of the system within units.
IMS Coordinator (specialist for the IMS)	— Planning and coordination of works; — Preparation or verification of projects of MS documents.
Legal Department	— Verification of MS documents.

Position or function	Main roles and responsibilities within the MS
Process owners (PO) (around 30 people)	— Description, monitoring, and review of the owned processes; — Review and development of process documents; — Responsibility for 'audited area' during the internal audits.
Internal auditors (7 people)	— Execution of internal audits.
Improvement actions and projects leaders (temporary roles)	— Coordination of implementation of improvement actions and projects.

V.4. MANAGEMENT SYSTEM PLANNING AND DEVELOPMENT

Process based management system (MS) in PAA was developed from the former management system, which covered elements typical for the public administration office and also included vision, mission, quality policy and operating procedures.

In years 2014–2015, the first draft of the MS Manual was developed, based on former IAEA Safety Standards Series publication entitled *The Management System for Facilities and Activities*", No. GS-R-3, now superseded by the IAEA's GSR Part 2 [2].

In 2016, the following elements were completed:

- MS Manual (referring to GSR Part 2) and Safety Policy (replacing former quality policy);
- Final list of processes adopted, and process owners appointed and trained (internally);
- Process charter (descriptions) template and pilot process charters.

The project for development of IMS was set in the end of 2016. The plan of the project was based on the gap analysis against the GSR Part 2 requirements as well as recommendations of IAEA experts.

The timeframe, main goals, and scope of two main phases of the IMS project were:

- PHASE I (1 January 2017–30 June 2018): SETTING UP THE MAIN ELEMENTS OF THE SYSTEM
  - Development of three procedures: MS documents control, review of the MS, implementation of improvement initiatives (actions and projects);
  - Development of process and sub-process charters;
  - Carrying out comprehensive IMS review.

- PHASE II (1 July 2018–31 December 2019): DEPLOYMENT OF THE SYSTEM
  - Implementation the process management (including measurement of the processes);
  - Introduction of Internal Audit Programme (including training of auditors, pilot audits and the final procedure);

— Implementation of the IT tool (NND Integrum) supporting the IMS.

The main risks identified within the IMS project included delays in execution of tasks and low quality of work caused by lack of time or lack of commitment of people engaged. Mitigating measures were related to communication, supervision, training and support/consultation.

V.5. DOCUMENTATION OF THE MANAGEMENT SYSTEM

Document hierarchy

The following three-level structure of MS documents has been defined:

— Level I (directions and main principles): this set of documents includes the Statute, Mission, Vision, Safety Policy, Organizational Regulations, MS Manual, list of processes, long-term programs, and strategies (including the communication strategy);
— Level II (management of the organization and processes): this set of documents mainly corresponds to orders of the President and Director General, plans and process descriptions;
— Level III (mode of implementation of processes): this category of documents includes procedures, instructions, guidelines, and job descriptions.

Policies and objectives of the organization

In 2016, the PAA's Quality Policy developed in 2012 was superseded by the Safety Policy which sets the main principles that all individuals in the PAA are required to follow.

Other policies are the Personal Data Protection Policy (approved in the 2020) and the Policy of Counteracting the Corruption and Conflicts of Interest (approved in 2021). The development of the Information Security Policy has started in 2021. General rules and principles as well directions in other areas are specified in the MS Manual and other documents, e.g. in:

— Human Resources Development Program of the National Atomic Energy Agency;
— Rules for Issuing Recommendations of the PAA President;
— Code of Best practices for Internal Communication;
— External Communication Strategy.

Process map and processes

The first list of processes of PAA was identified using the bottom-up approach, based on comprehensive list of task and activities of the PAA. The current two-level hierarchy of processes includes main processes and sub-processes. Processes have been divided into three groups, depending on the objective and role played in the organization:

— Operating processes: through these processes, the PAA performs its basic functions and carries out tasks and services for clients and other external parties. The fundamental objective of these processes is to ensure nuclear safety and radiological protection;
— Management processes: through these processes, the PAA establishes objectives and plans; regulates, assesses and improves its activities; and maintains external relations.

The objective of these processes is to ensure effective functioning and development of the organization;

— Administrative / supporting processes: with these processes, the PAA manages its internal resources and ensures the proper conditions, handling, and support for implementation of operating and managerial processes.

Figure 9 presents the general process map of PAA.

