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Effective Management of Regulatory Experience for Safety

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EFFECTIVE MANAGEMENT OF REGULATORY EXPERIENCE FOR SAFETY

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EFFECTIVE MANAGEMENT OF REGULATORY EXPERIENCE FOR SAFETY

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2020

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FOREWORD

Learning from experience — one's own and that of others — has long been recognized as beneficial in helping to identify weaknesses and to prevent the recurrence of unwanted situations. For this learning to occur, organizations need to have in place arrangements to enable the collection and analysis of relevant information, to act upon the conclusions of the analysis, and to share and disseminate the lessons identified for others to benefit from them.

Recent conferences aimed at assisting safety regulatory bodies in fulfilling their mission have highlighted that regulatory bodies do not have in place systematic methods and processes for collecting, analysing, implementing, disseminating and sharing regulatory experience.

The analysis of operating experience of regulated facilities and activities has traditionally been considered an important source of learning for improving the regulatory process. However, regulatory bodies are continuously exposed to learning possibilities from multiple sources of experience, such as the implementation of regulatory functions, regulatory research and work carried out by international committees and working groups. Taking advantage of all these learning possibilities could be beneficial in further enhancing the effectiveness and efficiency of the regulatory process.

In developing this publication, information about existing practices in regulatory bodies for managing regulatory experience was collected and, through a series of experts meetings, assessed to identify possible measures that might help regulatory bodies enhance their current practices, where necessary.

The IAEA wishes to thank all those who contributed to this publication. Particular thanks are due to M. Recio (Spain) for his assistance in the preparation of this publication. The IAEA officer responsible for this publication was D. Senior of the Division of Nuclear Installation Safety.

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CONTENTS

1. INTRODUCTION

1.1. BACKGROUND

Principle number 3 of the IAEA's Fundamental Safety Principles states that **"Effective leadership and management for safety must be established and sustained in organizations concerned with, and facilities and activities that give rise to, radiation risks"** [1]. An organization's management system has to integrate all elements of management and also has to ensure the promotion of a safety culture, the regular assessment of safety performance and the application of lessons learned from experience.

Building on this principle, Requirement 15 of the GSR Part 1 (Rev. 1) states that **"The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities"** [2].

Whilst most regulatory bodies have some processes to review the efficiency and effectiveness of their regulatory activities, recent conferences aimed at assisting safety regulatory bodies in fulfilling their mission have highlighted that regulatory bodies do not have in place systematic methods and processes for collecting, analysing, implementing and sharing and disseminating[1] regulatory experience.

Specifically, the President's report of the third International Conference on Effective Nuclear Regulatory Systems, Transforming Experience into Regulatory Improvement, held in Ottawa, Canada, from 8 to 12 April 2013, noted: "Both the regulatory bodies and the operators utilize — to varying degrees — operating experience from nuclear power plants to improve nuclear facility safety on an ongoing basis. Additionally, regulatory bodies perform detailed assessments of regulatory requirements, systems and processes following significant operational events such as those at Three Mile Island, Chernobyl and Fukushima. However, they do not routinely assess less significant events and issues, which would contribute towards continuously improving the regulatory process." [3].

Action item number 2 of the above report calls for assessing the need for a regulatory experience programme that is directed towards improving regulations as well as regulatory systems and processes. The IAEA was called upon to develop guidance.

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[1] The terms 'share' and 'disseminate' are often used in the literature as synonyms for 'spreading (information, knowledge, lessons learned) widely'. In this publication, the term 'share' is used to refer to proactively exchanging lessons learned from regulatory experience with other parties (for instance, in meetings, workshops or seminars), while the term 'disseminate' is used to refer to the spreading of the lessons learned from regulatory experience without direct involvement of the recipients (for instance, through web sites or by publishing the information in articles of journals or magazines).

In 2015 and 2016 the IAEA organized two meetings with experienced regulators to receive advice on how to address the above Ottawa conference request. Following the advice received at these meetings, the IAEA initiated the preparation of this publication to provide information on processes and methods to assist regulatory bodies in establishing an effective regulatory system for collecting, analysing, implementing and sharing regulatory experience. The publication also includes examples of the approaches currently followed by regulatory bodies of various Member States, including countries with and without nuclear installations in operation.

1.2. OBJECTIVE

The objective of this publication is to provide information to assist regulatory bodies in establishing and enhancing arrangements for proactively collecting regulatory experience, analysing this experience, implementing any improvements to the regulatory process and sharing and disseminating the lessons learned for their use by the regulatory body, authorized parties, and other relevant authorities of the State and of other States.

It is not the objective of this publication to encourage the regulatory bodies to create dedicated programmes or processes to manage regulatory experience. It is up to the regulatory bodies to use the information in this publication to assess their present arrangements and decide whether appropriate mechanisms are already in place or not to effectively identify lessons to be learned from regulatory experience and for sharing and disseminating the lessons learned.

1.3. SCOPE

The publication is applicable for the management of regulatory experience gained from the regulation of all facilities and activities[2].

1.4. STRUCTURE

The main body of the publication is organized in 5 sections, as follows:

— Section 1 contains background information, objective, scope and structure.

— Section 2 discusses the concept of regulatory experience and the relationship with the concept of operating experience.

— Section 3 includes an assessment of the feedback provided by a number of regulatory bodies about existing practice and, in the light of it, a discussion of the factors that can contribute to establishing and sustaining appropriate arrangements in order to effectively manage regulatory experience.

[2] Facilities and activities is a general term encompassing: nuclear facilities, all uses of all sources of ionizing radiation, all radioactive waste management activities, transport of radioactive material and any other activity or circumstances in which people may be exposed to radiation risks arising from naturally occurring or artificial sources. See footnote 3 of GSR Part 1 (Rev. 1) [2] for a complete definition of the term.

— Section 4 illustrates parts of a regulatory experience management programme to show the application of the concept of regulatory experience. This is followed by a discussion about means to ensure continuous improvement of the arrangements for managing regulatory experience. The Section concludes with a discussion about challenges to establish arrangements for effective management of regulatory experience.

— Section 5 presents the summary and conclusions of the publication.

A set of appendices to the main body provide detailed insights of some of the topics discussed in the main body of the publication:

— Appendix I discusses sources of regulatory experience.

— Appendix II discusses research and development as a source of regulatory experience

— Appendix III discusses the handling of regulatory experience in regulatory bodies with regional offices or shared regulatory functions.

— Appendix IV discusses the management of regulatory experience identified by Technical Support Organizations

— Appendix V discusses how to identify regulatory experience and shows an example of a syllabus of a training programme on the effective management of regulatory experience.

— Appendix VI discusses measures to share and disseminate regulatory experience and available international mechanisms to that end.

— Appendix VII includes a question set that can be used for self-reflection about the arrangements in place for the management of regulatory experience.

— Appendix VIII discusses sources of regulatory experience from non-nuclear areas that could be used in the context of improving the nuclear regulatory process.

Annexes I to IX present information collected about existing practices for managing regulatory experience. Annex I is an analysis of the responses to a feedback request on regulatory experience practice sent out by the IAEA to a large group of regulatory bodies in June 2017. This is followed by Annex II that summarizes the conclusions and recommendations of a regional workshop, organized by the IAEA in the framework of a technical cooperation project, where existing practice for managing regulatory experience was discussed. Finally, annexes III to IX present specific case studies provided by several regulatory bodies.

2. THE CONCEPT OF REGULATORY EXPERIENCE

Consistent with Requirement 15 of GSR Part 1 (Rev. 1), regulatory bodies are expected to establish ownership and make appropriate arrangements to identify lessons learned from regulatory experience, including of regulatory experience in other States, use and share and disseminate them.