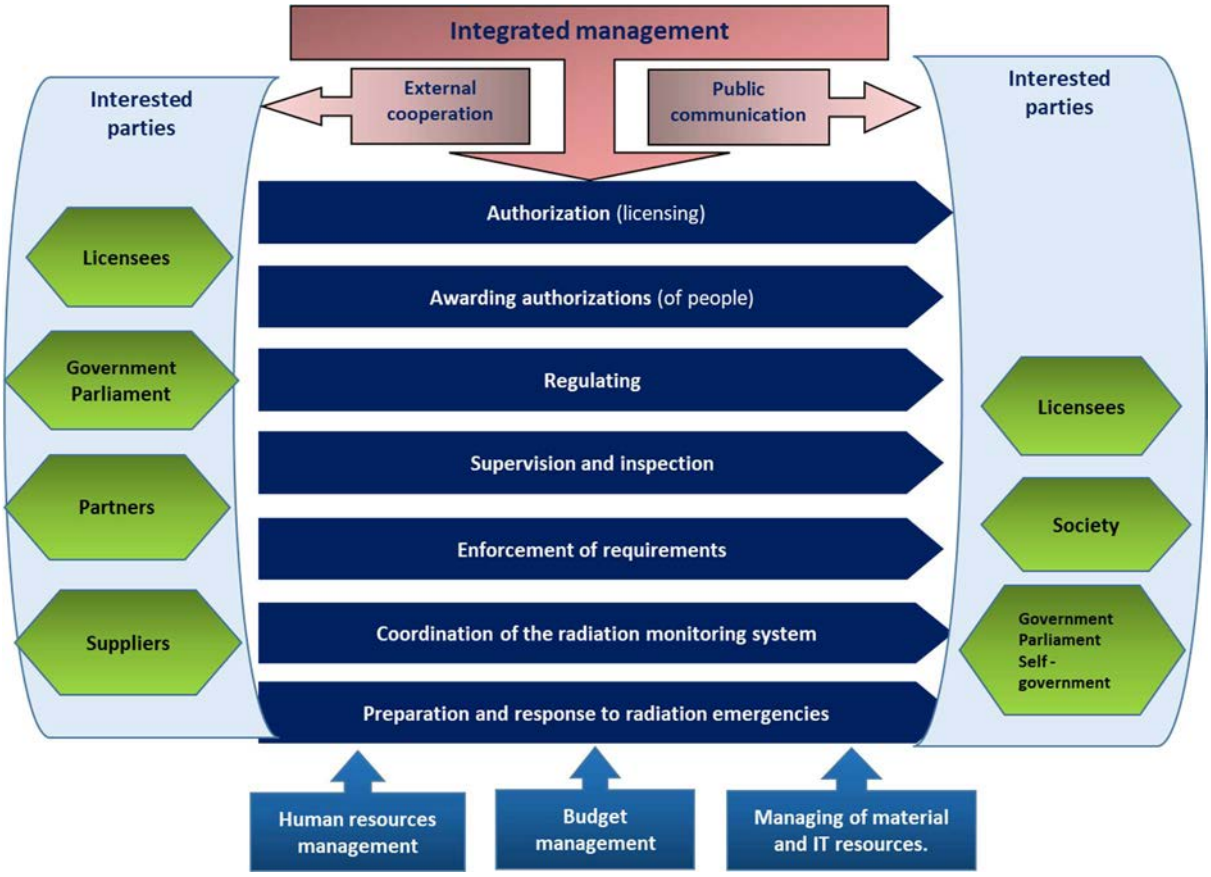

FIG. 9. PAA process map

The PAA approach is to define activities as the processes while they are key, systematic, and necessary for execution of the mandatory tasks of PAA, and have common goals consistent with the mission, vision of the PAA. Sub-processes generally are repeatable sequences of actions for which it is possible to define boundaries, inputs and outputs, phases/steps as well as targets and indicators.

Each proposal of a new process is analysed and discussed by responsible director and senior management representatives. New/changed process and appointment of Process Owner are approved by the PAA President. The design of the process (or sub-process) is primarily based on the legal requirements.

Other input information for process development includes:

— Requirements and directions set by the Government (if applicable), including programmes and strategies (the example is PNPP itself);

— Requirements and expectations of clients and other parties concerned;
— Internal regulations (acts of internal law, MS documents);
— Requirements and conditions resulting from links with other processes and from other internal or external interfaces;
— Organizational structure implications;
— Available competence and resources.

The PAA finds it very helpful to take into account the recommendations and guidelines of international organizations as well as best practices applied by other Regulatory Bodies.

When designing and developing the process, the following rules are followed:

— The priority for safety is respected;
— Graded approach is to be considered;
— Key process participants take part in the process design and description;
— Process descriptions and documents are consulted with directors of relevant units (participating in the process);
— Process descriptions and procedures are verified and approved accordingly.

Up to 2019, the processes were described using paper process charters (descriptions). Since 2020 the description of the process has been made only in electronic version (in the application NND Integrum).

The only formal role set for the processes is the Process Owner, whose duties relate to implementation of process approach (including description, monitoring, review, and improvement of the process).

Lower-level documents

The decision concerning development of procedures and instructions is made by the director of unit responsible for the process in consultation with the Process Owner and considering the following criteria:

— Impact of the process on safety;
— Degree to which the course of the process is regulated by legal provisions;
— Frequency of process implementation;
— Number of people involved in the process and their competences;
— Complexity of the process (elaboration, difficulty of tasks in the process, time limitations);
— Possibility of standardization of the process;
— Level of direct supervision.

The basic principles of MS documents control comply with the requirements and guidelines of the IAEA publications and are set in the MS Manual and MS documents control procedure. All documents are being consulted, verified, approved, and published accordingly.

Records control and archiving

The required records are indicated in the MS procedures and internal regulatory acts. Additionally, they are presented on process diagrams. The mode and method of handling of the documentation /record has been specified in detail in the following documents:

— Office instruction (which provides for a uniform manner of development, marking, recording, and storing of documents and their protection against damaging, destruction, or loss until their transfer to the archive);
— Uniform subject file index (containing a classification of documentation, division into subject groups and archival categories);
— Archive instruction (instruction on organization and scope of archiving activities).

In 2019, PAA has implemented the Electronic Documentation Management system enabling performance of office tasks, documenting of the status of cases, and gathering and development of electronic documents. It also provides for archiving of electronic documents.

Special rules, strictly based on law regulations, are applicable to documents containing classified information and personal data. The comprehensive Information Security System (referring to the ISO standard 27001 [19]) including Information Security Policy and systematic risk analysis is planned to be developed and implemented in 2021.

V.6. INTEGRATION OF THE COMPONENTS

One of the objectives of the IMS is to make sure that the PAA meets all relevant requirements in all its processes and activities. The requirements include mandatory legal requirements, adopted standards (e.g. for IMS development) and expectations of the interested parties identified by the PAA. These requirements are being identified in respect to each of the key areas indicated in the definition of the IMS (safety, health, environment, protection of resources of the organization, quality, and social and economic components).

In addition to the above-mentioned requirements, it is assumed that necessary ‘red threads’ of integration of MS are:

— Goals: consistency of goals through cascading them down and planning;
— Safety priority: making sure that each component of IMS, each goal and plan and each decision take Safety into account and is consistent with the Safety Policy;
— Process approach: integration of requirements, goals, resources, actions and their monitoring at process level.

The tools for ongoing integration of PAA plans and actions are:

— The PAA President’s action plan;
— Activity-based budget;
— Processes and MS documents (supporting execution of actions in planed, systematic way consistently with goals and requirements);
— Projects (cross-functional teams);
— Review and assessment within the IMS;
— Ongoing monitoring and supervision by the management.

V.7. GRADED APPROACH

The graded approach is applied, in particular (but not only) to processes and activities related to supervision of activities associated with exposure to ionizing radiation. To determine the weight of a given process, action or supervised activity, the following criteria are considered:

— Significance (impact on safety);
— Complexity;

— Hazards and risks related to safety, health, environment, security, quality, human and organizational factors, and social and economic aspects;
— Consequences of inappropriate performance of a given process or action.