2.1. DEFINITION OF REGULATORY EXPERIENCE AND USE OF OTHER TERMS

The IAEA Safety Glossary [4] does not contain a definition of the term regulatory experience, and currently there is no universal understanding of the term. For the purpose of this publication, regulatory experience is to be understood as:

Information and knowledge collected by the regulatory body that can be used to improve the effectiveness and efficiency of the regulatory process of the country. Sources of regulatory experience can be:

a) Internal, from regulation of facilities and activities;

b) External, from national and international sources of information and knowledge relevant for regulating facilities and activities.

The term the 'regulatory process' as used above and throughout this publication has to be understood in its widest possible meaning to refer to the whole of the regulatory activity as the sum total of:

a) The regulatory framework of the country;

b) The processes for the implementation of the regulatory functions established in the regulatory framework; and

c) The knowledge, skill, and practice applied by the regulatory body for conducting these regulatory functions.

This meaning is consistent with the use of term across the GSR Part 1 (Rev. 1).

Specific regulatory processes and processes will be referred to in this publication by the name of the process or function given in the IAEA Safety Standards Series No. GSG-13 [5]. Unspecified regulatory processes and functions by the term regulatory process or function preceded by an indefinite article as appropriate.

The term regulatory framework is used in this publication to refer to the legal and regulatory doctrine of the country for regulating safety of facilities and activities, which includes rules, regulations, mission and policy statements and guidelines based on which the regulatory body implements assigned regulatory functions and makes regulatory decisions.

By continuously obtaining regulatory experience from internal and external sources and by taking a more explicit and, where appropriate, systematic approach to managing its regulatory experience, the regulatory body will have access to a broader range of information that may potentially lead to improvement opportunities not otherwise envisioned. Proactively seeking improvement opportunities will help the regulatory body to accomplish its mission and mandate ensuring that the regulatory process remains effective and the national regulatory framework is up to date.

The existing regulatory process in a country reflects the regulatory experience accumulated up to a given moment in time. New regulatory experience and context developments (e.g. international commitments, political changes, new facilities and new legislation) can lead to

changes to the regulatory process. Therefore, better integration of the concept of regulatory experience management into the day-to-day work of the regulatory bodies will add value to keep the regulatory process up-to-date, effective and efficient over time.

2.2. LINK BETWEEN REGULATORY EXPERIENCE AND OPERATING EXPERIENCE

Operating experience and regulatory experience are sometimes referenced together throughout the IAEA publications, and these concepts are related within a regulatory body. However, it is important to note both the connections and differences between these two concepts.

Operating experience refers to insights and lessons learned from the review of information related to the operation of regulated facilities and activities, including events, conditions, and other observations. Many regulatory bodies require operating organizations to have processes and programmes to review and assess operating experience in line with the IAEA General Safety Requirements and Specific Safety Requirements applicable to different facilities and activities. These operating experience programmes are intended to learn from events and abnormal conditions arising in the operation of facilities or the conduct of activities[3]. In addition, many regulatory bodies have their own programmes and processes that utilize operating experience from the operation of facilities and activities towards maintaining a high level of safety. These programmes and processes are well documented in various IAEA publications [6, 7, 8, 9, 10, 11,12].

Although referenced in several IAEA publications, regulatory experience is not defined or documented in these. In the context of this publication, regulatory experience refers to insights and lessons learned from the analysis of information gathered from all activities related to the regulatory process, including lessons learned from external regulatory experience (see Section 2.1). Regulatory experience findings, referred to as 'findings' throughout this publication, include information related to issues, difficulties, inefficiencies, as well as good practices of the regulatory process.

Operating experience and regulatory experience are related in that the feedback of both can result in improvements to the regulatory process. However, the scope of regulatory experience is much broader, and the process and staff involved in the analysis of the findings and implementation of lessons learned might also be different. Therefore, to meet Requirement 15 of the GSR Part 1 (Rev. 1), in addition to using operating experience, regulatory bodies are expected to assess information from other relevant sources that could contribute to continuously improving the regulatory process. Appendix I contains a discussion about potential sources of regulatory experience.

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[3] Requirement 24 of IAEA Safety Standards Series No. SSR-2/2 (Rev. 1) [9], applicable to nuclear power plants, states that "**The operating organization shall establish an operating experience programme to learn from events at the plant**". Similar requirements apply to research reactors (Requirement 73 and para. 9.133 of IAEA Safety Standards Series No. SSR-3 [10]) and to fuel cycle facilities ((Requirement 73 and para. 9.133 of the IAEA Safety Standards Series No. SSR-4 [11]). Requirement 16 of the GSR Part 3 also states that Registrants and licensees shall conduct formal investigations of abnormal conditions arising in the operation of facilities or the conduct of activities and shall disseminate information that is significant for protection and safety [12].

3. FEEDBACK PROVIDED BY REGULATORY BODIES ABOUT CURRENT PRACTICE

3.1. IAEA FEEDBACK REQUEST

To inform the development of this publication, the IAEA sent out in June 2017 a feedback request to 42 regulatory bodies of various sizes and characteristics to gain a good understanding about how the regulatory bodies use the concept of regulatory experience and about the current practices to manage that regulatory experience. The feedback request included a questionnaire.

The IAEA received 27 responses to the request. Out of this information the experts who have drafted this publication reached the following general conclusions:

— The term regulatory experience does not have an official definition in the national regulatory framework of the countries that replied to the questionnaire. However, there is a general understanding that the term is basically consistent with the definition given in Section 2.1.

— Very few regulatory bodies have policies in place specifically addressing the management of regulatory experience. On the other hand, many reported on existing processes and/or practices of their management system that address, to varying extents and degrees, the management of regulatory experience.

— Most regulatory bodies routinely explore a wide range of internal and external sources in search of information and experience through different processes and following different approaches. However, very few have integrated arrangements for managing regulatory experience.

— Few regulatory bodies have incorporated or are in the process of incorporating the management of the regulatory experience into their management systems as a stand-alone core or support process.

— Incorporating the management of regulatory experience as a dedicated programme into an Integrated Management System is perceived as beneficial by some regulatory bodies to emphasize the importance of managing the interfaces among regulatory functions and activities.

— All regulatory bodies share regulatory experience routinely through local means and using international platforms. However, most of the time they do so on a case by case basis. Very few have a systematic approach to the sharing and dissemination of regulatory experience.

The responses to the questionnaire also identified obstacles and limitations for the effective and efficient management of regulatory experience. These obstacles and limitations are discussed in Section 4.4.

Annex I presents additional information about the responses provided by the regulatory bodies to the questionnaire. The assessment of this feedback has been a key input for the preparation of this publication.

3.2. CONTRIBUTING FACTORS TO SUCCESFUL MANAGEMENT OF REGULATORY EXPERIENCE

This Section gives examples of factors that could contribute towards establishing and sustaining an effective and efficiency management of regulatory experience. These factors are based on the analysis the existing practice in regulatory bodies and relate to policy elements, organizational arrangements, the management system of the organization and the attitude of managers and individuals. These factors are illustrated with practical examples taken from the feedback provided by regulatory bodies (see Section 3.1).

3.2.1. Mission and mandate statements of the regulatory body

The mission and mandate statements of the regulatory body can be an important vehicle for senior management to promote effective and efficient delivery of regulation as part as the positive safety culture approach of the organization. These statements can be instrumental to promote the routine collection, analysis, implementation and sharing of regulatory experience and to motivate staff towards fulfilling Requirement 15 of GSR Part 1 (Rev. 1) [2]. The high-level mission and mandate statements of the regulatory body provide a basis of formally documenting the organization's intent and senior leadership commitment to maintaining effective regulation through continuous review and improvement and the use of regulatory experience feedback. These high-level statements of intent set the tone for the performance of the organization which will then cascade to all staff through the management system structure.

Practical example

The UK's Office for Nuclear Regulation (ONR) Framework Document states that ONR's mission is: "To provide efficient and effective regulation of the nuclear industry, holding it to account on behalf of the public" [13].

This mission statement highlights ONR's responsibility for establishing and sustaining efficient and effective regulation and sets the aims and values to which all ONR staff are called to subscribe.

3.2.2. Regulatory policy statements

The use of regulatory experience can also be reflected in regulatory policy statements. This could be alongside other approaches that link to regulatory body's safety culture, effectiveness, efficiency and continuous improvement. The policy statements are generally expected to be concise and established within the regulatory body's management system.

Decision makers and all levels of management can proactively support and promote the management of regulatory experience. This can start from the high-level policy and leadership statements embracing the collection, analysis, implementation and sharing of regulatory experience for the purpose of continuing improvement.

Practical example

The U.S. Nuclear Regulatory Commission (NRC) issues Management Directives that contain the policies and procedures that govern the internal NRC functions necessary for the agency to accomplish its regulatory mission. Management Directive 6.8, Internal Management Lessons-Learned Programme, sets the policy of the NRC to continuously self-evaluate and improve agency processes, procedures, and programs. This directive provides guidance to NRC personnel to implement an agency-wide program that will ensure that knowledge gained from significant lessons learned is retained and disseminated in a manner that will maximize its benefit to the Commission. The availability of this programme is an important advantage to manage regulatory experience.

3.2.3. Senior management commitment, leadership and responsibility

Leadership and commitment of senior management is a critical contributing factor to the effectiveness of regulatory experience management. The concept of using regulatory experience needs to be positively embraced by senior managers and communicated through their engagement with regulatory body staff such that there is a clear message that the process is supported and seen as a vital element in maintaining efficient and effective regulation. If such messages are not heard periodically by staff at all levels in the organization, then regulatory experience will not be regarded as important. Regular emphasis by senior managers on the importance of proactive approach to enhance regulation can foster a culture of continuous improvement. Messages from senior management may also refer to the benefits that can be obtained from effective management of regulatory experience by highlighting real examples of how the use of regulatory experience has contributed to enhance the regulatory process.

The senior management of the organization can demonstrate leadership for effectively managing regulatory experience, for instance by:

— Establishing, advocating and adhering to an organizational approach that stipulates that collecting, analysing, implementing and sharing and disseminating regulatory experience contributes to ensure an effective regulatory process;

— Ensuring that managers at all levels in the organization demonstrate leadership towards establishing and sustaining effective management of regulatory experience;

— Providing resources to effectively establish and sustain effective management of regulatory experience;

— Establishing behavioural expectations and fostering a strong questioning attitude towards establishing and sustaining effective management of regulatory experience;

— Motivating staff to utilize arrangements established to manage regulatory experience;

— Raising staff awareness of their responsibility for reporting on regulatory experience findings;

— Ensuring that lessons learned from regulatory experience are timely acted upon and shared internally with interested parties and with other organizations as needed;

— Including the effective management of regulatory experience periodically in the agenda of the management review meetings and reporting on the achievements from effective regulatory experience in official reports of the organization.

Practical Example

The Canadian Nuclear Safety Commission (CNSC) has in place the Regulatory Framework Steering Committee (RFSC) to drive regulatory framework priorities and provide leadership, guidance and direction to achieve a clear and pragmatic regulatory framework. It exists to engage senior management at an early stage to ensure that the regulatory framework continues to benefit from lessons learned and strives for continuous improvement of the regulatory process.

3.2.4. Management system

The availability of a management system with well-integrated processes, in line with the requirements of GSR Part 2 [14], can facilitate effective management of regulatory experience by integrating it with existing processes relevant to it. Examples of these processes include quality management (see also 3.2.10), knowledge management (see also 3.2.6), the promotion of a culture for safety (see also 3.2.5) as well as the analysis of operating experience. Management of regulatory experience could be implemented as a dedicated programme or embedded in existing programmes or processes of the management system relevant to sustain the effectiveness and efficiency of the regulatory process. What is essential is that the concept of regulatory experience is well understood by the organization and its essential elements are fully covered and integrated within the management system to maximize the benefit from regulatory experience.

Practical Example

The National Nuclear Safety Administration (NNSA) of People's Republic of China developed its Integrated Management System (IMS) for Nuclear and Radiation Safety Regulation following the recommendations of an IRRS mission. In 2017, NNSA initiated a project to develop and revise its guidelines, programs, instructions and procedures. According to the project plan, the documents are classified into 4 levels with IMS as top-level document. The second level includes three categories: administrative guidelines, management guidelines and technical programs. Guideline of experience feedback for nuclear and radiation safety, together with the core processes identified in IMS, is one of the key management guidelines.

The availability of an IMS allows NNSA to manage regulatory experience feedback to continuously improve the Chinese regulatory process based on an integrated and unified approach to ensure consistency and organization-wide involvement.

3.2.5. Positive culture for safety

Positive culture for safety and safety focus are widely recognized by the international community as one the principles that set the basis of conduct of regulatory bodies [14, 15, 16]. The regulatory body's culture for safety and overall approach to continuous improvement will determine the level of 'added value' gained from the use of regulatory experience. If generating feedback from the use of regulatory processes is not encouraged throughout all levels of management through an open and no-blame reporting environment, then little will be gained as staff will feel unable to speak up when they identify shortfalls and opportunities to improve the regulatory process. Conversely, recognizing in leadership messaging and organizational working practices the value of regulatory experience feedback and acknowledging staff that provide the feedback can be an important factor to motivate and engage staff. Ideally, staff need to perceive the identification of opportunities for improvement as a performance expectation and a part of their duties.

Practical Example

The Argentinian Nuclear Regulatory Authority (ARN), through its policy for safety, as reported for the first review meetings of the Convention on Nuclear Safety and the Joint Convention, commits to ensure the protection of society and the environment from the harmful effects of ionizing radiation and controls that regulated activities are used for peaceful purposes. This policy for safety has been reflected also in the quality policy. Based on these policies, the ARN implemented a management system that promotes a safety culture based on a questioning attitude, focused on a rigorous and thoughtful approach to regulatory work, and fosters transparent regulation, granting access to relevant information to interested parties. ARN´s safety culture is a major promoter of regulatory experience for improving its regulatory activity.

3.2.6. Knowledge management

Regulatory experience information and data can be seen as a subset of the totality of the regulatory knowledge. It is therefore important when establishing arrangements for managing regulatory experience, in particular if dedicated information and data feedback system are envisaged, that the collecting and use of such information is properly integrated within the overall approach to knowledge and information management. This relates to how the approach to using regulatory experience is positioned within the regulatory body's management system. For example, the use of an integrated information management system may be a more effective approach than setting up a standalone regulatory experience database.

Techniques, know-how and tools used for knowledge management are useful for informing the management of regulatory experience, in particular for identifying and collecting regulatory experience (see also 3.2.11). When collecting and storing regulatory experience information is established through a dedicated function of the regulatory body's management system, care has to be given to ensure that this function is subject to recognized governance and, ideally, is well integrated in the overall approach to information and knowledge management of the organization.

Experienced staff can assist new staff in developing appropriate skills for identifying potential findings and for formulating them within the broader context of the regulatory process. Before experienced staff leave the regulatory body, their professional experience can be captured and used as input for the management of regulatory experience. Identifying the knowledge, skills and attitudes necessary for establishing and sustaining effective regulatory experience could, therefore, be considered in a succession planning process.

Practical Example

The Canadian Nuclear Safety Commission (CNSC) has a Knowledge Management (KM) Policy that provides high-level vision and direction; in addition, it has implemented a 3-year KM plan which identifies strategies to mitigate risks associated with knowledge loss. The CNSC's policy statement affirms the organization's commitment to enhance measures to capture, share, and build knowledge through people, processes, and technology to maintain the organizations' capacity and capability to deliver on its mandate now and in the future. The Chief Science Officer is the Executive Champion of this important work and provides organizational oversight.