The grading criteria for other processes may be of different nature e.g., cost. The detailed principles of application of graded approach are established for each area or process separately and described in the process descriptions (generally) and MS documents (in details).

V.8. IMPLEMENTATION OF THE MANAGEMENT SYSTEM

The information and MS documents are available on the Intranet. Additionally, IMS coordinator (or other relevant person) communicates current developments through e-mail, the Electronic Documentation Management system and internal meetings and trainings. Senior management communicates main plans and developments during general or departmental meetings.

Making sure that people follow the MS, its processes and documents is responsibility of directors supported by Process Owners. Implementation/use of the system is also assessed through internal audits. People feedback and proposals of changes may by submitted through:

— Direct communication with Process Owner and relevant managers;
— Consultation of documents;
— Self-assessment questionnaire;
— Intranet and IT tool (NND Integrum).

V.9. VALUES AND ORGANIZATIONAL CULTURE

The PAA management treats safety as the highest priority and promotes the appropriate principles, values, attitudes, behaviours, and relations in order to develop the safety culture in the PAA. The values, attitudes and expected behaviours of employees have been formulated in line with the IAEA and NEA requirements and guidelines. The culture of PAA is being developed with use of these guidelines and best practices of other regulatory bodies.

Nevertheless, the following elements of the original PAA culture hindered the development of the management system:

— The considerable autonomy of organizational units and habit to proceed things in the way that was set and adopted in the particular unit/department;
— Low significance of internal documents – the employees of the PAA are capable to work based on the legal acts – this causes the low engagement in keeping the internal documents up to date;
— Most people are used to direct communication – it is another factor which decreases the importance of MS documents and use of formal communication channels (being the elements of MS).

V.10. MEASUREMENT, ASSESSMENT, AND IMPROVEMENT

Consultation (where applicable), verification and acceptance of key activities and products are foreseen in course of each process. Thanks to that majority of non-conformances are detected and corrected before the final approval and/or ‘delivery’. Non-conformances which were identified after the ‘product’ was delivered are proceeded according to the legal regulations and

process procedures/instructions. The complaints received are registered, analysed, and proceeded according to the procedure for handling complaints.

The process owners are required to summarize during the process review the nonconformities and corrective actions taken since the last review, and to propose and plan additional corrective actions if those already implemented are deemed insufficient. Non-conformances resulting from the internal audits are proceeded according to the procedure for internal audits.

Since 2012 PAA carries out self-assessments according to standards of management control, using questionnaires, anonymous surveys of employees' opinion as well as overt assessment of MS by unit directors. Questions in the employees' opinion surveys partly refer to the individual behaviours (e.g. understanding the mission, following rules and values, cooperation) and partly ask for people opinion on various elements of the MS, communication, and leadership. Some questions refer to individual satisfaction e.g. on training and development opportunities.

Results of a self-assessments as well as results of risk management constitutes the input to the IMS review as shown on Figure 10.

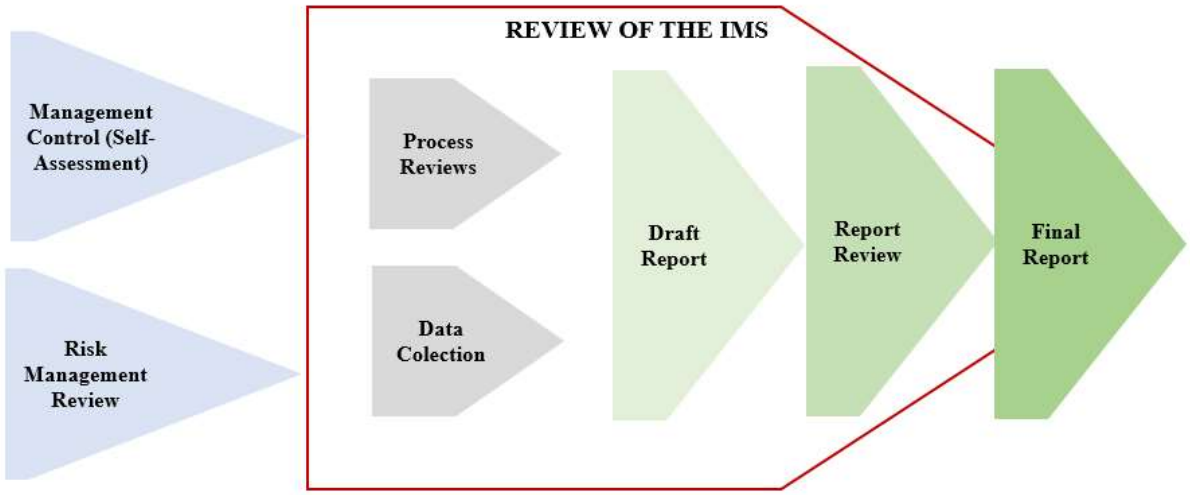

FIG. 10. IMS review process

Risk management review results include information on materialized risks and completion of risk mitigating actions.

Process review is carried out by Process Owners as the first stage of IMS review. Data and Information collection covers following areas:

- Accomplishment of PAA goals, plans, strategies;
- Results of audits and controls (internal, external);
- Review of projects/programmes if applicable;
- Improvement actions.

Based on all the information, the initial report of the review is prepared and consulted with directors and all Process Owners. After correction/amendments it is delivered to the senior management and the main conclusions are then discussed during the meeting/workshop summarizing the review. During this meeting, final decisions about improvement initiatives

and changes are made. Final report is again consulted and approved by the President of the PAA.

Periodic self-assessments, reviews and internal audits are the systemic tools facilitating continuous improvement. Possible changes and modifications in the MS may be also proposed by IMS Coordinator or any other person concerned by the management system, e.g. directors, Process Owners, senior management or any employee of the PAA. Approved changes are incorporated into the MS documents accordingly.