3.2.7. Proactive attitude of process owners

The regulatory experience concept has to become embedded at all levels in the organization to ensure that it is successfully managed. Therefore, a proactive attitude of individual process owners is an important contributing factor. The owner of a specific regulatory process would be expected to proactively take regulatory experience feedback into account in reviewing the process to keep it up to date and suitable. The process owners can play an important role by proactively raising regulatory experience findings to the attention of senior management. At a higher level, the senior management would be expected to use regulatory experience feedback as one of the inputs when completing a review and updating the regulatory framework. This approach will also encourage dialogue and discussion about the benefits to be gained from effective management of regulatory experience throughout the organization and promote its daily utilization.

Practical Example

The manual of the Management System of the Spanish Nuclear Safety Council states in Section 5.2 (Process Management) that every process has to have a process owner assigned. This individual is be responsible, among other things, for monitoring and reporting on the performance of the process, for proactively seeking continuous improvement of the process and for ensuring that the process, including any subsequent changes to it, is aligned with the objectives, goals, strategies and plans approved by the organization.

3.2.8. Individual commitment to improvement

It is important that all regulatory body staff are conversant with the objective for using regulatory experience, the programme and the added value of regulatory experience for improving the effectiveness of regulation. Staff need to be aware that it is part of their role and responsibilities to identify opportunities for enhancing the regulatory process through

regulatory experience feedback. They need to know how to do this and the organization has to provide them with appropriate means and tools to do so. The organization can encourage staff to actively seek and use regulatory experience by providing training on the management of regulatory experience all along with the different topics covered by the overall organization's staff training programme. Managers can complement that by gibing positive recognition of staff who raise regulatory experience findings.

The communication and messages to staff can utilize positive culture for safety behaviours and values emphasizing an open reporting and no-blame approach when raising regulatory experience information.

Practical Example

The Indian Atomic Energy Regulatory Board (AERB) periodically holds training courses and discussion meetings to improve the understanding of AERB staff about the changes to the regulatory process resulting from lessons learnt and raise awareness about the importance of individual commitment. Periodic theme meetings are also organized on topics of regulatory interest wherein AERB staff along with other stakeholders are involved.

3.2.9. Willingness to learn from external sources

An effective management of regulatory experience makes necessary to follow approaches beyond the limited use of internal sources of information generated within the regulatory body. Learning from external sources, including from non-nuclear organizations, adds value to the management of regulatory experience of the organization. There are many potential external sources of regulatory experience information (see Appendix 1) and the willingness of the organization and of the individuals within the organization to learn from them is an essential driver.

The regulatory bodies can proactively consider training staff to recognize those external sources of regulatory experience that could be more valuable for the organization and to motivate them to regularly use these external sources to identify lessons to be learned as part of their duties. The regulatory body can also decide on measures to facilitate access to strategic potential sources of experience (e.g. hosting peer-review missions, encouraging staff to participate international training and to enrol in fellowship programmes or scientific visits, etc.) or to remove access barriers (e.g. engaging the organization in international research, concluding bilateral agreements with other countries, etc.). Essentially what is advocated is for the organization to pave the way to reach the external sources and for staff to maintain an open mind and to exercise judgement on what information may or may not be useful to capture. For example, this could include feedback gained by participating in international events or feedback from collaboration with other regulatory bodies, including forums and through bilateral arrangements.

Practical Example

In seeking regulatory experience from other organizations, the Japanese Nuclear Regulatory Authority (NRA) concludes bilateral and multilateral memorandums of understanding with the regulators of other states on mutual cooperation and information exchange. The NRA holds information exchange meetings with other regulatory bodies bilaterally and multilaterally to collect and exchange information on regulatory experience. The NRA proactively participates in activities held by international organizations and obtains regulatory experience from other regulators through their websites. As various languages are used in such websites, the NRA uses contractors if necessary, to translate the contents of information to extensively obtain latest knowledge.

3.2.10. Quality management

The existence of sound quality management as part of the management system is a useful basis to establish and maintain effective arrangements for managing regulatory experience. The application of quality management is, at the same time, one of several sources of regulatory experience.

Understanding well the links between the quality management and the arrangements for managing regulatory experience will maximize the benefits and will avoid duplication or inconsistency. Possible measures to build these links are:

— Establish the arrangements for managing regulatory experience as one or several of the working processes subject to quality management control;

— Define the effectiveness of the regulatory process as one of the desired features of the 'product' of the regulatory body to take advantage of the quality management improvement process to manage in parallel regulatory experience towards improving the regulatory process;

— Intermediate possibilities are to distribute the various activities associated to the management of regulatory experience among several working processes taking advantage again of the quality management improvement loops.

Practical Example

The Lithuanian Radiation Protection Centre (RSC) has in place a procedure within its quality management system for managing non-conformances that sets requirements for the reporting of non–conformances affecting its processes and activities, determining the causes of the non–conformances and taking corrective actions (assessment of the effectiveness of the corrective actions). This procedure is widely recognized and used within the RSC as an important source of regulatory experience. Non-conformances can be reported by each employee. Additionally, each employee has a right to raise matters of concern during quarterly organized whole-day meetings of the RSC staff.

3.2.11. Training policy and strategy

The availability of a solid training policy and strategy in a regulatory body, implemented through an integrated training programme, can help familiarize staff with the concept of regulatory experience and with the arrangements in place in the organization to conduct the collection, analysis, implementation and sharing of lessons learned from regulatory experience. Given the horizontal nature of the management of regulatory experience, these arrangements have to be presented to staff in an integral manner, showing interfaces with other processes of the management system (e.g. knowledge management, quality assurance and culture for safety, among others) and providing practical examples to illustrate the benefits from its effective management to improve the regulatory process.

Practical Example

The U.S. Nuclear Regulatory Commission provides training that improves individual and organizational performance in support of achieving the agency's mission. The NRC is committed to provide sufficient time and resources for employees to maintain skills and broaden capabilities to meet expected future skills needs. Additionally, the NRC ensures that regulatory experience is captured and integrated into agency programs through the training and qualification programs. The training program includes formal qualification requirements for specific positions, and many of these qualification programs include training on the history of the NRC and significant changes that are the results of lessons learned from regulatory experience.

4. MANAGING REGULATORY EXPERIENCE

4.1. OVERALL FRAMEWORK

Regulatory bodies manage regulatory experience through various arrangements aimed at facilitating the collection and analysis of internal and external regulatory experience. In accordance with GSR Part 1 (Rev. 1), regulatory bodies are required to use regulatory experience to identify lessons to be learned to continuously improve the regulatory process. The arrangements may also include the dissemination of the lessons learned for their use within the organization of the regulatory body, throughout license holders and other relevant authorities.

The assessment of the feedback provided by regulatory bodies (see Section 3.1) and the case studies presented in several annexes of this publication show that although regulators do manage regulatory experience and share the lessons learned, most of them do not have in place a dedicated or recognizable process to that end. The existing arrangements take multiple forms, ranging from a single process for managing all sources of learning up to an intricate combination of processes, mechanisms and elements from which the regulatory body obtains valuable information to continuously enhance its regulatory process.

Based on this feedback, creating a single dedicated process to manage the regulatory experience from all the sources of experience may not be appropriate or practicable for most regulatory

bodies. Moreover, the regulatory bodies have in place various processes that partially serve the purpose of managing regulatory experience.

Regardless of its specific organization and practice, a regulatory body is expected to make a well-informed decision on how to establish appropriate arrangements for managing regulatory experiences. This can be achieved using a single dedicated programme or process or using the outputs generated from multiple programme or processes in an integrated manner. The important point is that the arrangements need to be properly and effectively interconnected with other related processes of the management system of the organization.