V.11. LESSONS LEARNED FROM THE DEVELOPMENT AND IMPLEMENTATION OF THE MANAGEMENT SYSTEM

The main lessons learned and other suggestions to share are as follows:

- Give due consideration to the goal and scope of the undertaking: What is an Integrated Management System (IMS) complying with GSR Part 2 versus a Quality Management System? (QMS is the first stage only);
- The implementation of the quality management system is possible within one (even though complex) project. For implementation of IMS, long-term program /programs and several teams and project (depending on the size of the organization) are needed. To meet the requirements of GSR Part 2, strategic thinking and a strong and consistent engagement of the entire management team and the entire organization over time is required, as well as continuous review and improvement of what has been done so far;
- Implementation of a management system from an existing one is probably not easier than developing it from scratch (resistance to change, conviction that 'it was working well so far' and 'law is enough', etc.);
- Management awareness and engagement are essential for development of the MS. The key elements are: (a) using the MS and role modelling; (b) communication; (c) enforcement of the MS rules/documents;
- The nomination of a member of the senior management (management representative) who will be in charge of the MS on the long-term is recommended for consideration;
- In case of PAA, the top-level Steering Committee (SC) within the Project did not work very well (e.g., it was difficult to organize meetings of all the members);
- Project structure may be quickly replaced by the basic elements of the MS itself. In case of the PAA, the rules set in documents control procedures quickly replaced the rule of approving the MS by the Steering Committee, review of the MS and improvement actions planning replaced the Project schedule (probably the 'project approach' was not established strongly enough);
- Think and plan the use of electronic tools as early as possible: introducing e-tools later causes considerable changes to the MS and a lot of work to be done again;
- Use the MS systematically and timely: used partly/ with delays does not bring visible added value;
- Think and plan 'quick wins' and 'subsequent wins' e.g. through solving of the urgent problems to engage the personnel and show the usefulness of the MS;
- Train and engage into the MS development as many people as possible (and manageable). Too few people engaged excessively lengthens the timeframe, leads to delays and low effectiveness of the MS implementation;

— Introduce easy way/tool for ongoing communication of any developments and changes in the MS as well as for collecting feedback from the employees.

APPENDIX VI

CASE STUDY – POLISH NUCLEAR POWER PLANTS LTD. (PEJ), REPUBLIC OF POLAND

VI.1. INTRODUCTION

Efforts to renew Poland's nuclear power programme began in 2009. The Polish Government designated Polska Grupa Energetyczna (PGE) as the leading entity for construction of Poland's first nuclear power plant. PGE's wide experience in the completion of large investments as well as its stable economic standing and financial capability were decisive factors. In 2014, the Government engaged domestic business partners to support PGE in establishing a special purpose vehicle (SPV) named PGE EJ1 sp. z o.o., responsible for preparing the investment process and construction of the first nuclear power plant in Poland. In March 2021, the State Treasury took over all the shares in the PGE EJ1 and an amendment of the Articles of Association of PGE EJ1 was entered into the National Court Register in June 2021, by which the company runs its business as Polskie Elektrownie Jądrowe (PEJ sp. z o.o.).

In 2020, the Government (Council of Ministers) approved the revised Polish Nuclear Energy Program (PNPP), the objective of which is the construction and commissioning of nuclear power plants in Poland with a total installed capacity of around 6 to 9 GWe based on proven technologies of large pressurized water reactors of generation III (+).

Currently, the infrastructure development for nuclear power in Poland corresponds to Phase 2 of the IAEA Milestones Approach (see Ref. [1]).

The management system of PEJ was created from scratch (initiated as PGE EJ1) and managed as a project. Apart from the technical advisor support, the project also involved several international experts from the nuclear industry as well as the own resources of PEJ and national consultants.

The implementation of the management system (MS) was also supported by the IAEA through expert missions and workshops aimed at evaluating the most important elements of the system documentation carried out under the PUI Programme.

VI.2. REQUIREMENTS

The main source of legal requirements for the management system in Poland is the Atomic Law Act, Articles 36 k.1 and k.2, which defines the obligation to implement an Integrated Management System (IMS) and lists the documentation that needs to be submitted to the Regulatory Body for approval.

Initially, PEJ considered the requirements from the IAEA's GS-R-3 (The Management System for Facilities and Activities) before it was superseded by GSR Part 2 (see Ref. [2]) used as a reference since 2016 to further develop PEJ's MS. PEJ also takes into account the IAEA guidelines GS-G-3.1 (see Ref. [7]) and GS-G-3.5 (see Ref. [8]), together with a selection of ISO standards.

VI.3. RESPONSIBILITIES FOR THE IMS

The implementation and development of the MS is supported by the roles defined in the organization and described in the MS Manual. The Management Board plays a special role having full responsibility for the management system.

Independent of the roles defined under the MS, the responsibilities related to the operation of the MS may be assigned to program and project roles, e.g., program manager, deputy program manager or project manager.

Process management is performed by the Process Owners at process level and by the Management Board at company level, in line with the roles defined in the process descriptions.

Process Owner's responsibility resulting from the MS Management Model includes defining and monitoring process KPIs, managing interfaces with key process stakeholders and requesting the resources needed to perform the process.

Assessment of the implementation and effectiveness of the MS includes conducting management reviews, internal audits, process self-assessments, process risk analyses, and documentation reviews, at intervals specified at process level and based on a graded approach. The MS is also subject to external assessments conducted by experts from outside PEJ.

The implementation and development of the MS at PEJ was supported by the IAEA activities in the form of a number of expert missions and workshops aimed at reviewing MS elements, assessing the revised process model, as well as a specific scope like e.g. stakeholder involvement strategy, systematic approach to training (SAT) or safety culture.

VI.4. MANAGEMENT SYSTEM PLANNING AND DEVELOPMENT

The documentation of the Management System started to be prepared in mid-2015 as part of the quality assurance for the environmental and site studies.

Each change in the scope of PEJ resulted in an adaptation of the MS. This was the case in mid-2016 with the limitation of the scope of the PNPP and similarly when the decision was taken to give up developing a management system in accordance with ISO standards (with the objective of certification) in favour of a management system meeting the requirements of GSR Part 2 and related IAEA publications.