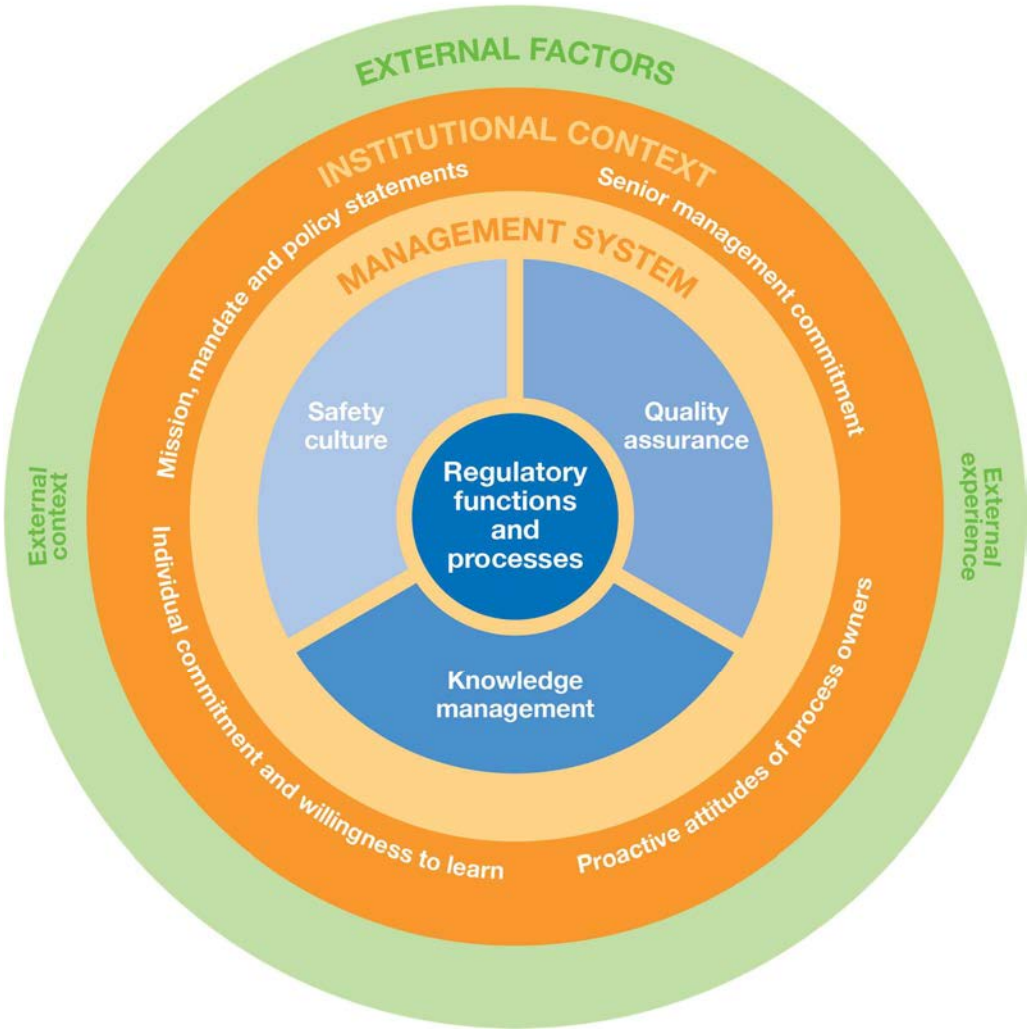

Fig.1. Internal and external factors to be considered when designing arrangements for managing regulatory experience

Figure 1 shows a representation of the internal and external factors to which the design of the arrangements for managing regulatory experience will need to be adapted. The regulatory body needs to take into consideration these factors, as well as the interrelation among them, when designing and putting in place arrangements to ensure effective and efficient management of regulatory experience. These factors include the assigned regulatory functions and the

associated processes to exercise them, the management system of the organization (in particular those processes that focus on the functioning of the organization such as the promotion of a positive safety culture and the management of knowledge and quality) and the overall institutional context of the organization (e.g. mission, mandate, policy statements, senior management involvement, promoting individual commitment…). Finally, the regulatory body does not function in isolation as the whole regulatory process can be influenced by external actors and influences, such as: international peer pressure, international peer reviews, the public, the national government, local governments, neighbouring countries, media, NGOs and special interest groups [17]. These external actors can influence the functioning of the regulatory body and, as such, can also play a role in managing regulatory experience. For example, the regulatory body can benefit from the feedback provided by external advisory bodies, from exchanges with other regulatory bodies on a bilateral basis or from its involvement in forums of regulators. It can also share responsibilities with other national or regional authorities and thus arrangement could be needed to exchange lessons learned from regulatory experience among them.

4.2. ILLUSTRATIVE REGULATORY EXPERIENCE MANAGEMENT PROCESS

To explain the structure and elements for managing regulatory experience, for simplicity a regulatory management programme is represented in this Section by a single illustrative regulatory experience management process[4]. The process is in line with the one presented in IAEA Safety Standards Series No. SSG-50 for the management of operating experience of nuclear installations by the regulatory bodies [6]. It has however been modified to address the broader scope of this publication, which includes all facilities and activities.

Regulatory bodies can use the illustrative regulatory experience management process shown in this Section to map out their existing arrangements for managing regulatory experience. Based on this mapping, they can decide whether there is any need to adapt their existing arrangements or to establish new ones. Account needs to be taken of the size and structure of the organization, the duties assigned in the legislation, the interfaces with other national authorities and advisory services, the facilities and activities regulated, the interaction with license holders and interested parties and the international commitments.

[4] The term ‘programme” is used in this Section to refer to the set of related measures or activities aiming to improve the regulatory process based on lessons learned from experience in a regulatory body. This programme can include one or several processes or subprogrammes existing or specifically designed for this aim. The term “process” is used to make reference to the illustrative regulatory experience process described in this Section.

The structure of the illustrative regulatory experience management process consists of three parts:

Part 1: Collecting
The collection part covers all activities related to the identification, collection and storing of regulatory experience findings (findings henceforth), as well as filtering and categorizing them for further analysis across the organization as necessary. It concerns staff directly responsible for implementing regulatory processes and staff in charge of administering the illustrative regulatory experience management process.
Part 2: Analysing
The analysing part covers all the activities aimed at carrying out the assessment of the findings, proposing a solution and taking decisions on how to address them. It primarily concerns senior staff, management and ultimately decision makers of the organization.
Part 3: Implementing
The implementing part covers all the activities relative to the implementation of the solution adopted, including monitoring the implementation of the solution, and sharing and disseminating the lessons learned as deemed necessary. It concerns the staff responsible for regulatory processes affected by the finding. It also concerns staff involved in reaching out to those players outside the regulatory body, including, but not limited to, staff in charge of communication, inter-institutional relations and international relations and cooperation.

Figures 2 and 3 show, respectively, a block diagram representation of the illustrative regulatory experience management process and its logical framework. In Fig. 3 each row shows the input, the actions to be performed at each step within each part of the process, the staff involved and the output to be produced. The output generated at each step becomes the input for the next one. The bottom row of the figure shows an associated process to continuously improve the illustrative regulatory experience management process.

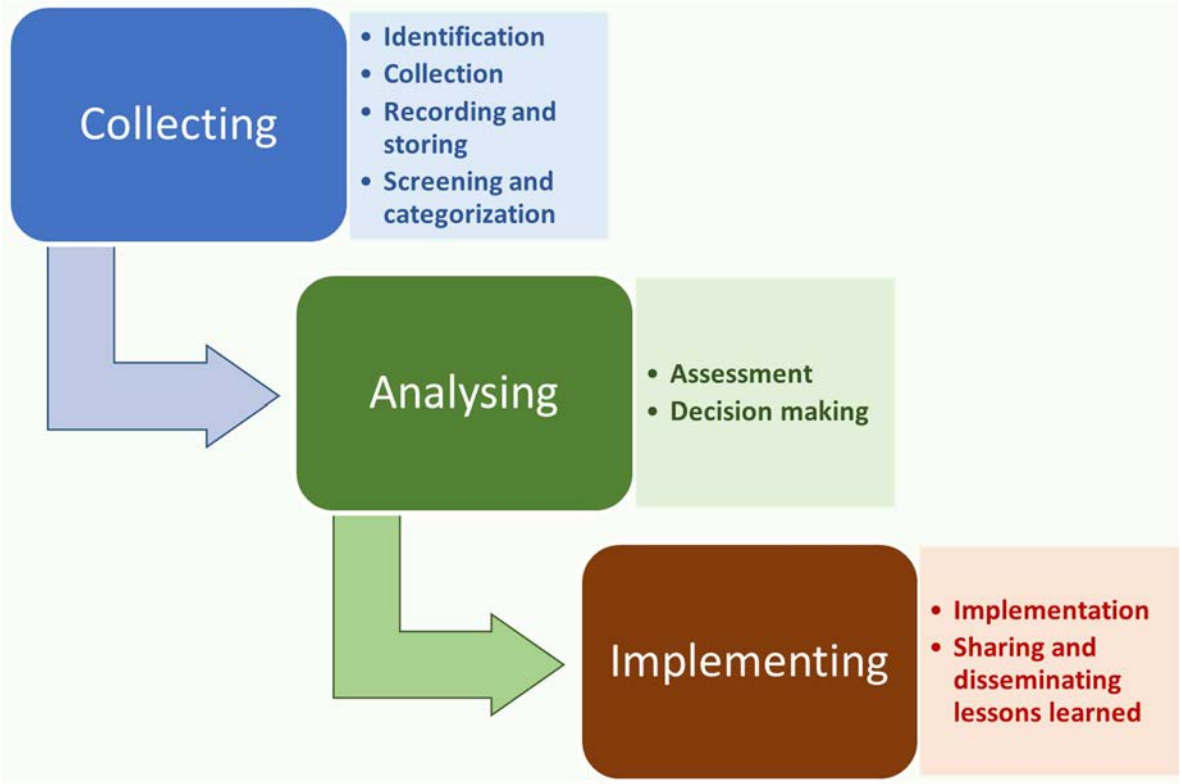

Fig.2. Schematic representation of the illustrative regulatory experience management process

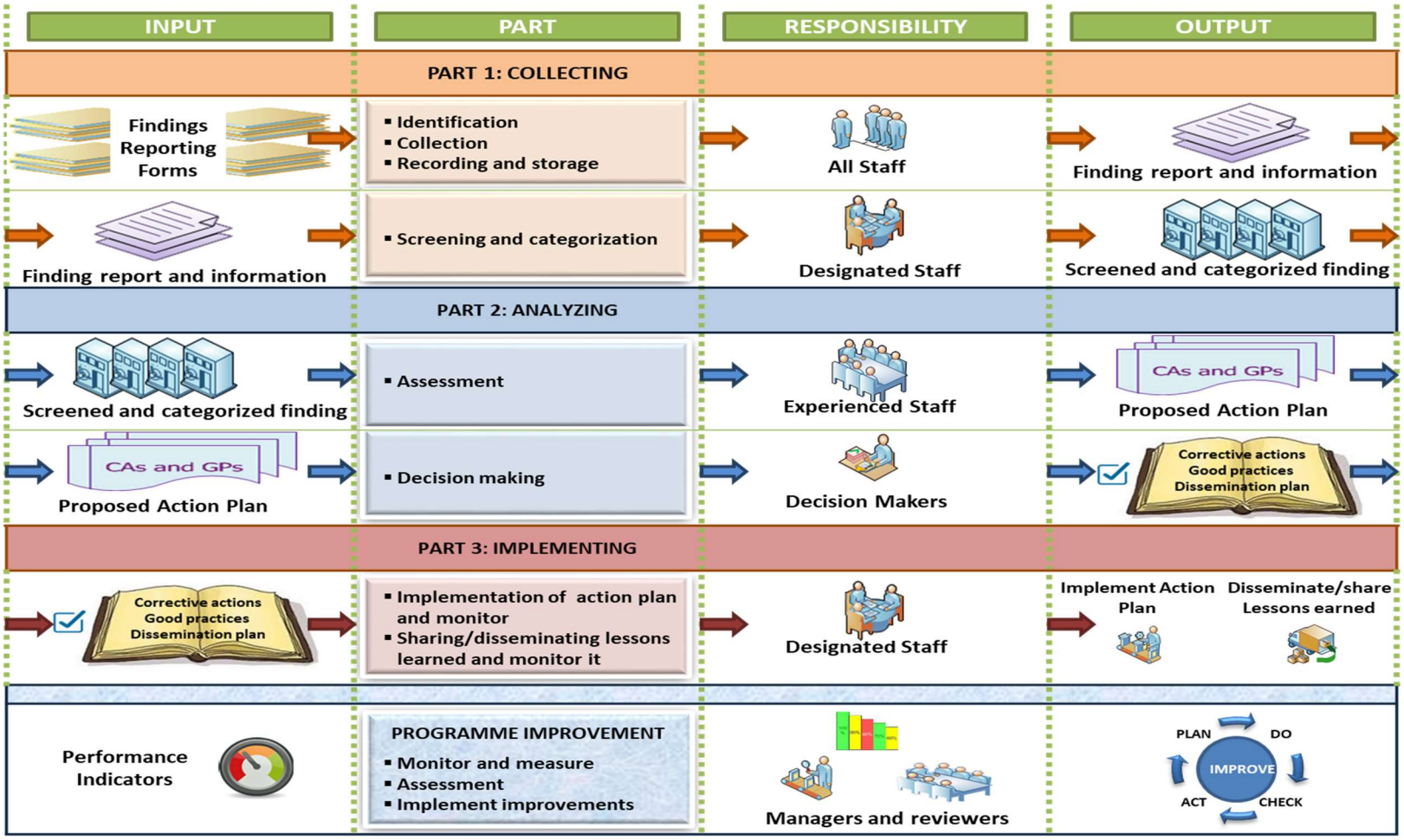

Fig.3. Logical framework for the implementation of the illustrative regulatory experience management process

Figure 4 shows a workflow diagram of the illustrative regulatory experience management process. The solid lines show the flow of implementation actions, while the dotted lines show reporting and documenting activities. The process starts by collecting findings from internal and external sources, recording and storing relevant information to be used throughout the process and to be kept for future consultation. The information collected is utilized to screen and categorize the findings. Those findings screened out are documented and relevant information stored. Those screened in are analysed. Designated staff assess the relevance of the finding to improve the regulatory process and, when applicable, prepare an action plan that is submitted to decision makers at the corresponding level of authority. If the decision entails enhancement of the regulatory process, the changes are implemented, and the lessons learned shared and disseminated. The staff who raised the findings receive feedback about the analysis, approved action plan and sharing and dissemination activities. The tasks carried out along the process are documented and relevant information stored. After implementation of the enhancements to the regulatory process, designated staff monitor the impact of the enhancements and assess feedback received from those with whom the lessons learned were shared. These activities can also be documented, and relevant information stored for future consultation. The left-hand corner of the figure shows an associated process intended to continuously improve the illustrative regulatory experience management process (for simplicity called REGEX in the figure).