Different phases in the PNPP require adaptations of the MS:

- By the end of the first phase of the program, Owner–Operator organization needs to be ready to cooperate with the future technology provider (strategic partner). Therefore, the MS needs to be developed to perform the quality supervision over the works performed and to select and evaluate potential technology vendors and their supply chain.
- The second phase will integrate those elements of PEJ's MS and EPC contractor's MS to manage the interfaces between the two organizations during the detailed design of the nuclear power plant (adaptation of proven design to site conditions and Polish regulations).

— In the next phase, key developments will focus on implementing the documentation for the construction phase (including supervision) and oversight of vendor and its supply chain.

PEJ's risk management approach is based on two levels. First level concerns the management of program and project risks that are handled within the program and projects management methodology based on Managing Successful Programmes (MSP) and PRINCE 2. It is aimed at identifying the key risks from the program and project perspective. Second one concerns process risks and is conducted based on the FMEA methodology as part of the management system maintenance.

The result of the program and projects risks is information reported monthly to the Management Board and the Supervisory Board. The result of the process risk analysis defines a process grade which differentiates the level of requirements application and frequency of use of the process control tools.

In order to supervise the management system, simple and generally available tools in the form of excel registers are used, such as e.g.: management system elements register, program impact database, risk registers, and SharePoint based tools such as the Management System Portal with public access to all system documents.

Moreover, the company maintains a documentation database covering all the company's documents. It is planned to implement a comprehensive tool for document management in the near future.

VI.5. DOCUMENTATION OF THE MANAGEMENT SYSTEM

In the initial phase of planning the management system, which was assumed to be compliant with a number of ISO standards, the requirements indicated the need to develop many independent system policies. The currently adopted approach has limited the number of management system policies which fully cover all system requirements and national legal requirements. These policies are:

— Leadership and Management for Safety System Policy;
— Quality Policy,
— Security Policy.

PEJ process map contains 15 active and 5 inactive processes specific to the current phase of the program grouped into three categories: management process, main process and support process. For the following phases of the program, the main processes will be activated or deactivated as the program progresses.

Processes are described in a standardized way which provides clarity on the process steps and responsibilities, interfaces with other elements of the MS, inputs and outputs.

Process roles are defined directly in the process descriptions.

Process Owners are chosen by the Management Board. In most cases, Process Owner is a head of department but it can also be a subject matter expert in a specific area.

Risk management in processes is subject to regular and ad-hoc verification in intervals that are set out based on the classification of the process or process step. The results of the risk analysis and its estimation is recorded in a Process Risk Register.

In the case of simple processes, it is acceptable that the process description is the only document as long as it fully covers the steps and activities necessary for its implementation and achievement of the process objectives. If the complexity of the process does not allow the application of such approach, the Process Owner may further develop the structure of documentation that is necessary to properly manage the process. Process steps may be described in a lower tier document such as a procedure and specific steps in the procedure may also be detailed in a dedicated instruction. However, it is allowed to omit a given level of documentation when justified e.g. direct reference from a process step to instructions to simplify the documentation.

PEJ has developed a MS Manual describing the process model and templates for MS documents at all levels, i.e.: policies, regulations, processes, procedures, instructions and templates. The rules for identifying the need for new documents, their requirements, the process of preparing, reviewing and giving opinions as well as approving all types of MS documentation were also described. A dedicated instruction for creating a diagram according to the chosen elements from BPMN 2.0 notation was also prepared.

The Process Owner has to systematically report to the MS team and justify any need for a new document or change proposal to an existing document. The head of the MS team decides whether the document fits in with the MS documentation and appoints a person from the MS team to support the author during the document development process.

The most important step is to collect the requirements that apply to the document from participants of the process, stakeholders and external sources like standards and laws. The author of the document, together with the designated MS Team member, prepares a draft of the document and submits it to another MS Team member for verification in accordance with the checklist of the MS elements. Comments are discussed together and taken into account as far as possible, and then passed to the Process Owner for approval. These actions may be repeated until the document is considered fit for purpose.

Each new or changed document goes to an employee of the MS team who supervises and maintains the MS documentation (MS elements ‘Register’ and ‘MS Portal’ on the SharePoint platform). All applicable MS documentation is made available to all employees through a graphical interface accessible via a SharePoint. Document versioning is applied to version change and technical changes. Former versions of MS documents are archived and not available on the employee’s view.

VI.6. INTEGRATION OF THE COMPONENTS

One documentation is used to integrate all components of the MS including the use of management tools such as reviews, self-assessments, audits that are carried out considering all requirements in total. Single registers and an integrated approach are used for assessment of risks and result in the grading of processes, documentation, and applicable controls.

The decision-making process in PEJ is carried out at three levels: program and projects level, process level, and corporate level. Depending on the type of decision a program-project, process or corporate path is chosen, or these paths are integrated in order to achieve the expected goals while following the applicable company rules.

VI.7. GRADED APPROACH

In PEJ, grading is applied to subcontractors' s activities as well as in relation to internal processes. The grading is determined by a team of experts and results in grades that differentiate the levels of requirements and controls implemented.

For subcontractors, manuals on quality, environmental protection, occupational health and safety and a number of contract obligations are prepared, the requirements of which depend on a given grade.

For the implementation of processes, the graded approach is based on the risks identified using the FMEA analysis, and reflected in the type and frequency of controls defined to achieve the desired outcome at an acceptable level, e.g. frequency of audits, number and nature of document reviewed or self-assessments.

VI.8. IMPLEMENTATION OF THE MANAGEMENT SYSTEM

The implementation of the MS started with the preparation of training materials for the target group focused on roles in the MS and expectations related to the efficient implementation of the MS. All employees were introduced to the legal requirements and standards, the process approach, the benefits of MS implementation and information on MS documentation. All department directors and Process Owners and selected key executive personnel were trained to become internal auditors in accordance with ISO 9001 (see Ref. [13]) and several employees acquired the qualification to ISO 9001 Lead Auditor.

The basic rule for the implementation of each element of the management system after its publication on the MS Portal is mandatory training conducted by the Process Owner, author of the document or open questions sessions for all interested employees.

Supervision over subcontractors is carried out by the dedicated 'vendors supply chain oversight' (VSCO) team. For each contractor and each contract, a company representative is appointed who carries out ongoing supervision over cooperation and quality of deliverables.