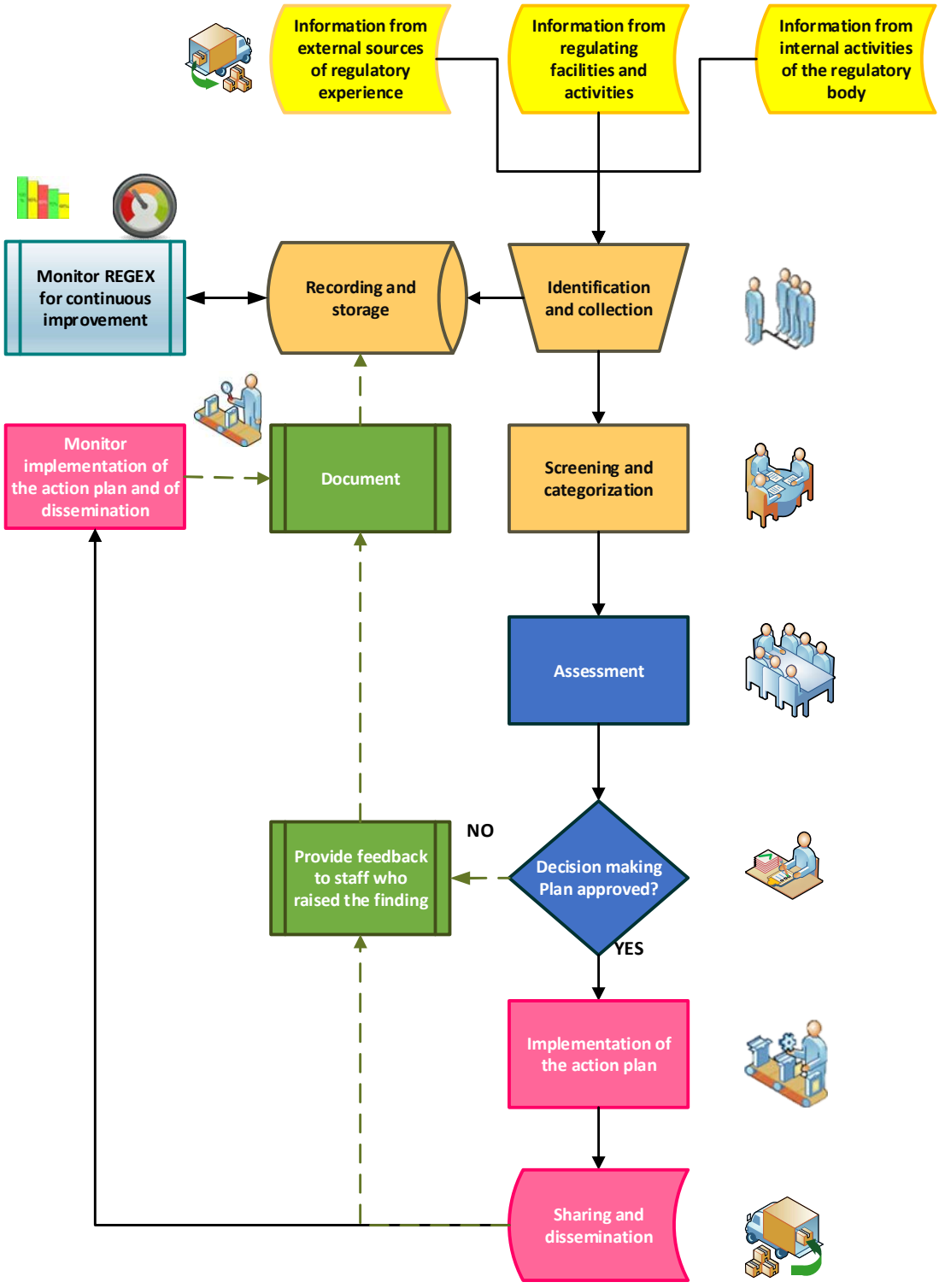

Fig.4. Workflow diagram of the process representing the illustrative regulatory experience management process

The following sub-sections provide the details of the three parts of the illustrative regulatory experience management process. The process intended to monitor and improve the process is discussed in Section 4.3.

4.2.1. Part 1: Collecting

4.2.1.1. Identification

Identification of regulatory experience findings is an essential element of any regulatory experience management programme and, at the same time, the most challenging. Maintaining an environment that fosters a permanent questioning attitude of the staff of the regulatory body, as well as a proactive approach in identifying and raising potential regulatory findings[5], can contribute to motivate staff to that end.

The organization can provide staff with guidance in relation to the sources of experience that warrant particular attention, criteria for identifying potential findings and appropriate means to collect and report. A proper balance between the expected benefits and the effort needed to sustain the programme can help staff and key stakeholders to perceive the regulatory experience management programme as 'adding-value' and be recognised as the behaviour-based philosophy of the regulatory body,

As shown in Fig. 4, the primary input to the illustrative regulatory experience management process are the findings collected by the staff resulting from the daily implementation of regulatory functions and processes. Therefore, staff ownership, commitment, motivation and willingness to learn are essential factors to sustain an effective regulatory experience management programme. Staff contribution to timely identification of potential findings and subsequent submission of them for review is the main driver of the illustrative regulatory experience management process management programme.

Typically, the conduct of regulatory functions and processes lead to the question: is the license holder operating the facility or activity safely and fulfilling regulatory requirements? The regulatory experience concept takes this a step further by encouraging the staff of the regulatory body to regularly ask themselves questions like: could the regulatory process be enhanced to ensure a more effective and efficient regulation of the facility or activity? If the reply to this question is yes, many other subsequent questions may need to be answered before raising the finding, such as: is a specific regulatory process faulty? Are there missing regulatory requirements? Are the regulatory requirements in place unnecessary?

Staff of the regulatory body, either as individuals, teams, or organizational units, trigger the process through the identification of a potential opportunity (i.e. finding) to improve the regulatory process. The information leading to the finding may be obtained internally or externally, for example from another regulatory body or resulting from the analysis of an operating event.

Transparency is required for the credibility of the illustrative regulatory experience management process and is also essential for motivating the staff to use it and be committed to it. Ideally, all the findings identified and submitted for review need to be properly collected, stored and preserved regardless whether the findings are screened out at any step throughout the review process. If the regulatory experience management programme in place allows oral

[5] For simplicity, the term finding is used in this publication to refer to issues identified with potential interest towards enhancing the regulatory process, regardless if they are later screened in or not.

or other type of informal reporting with means not suitable for proper recording (e.g. via emails or through discussions in meetings), it is still important at least to keep track of the conclusions of the screening process, for instance by reflecting it in the minutes of the meetings.

Records can be important for instance to detect trends. The documentation of older findings can provide valuable information to gain a better insight of connected issues. Moreover, statistical information about the use and operation of the regulatory experience management programme will facilitate monitoring, trending, assessment and continuous improvement of the review process.

Staff of the regulatory body who have submitted findings for review could be involved in the analysis and receive feedback about the actions taken in connection with the findings. This will contribute increased engagement and help motivate staff to use the program. Written feedback, when provided to the staff, can also be stored and preserved, as appropriate, for future consultation.

Regulatory experience is primarily sourced with the feedback gained from the implementation of the core regulatory functions and processes. This feedback can be obtained either from day to day internal operation of the regulatory body or from the lessons learned about the operation of other regulatory bodies. IAEA Safety Standards Series No. GSG-13 describes in detail the core regulatory functions and process [5], which namely are:

— regulations and guides;

— notification and authorization;

— review and assessment of facilities and activities;

— inspection of facilities and activities;

— enforcement;

— emergency preparedness and response; and

— communication and consultation with interested parties.

Regulatory bodies can also consider other internal sources of information and knowledge, for example feedback from the implementation of supporting functions, as well as issues associated to the organization, management and staffing of the regulatory body to effectively and efficiently deliver the regulatory functions [18].

The identification of findings can also include external sources of experience from the domestic and global safety regimes. Individual staff or organizational units may become knowledgeable of relevant information from their involvement in national or international affairs, from their participation in meetings and conferences, from information received through bilateral agreements, etc. Potential findings from this experience could also be collected and used as input for the regulatory experience management programme and analysed in a similar way as internally-generated findings.

Figure 5 shows a schematic representation of the sources of regulatory experience of domestic and global safety regimes used in the illustrative regulatory experience management process.