Several benefits from MS implementation for each group of internal stakeholders were identified to empower their engagement. In short, an effective MS makes your job simpler and gives you predictable outcomes from the activities you perform.

VI.9. VALUES AND ORGANIZATIONAL CULTURE

The development of the organizational culture was built-in into the *MS Implementation Plan* in PEJ from the very beginning and announced for the first time in the form of vision, mission and key values of PEJ.

The MS itself is planned in such a way that its implementation creates and strengthens appropriate attitudes and cultural behaviours. On the other hand, organizational culture influences the form of the MS documentation adopted and the mode of cooperation in the implementation of the objectives of the company.

VI.10. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

Non-conformities are identified using standard quality tools, such as audits, management reviews, self-assessment, process risk analyses, and results from reported observations and lessons learned from operational experience. All data on non-conformities, potential non-conformities and observations are entered into and managed using the MS Actions Register.

Self-assessments, management reviews and internal audits are planned in accordance with the grades assigned to a given process based on a risk analysis and yearly programs. Self-assessment is documented in accordance with the checklist containing process issues based on the IAEA guidelines and adapted to the diverse complexity of the processes. Management review is based on required inputs and outputs in accordance with ISO standard. Audits focus not only on the processes themselves, but also on the interface between processes where the greatest number of non-compliance occurs usually. Internal auditors are selected considering their independence in relation to the audited area, but also in such a way that the customer of the process audits his internal supplier.

Inter-process links are identified and managed by a list of process inputs and outputs and between documents by a list of relationships, which shows dependencies and uncontrolled inter-process relationships. Some dedicated KPIs are also focused on the assessment of cooperation between processes.

From the beginning PEJ engaged external experts with international experience to evaluate and support the system development as well as consultants from the technical advisor side and domestic market who conducted audits and assessments of the management system.

Introducing changes in the management system is always supported by an analysis of consequences and influence on the cohesion of MS and requires a decision by the manager of the unit responsible for MS. In each case, the change is approved by the Process Owner and in most cases by the Management Board especially when the change requires a decision regarding finance, human resources or assigned corporate responsibilities. PEJ is working on a procedure that will comprehensively describe the management of change, including MS change, and will address management of issues from the PPM methodology.

All PEJ employees can propose improvement to the MS. Employees take an active part in MS activities such as audits or self-assessments. Almost 20% of them have the qualifications of internal auditors or lead auditors for different standards, so they not only understand the management system, but can also accurately assess its functioning, identify non-conformities, and describe them in a systemic way.

VI.11. LESSONS LEARNED FROM THE DEVELOPMENT AND IMPLEMENTATION OF THE MANAGEMENT SYSTEM

Several lessons can be drawn from PEJ's experience:

— The MS implementation project in PEJ brings conclusions for other similar projects, especially in the area of availability of resources, schedule, cooperation with parent organization and stakeholders, integration of requirements, change management and others;
— The formalized structure of the MS is the only solution for organizations dealing with nuclear energy. The increasingly popular so-called agile approaches do not yet

guarantee the appropriate level of safety, trust, and public support that a nuclear program needs to have.

— The legal requirement to have a management system implemented in the organizations developing or supervising a nuclear power programme contributes to safety and constitutes a means of building trust with stakeholders.
— Implementation of a MS in organization involved in nuclear power programmes has to be carefully considered from the early days. This requires that program managers plan long enough time for the MS development and treat the implementation of MS not only as an organizational change but also as a cultural change.
— In addition, it is not advisable to use the PRINCE 2 type projects methodology approach or similar in relation to the implementation of the MS due to the different nature of the products to be delivered, which are difficult to be described and managed with project methodology.

Appendix VII

CASE STUDY – NUCLEAR REGULATORY AUTHORITY (NDK), REPUBLIC OF TÜRKIYE

This summary report has been compiled from the case study prepared at the time the management system was in development and reflects the activities at that time.

VII.1 INTRODUCTION

In line with the increasing energy needs, Türkiye has planned for many years to include nuclear power in its energy mix. Türkiye is currently engaged in the construction of its first nuclear power plant, the Akkuyu Nuclear Power Plant (Akkuyu NPP), which comprises four units (VVER-1200 type reactors), of which three are under construction following construction licenses granted respectively in 2018, 2019 and 2020. A second nuclear power plant is planned to be constructed and operated in Sinop Province (Sinop NPP). The environmental impact assessment (EIA) process for the Sinop NPP has been completed and site studies are being conducted.

The first nuclear Regulatory Body in Türkiye was the Atomic Energy Commission, established in 1956, which was reorganized under the Turkish Atomic Energy Authority (TAEK) in 1982. In July 2018, the legal infrastructure of Türkiye has been reorganized by the Decree Law No. 702 (The Organization and Duties of the Nuclear Regulatory Authority and Amendments to Certain Laws). The Decree Law established the current Nuclear Regulatory Authority, namely Nükleer Düzenleme Kurumu (NDK) as a nuclear Regulatory Body of Türkiye. This Decree Law also includes provisions regarding the transition of TAEK's regulatory infrastructure and personnel to NDK.

NDK consists of a board, which is the decision-making organ, and a presidency. The NDK Presidency consists of the President of NDK, two vice-Presidents and Service Units. As a newly established and structured authority, NDK's management system is under development at the date of preparing the case study. However, considering the management system activities carried out in the previous Regulatory Body TAEK, it is possible to say that it is structured on a certain accumulation.

The management system of NDK will cover the regulatory control activities defined by law, i.e. Establishment of Regulations and Guides; Review and Assessment; Authorization; Inspections; Enforcements.

VII.2 REQUIREMENTS

NDK is established as an independent Regulatory Body by the Decree Law No. 702 which is a comprehensive nuclear law regulating nuclear safety, security radiation protection and other related subjects. The duties and responsibilities of NDK are defined in the related Presidential Decree.

The Decree Law No. 702 is not prescriptive in terms of establishing a management system in NDK, but as any governmental organisation, NDK has to develop management arrangements to execute its duties.

Development of the management system within NDK is coordinated by the Department of Strategy Development, which as the responsibility "to establish a performance and efficiency-based management system in the Authority, to determine job descriptions and work and process flows, to carry out or have work and transactions related to the development and improvement of work processes".

NDK also benefits from the project named *Support to the Regulatory Authority of Türkiye* initiated in 2018 for strengthening the regulatory capabilities in the scope of European Union Instrument for Nuclear Safety Cooperation (INSC) program, which has a task with the objective to transfer to NDK the European knowledge and experience in the use of IMS for regulation of nuclear safety. NDK has planned to establish an integrated management system (IMS) in accordance with the requirements of ISO 9001 (see Ref. [13]) and ISO 45001 (see Ref. [18]), with the objective of its certification by an authorized certification body. The IMS will cover all activities and units of NDK.

Since the IAEA standards and guidance publications are used widely in regulatory activities, the GSR Part 2 [2] has been considered in the management system development works, in addition to other IAEA guides.

Specific Turkish regulations apply to public institutions and organizations, thus to NDK, which have to be considered in the IMS, e.g. regulations related to information security and archiving.

VII.3 RESPONSIBILITIES FOR THE IMS

Management system development efforts in NDK are supported and adopted by all senior management, especially by the President of the authority. Although it was established recently, technical support for the IMS development in NDK was procured and works for this purpose have been intensified.

The Department of Strategy Development is given the overall responsibility for coordinating the IMS development within NDK.

Management system development activities are carried out with the participation of all managers, including heads of groups and departments, and representatives from the different Units of NDK. A dedicated Working Group (WG) has been set up in June 2020 to this goal. Unit representatives are responsible for coordinating the development of management system documents in their Unit. They have been given the necessary training accordingly.

In addition, Process Owners also have roles regarding the cross-cutting aspects in the development of the processes.

A technical support is also procured locally to help develop the IMS.

VII.4 MANAGEMENT SYSTEM PLANNING AND DEVELOPMENT

The genesis of the management system dates back to the period when the nuclear regulator was TAEK.

Management system development work was triggered by the progress of the nuclear power programme. The first procedures governing the activities of TAEK were established in 2009 and their development continued within the Nuclear Safety Department of TAEK over the period 2012–2015 which precedes the license applications for the Akkuyu nuclear power plant.

Quality Management System (QMS) started to be implemented in TAEK with the Presidential Circular issued in 2014.In 2016, it was decided to establish an integrated management system (IMS).

Development activities are ongoing with the objective to publish the main elements of the NDK IMS in 2021. In the meantime, the procedures and guidelines inherited from TAEK will remain in use until they are superseded by the new/updated IMS documents under development.

IMS document development involves personnel who plays a role in the activities subject to the document.

VII.5 DOCUMENTATION OF THE MANAGEMENT SYSTEM

According to the IMS hierarchical document structure, the policy, mission and vision are at the top. Below are the main processes, sub-processes, procedures, instructions, forms, etc. An application guide similar to a management manual is used to explain the basic principles of the IMS and its use within NDK.

Since the plan is to build a management system that integrates several components, the integration is expected to be reflected in the policy of NDK. The policy has not been announced officially at the date of the preparation of this case study.

The processes are planned to be categorized as core processes, management processes, and support processes:

— Core processes include authorization, inspection, emergency preparedness and response, regulation preparation, and enforcement processes. The core processes are derived from NDK's duties and responsibilities which are given by decree/law.

  Other processes are defined in accordance with the management needs and consideration of the support activities necessary for the proper functioning of the organization;

— Before the establishment of NDK, management processes included policy making, risks and opportunities identifying and stakeholder satisfaction measuring. Support processes included human resources, archive, maintenance and repair and purchasing.

In addition:

— Procedures are prepared for defining how to conduct specific steps of a process. The structure of a procedure includes: Purpose and Scope, Responsibility, Terms and Abbreviations, Application, Forms and Records, Reference Documents, Performance Criteria and Risk and Opportunities;
— Instructions are developed when further detail is needed to carry out some activities.

Development of the IMS documentation is supported by the following main procedures:

- **Management of Risks and Opportunities**
  Every process/procedure owner is required to identify the risks and related controls. A risk action plan is prepared, and the risk inventory form is filled in;

- **Document Management**
  The procedure gives directions for the preparation, publication, updating, control, cancellation, distribution, and storage of all IMS documents.
  It also defines the content and format of the IMS documents, in particular for the processes (e.g.: process identification cards, process flow charts, unit process owner, or process managers for processes involving several units).
  Process managers' roles are planned to be as monitoring the effectiveness, discussing indicators and master data collected as part of the use of the process, and recommendation of improvements.

NDK does not use any specific software tool for developing the management system documentation.

The responsibility for the distribution of documents or making documents available lies with the Department of Strategy Development which maintains the 'Current Document List' for all documents in force.

The Intranet is currently used for sharing documents with users in a controlled way. A dedicated document management system platform is planned to be developed

VII.6 INTEGRATION OF THE COMPONENTS

Activities related to nuclear energy and ionizing radiation and the facilities (or locations) where these activities are carried out are subject to the regulatory control of NDK in terms of safety, security, and safeguards.

The IMS will cover all activities carried out by NDK, not only for the activities subject to regulatory controls bult also for supporting activities such as budget and accounting., each of them being handled in all aspects when decisions have to be made.

The integration of the requirements referenced in Section VII.2 is another way to build an IMS, what will be ultimately checked by a certification body.

VII.7 GRADED APPROACH

The Nuclear Regulatory Authority (NDK) applies a graded approach in the implementation of its management system in different ways.

As an example, the level of approval of the IMS documentation depends on its level in document hierarchy:

— Top-level documents such as policy, vision, mission, and implementation guides are approved by the President;
— Unit processes and procedures are approved by head of departments.

Another example is the control activities on a risk-based approach, with controls proportionate to the risks identified.

VII.8 IMPLEMENTATION OF THE MANAGEMENT SYSTEM

All persons assigned to take part in the execution of the management systems including the personnel from the Department of Strategy Development and other units as well as other personnel determined by units' supervisors are subjected to mandatory training on management systems. Both activities with local contractor (ISO based trainings) and INSC project with EU (includes trainings, in-situ missions, planned On-the-Job Training regarding management systems of some European countries) include trainings regarding management systems.

Responsibilities regarding implementation of processes and procedures are defined in relevant documentation. Generally, the head of units are responsible for proper execution of activities defined in processes and procedures. Necessary announcements about implementation of management system are made by e-mail and official letters.

All management system documents are kept in controlled folder in NDK intranet system. If a revision is made to a document, ace to the old version is no longer possible for to users. Any revision of documents is announced to related personnel with official letters or e-mails. The control of implementation of revised documents is the responsibility of the head of units.

VII.9 VALUES AND ORGANIZATIONAL CULTURE

The Nuclear Regulatory Authority (NDK), which is recently established by a nuclear dedicated decree law, brought together competent and experienced staff in regulatory activities, as well as recently employed staff. In addition to the activities carried out such as trainings and seminars to develop the organizational culture, standardization efforts within the scope of management systems through processes, procedures and other documents also contribute to this development.

The supporting of management system development works by senior management revealing the importance of matter and the understanding of the impact of management system practices on the execution of activities by staff contributes to the management system development efforts.

It is aimed to increase service efficiency with due attention to safety and security with IMS implementations. This will contribute to the effective fulfilment of the Authority's roles and responsibilities as a nuclear regulator and to foster and support a strong safety culture through the development of safety attitudes and behaviours in individuals and teams.

VII.10 MEASUREMENT, ASSESSMENT AND IMPROVEMENT

Management reviews and audits are used to assess the implementation and effectiveness of the IMS:

- Management review meetings are planned to be carried out at least once a year under the chairmanship of the president, in presence of unit supervisors and other personnel as applicable;
- Internal audits are planned at least once a year to check the applicability and effectiveness of the IMS.

— Once the IMS of NDK is certified, regular external audits by certification bodies will also provide an outside perspective on the maturity of the IMS.

Different sources of information will be used to identify opportunities of improvement such as:

— Nonconformity and corrective actions (a procedure has been developed);
— Outcomes of internal and external audits;
— Risk assessment and opportunities (a procedure has been developed);
— Assessment of change proposals;
— Feedback from stakeholders including complaints;
— Self-assessments of the IMS performance including process monitoring (a procedure has been developed).

All unit managers and employees are held responsible for measuring, monitoring, reporting, and evaluating the performance of the processes they use and report to senior management as required.

VII.11 LESSONS LEARNED FROM THE DEVELOPMENT AND IMPLEMENTATION OF THE MANAGEMENT SYSTEM

For the Nuclear Regulatory Authority, several lessons are already learned from the development of the IMS:

— Making an early decision on developing the IMS is valuable as this allows the staff to be involved from the start in the formalization of their activities, thus facilitating the appropriation of the IMS tools.
— Working with an experienced consultant organization is also another important decision. Benefiting from the consultant's experience can help efficiency in the development of the IMS and better understand the requirements of the standards with which the organization is less familiar;
— Deciding to make IMS development a task of the EU INSC project was another positive step on the matter, that gave opportunities to learn from experienced European organizations similar to NDK;
— Implementing a safety-oriented IMS is an important element for the effective realization of the duties and strategic goals and objectives of the nuclear regulator (NDK);
— Support and leadership of the management is key to mobilize people around the development and then the implementation of the IMS.

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LIST OF ABBREVIATIONS

APR	Advanced Pressurized Reactor, Korean Technology
ARIS	Architecture of Integrated Information Systems
ASME	American Society of Mechanical Engineers
BPA	Bui Power Authority, Ghana
DG	Director General
EDMS	Electronic Document Management System
EIA	Environmental Impact Assessment
ENEC	The Emirates Nuclear Energy Corporation
EPC	Engineering, Procurement and Construction
EU	European Union
FANR	Federal Authority for Nuclear Regulation, UAE
FMEA	Failure Mode and Effects Analysis
GAEC	Ghana Atomic Energy Commission
GNPPO	Ghana Nuclear Power Programme Organization
HR	Human Resource
IAEA	International Atomic Energy Agency
IMS	Integrated Management System
INIR	Integrated Nuclear Infrastructure Review
INPO	Institute of Nuclear Power Operations, USA
INSC	Instrument for Nuclear Safety Cooperation, EU
IRRS	Integrated Regulatory Review Service
ISO	International Organization for Standardization
IWP	Integrated Work Plan
KEPCO	Korea Electric Power Corporation, Republic of Korea
KPI	Key Performance Indicator
MS	Management System
MSP	Managing Successful Programmes
NAWAH	Nawah Energy Company, UAE
NDK	Nuclear Regulatory Authority *(Nükleer Düzenleme Kurumu),* Türkiye
NEPIO	Nuclear Energy Programme Implementing Organization
NIDS	Nuclear Infrastructure Development Section, IAEA
NIMS	Nawah Integrated Management System, UAE
NIPM	Nawah Integrated Process Model, UAE

NNRI	National Nuclear Research Institute, Ghana
NPG	Nuclear Power Ghana
NPI	Nuclear Power Institute, Ghana
NPP	Nuclear Power Plant
NQA	Nuclear Quality Assurance Requirements (associated with ASME)
NRA	Nuclear Regulatory Authority, Ghana
OEF	Operational Experience Feedback
PAA	National Atomic Energy Agency (*Państwowa Agencja Atomistyki),* Poland
PEJ	Polskie Elektrownie Jadrowe (Polish Nuclear Power Plants Ltd.), Poland
PGE	Polska Grupa Energetyczna (Polish Energy Group), Poland
PO	Process Owner
PUI	Peaceful Uses Initiative
QMS	Quality Management System
RACI	Responsible, Accountable, Consulted, Informed
RPB	Radiation Protection Board, Ghana
RPI	Radiation Protection Institute, Ghana
SAT	Systematic Approach to Training
SC	Steering Committee
SPV	Special Purpose Vehicle
TAEK	Former Regulatory Body, Türkiye
TSO	Technical Support Organization
USA	United States of America
VRA	Volta River Authority, Ghana
WANO	World Association of Nuclear Operators
WG	Working Group

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