Fig.5. Sources of Regulatory Experience for the illustrative regulatory experience management process

Appendix I contains a detailed discussion on internal and external sources of information and knowledge for collecting regulatory experience in order to identify lessons to enhance the regulatory process and framework. Appendix II to IV discuss, respectively, the management of lessons learned from research, the management of regulatory experience when the regulatory responsibilities or duties are distributed across different federal or regional offices or separate organizations and the regulatory experience generated gained from external advisory bodies or technical support organizations (TSO).

The regulatory body can develop material to train staff on the collection of regulatory experience to ensure that the findings are relevant for the intended purpose of their specific regulatory experience management programme by taking into account factors such as:

— The definition of regulatory experience, the objective of the programme, how to use it and the expected value added from its use;

— The availability of written instructions, templates and available tools to raise and collect regulatory experience and relevant information/data;

— Actions and means to encourage active use of the regulatory experience management programme through identifying findings, either positive or negative, and lessons learned and through proposing possible solutions to either correct weaknesses or to reinforce good practices;

— Interfaces with other essential elements of the management system of the organization, particularly with knowledge management, quality assurance and promotion of a positive safety culture;

— Examples of regulatory findings that have been used for improving the regulatory process and of regulatory findings that were screened out at some point throughout the process;

— Mechanisms to monitor and assess the utilization of the regulatory experience management programme and associated means in order to ensure its correct use and efficient management.

Appendix V discusses possible forms of guidance and aids (i.e. templates, check lists, procedures…) that could be used by the regulatory bodies to assist staff in identifying potential findings and to motivate them to raise findings. It also presents a list of topics that could be considered by regulatory bodies for developing their training programmes tailored to the specific characteristics of their regulatory experience management programme.

4.2.1.2. Collection

After a potential finding has been identified, the next step is to make the finding and accompanying information available for the organization to undertake the screening process.

Findings can be collected using a wide range of approaches and means. These can include simple or sophisticated information technology solutions (e.g. databases, web-based portals)[6], written forms using official templates, and oral reporting in an appropriate setting to be recorded in minutes. Intermediate solutions, like the use of shared electronic files with information about the findings can also be considered.

[6] Annex IV contains a discussion of IT-based solution for collecting regulatory experience findings in use by the Hungarian Atomic Energy Authority.

An analysis of the benefits and limitations of possible approaches to collection can be carried out by the organization to choose the most suitable approach. Matters to be considered when designing an effective process for collecting regulatory experience could include:

— Means of reporting (oral, email, forms…);

— Organizational arrangements to reporting (roles and responsibilities of all staff, identification of staff to handle reports and records, reporting channels…);

— Development of specific templates for collecting regulatory experience and procedures explaining how to fill in the templates and how to deliver them for further processing;

— Managing information (e.g. access, distribution, volume of information…).

It is advisable to document the chosen approach in order to provide staff with clear expectations about the procedures and means to be followed.

4.2.1.3. Recording and Storage

In Fig. 4, the illustrative regulatory experience management process's flowchart envisages recording all collected regulatory experience findings. In practice, the recording of the collected regulatory experience findings may be conditional on whether the identification and collection are carried out following informal or formal approaches.

In the first case, findings can be reported orally (i.e. in meetings or to line-managers) or using simple means of communication that do not require formal documentation, like emails or feedback drop boxes. This may pose challenges to recording and storage, but still the organization can use simple electronic or paper files to keep track of the findings and store accompanying information as necessary.

In the second case, collected findings are documented using official forms and/or through an electronic platform provided to that end. This could facilitate recording and storage. Filling out forms and submitting them in an electronic platform would require additional effort, but at the same time will make it easier to produce and preserve the records for future consultation, as well as for monitoring the use and operation of the system.

The regulatory body would benefit from finding an appropriate balance between expected benefits and additional burden for the organization. Even if the front-end of the regulatory experience management programme is not fully documented, it could be advisable to start generating records at least once the findings have reached the screening step.

The records can leave a trace of the origin, the screening and of the analysis of the finding throughout the process by concisely describing essential elements, such the context, rationale, and the conclusion of the screening. If the finding does not warrant further analysis, the information will still be valuable for monitoring the use of the system and for trending analysis. If the finding is screened in and further analysis is warranted, it is important to start building a full dossier documenting all the subsequent actions undertaken until the implementation of action plan.

The recording system could be designed to store all the information pertaining to the processing of the same regulatory experience findings across the different parts of the regulatory experience management programme.

Before creating any new dedicated storage mechanism, the regulatory body would need to consider the operation of the whole regulatory experience management programme and explore the utilization of input from other processes and databases of the management system. A possible approach could be to collect the findings using another connected database of the management system to produce an integrated solution and for efficiency gains. For instance, existing databases associated with operating experience, knowledge management or quality management could be candidates for integrating regulatory experience management records.

Matters to be considered when designing the recording and storage system could include:

— Information to be stored (e.g. findings, records, supporting documentation);

— Reliability, including obsolescence;

— Easy access and use;

— Security;

— Storage time.

4.2.1.4.Screening and Categorization

The purpose of screening in the illustrative regulatory experience management process is to identify early in the process those findings that are of potential interest for further analysis, prioritise them and to establish ownership of any necessary actions. The output of this phase is a decision about whether further analysis of a finding is warranted, as well as a categorized finding.

Not all findings identified have to be forwarded up and across the organization for further analysis. Some findings may have relevance to only specific regulatory functions or processes or may be of low safety significance. These findings can be screened out (with appropriate justification and documentation) early in the review process to ensure efficient use of resources on those findings that are candidate for substantive improvements of the regulatory process.

Transparent and formalized screening would ensure that the outcome is verifiable, consistent and repeatable. Clear criteria are therefore needed to conduct the screening and to set a threshold. The threshold can be quantitative (e.g. risk-informed), qualitative (e.g. the finding may affect existing mandatory regulatory requirements) or a combination.

The regulatory body could decide on a threshold suitable for the organization. The higher the threshold, the fewer the findings that will be subjected to comprehensive analysis. However, there will be less chances of identifying lower level issues at the screening level that after a comprehensive analysis may turn out to be relevant for improving the regulatory process. The regulatory body may also decide to use different criteria and thresholds for different categories and sources of regulatory experience.

The screening and categorisation could include:

— Assigning findings to predefined categories, such as in relation to:

  - Regulations;
  - Regulatory guides;
  - Management system and processes;
  - Regulatory functions and processes;
  - Human resources;
  - Regulatory competences, education and training;
  - Regulatory safety criteria;
  - Regulatory review and assessment (methodologies, tools, validation and verification requirements, etc.);
  - Public communication and stakeholders' involvement;
  - Emergency preparedness and response.

— Conducting the screening on the finding based on applicable criteria and threshold[7] for each pre-defined category:

  - Screened-in findings will be subjected to further analysis;
  - Screened-out findings will be stored for future reference and trending analysis.

— Preliminary judgement of:

  - Safety relevance of the finding;
  - Impact on regulatory functions and processes;
  - Interfaces between processes;
  - Potential for escalating to a more serious issue if timely action is not taken.

Possible outcomes of the screening process are:

— Forwarding the information to process owners;

[7] Criteria and threshold can be either quantitative, such as risk-based or cost-based, or qualitative, such as relevance, urgency or feasibility.

— Performing a more detailed technical analysis;

— Determining and prioritising the action to be taken; or

— Storing the information for trending or taking no further action.

It could be advisable to document all the findings screened including information such as:

— Basic information (e.g. finding title, author, dates, processes involved, facilities and activities that could be affected);

— Brief description, including interim actions taken to correct the issue or to prevent recurrence;

— Category (e.g. based on safety significance, urgency or nature of the finding);

— Owner or coordinator for the assessment of the finding, together with recommendation about the individuals and/or organizational units to be engaged;

— Timeframe to complete the analysis.

A knowledgeable person or group of staff, designated by the senior management, with broad understanding of the regulatory process and the organization of the regulatory body could be responsible for screening and categorizing the findings.

4.2.2. Part 2: Analysing

The purpose of this part of the illustrative regulatory experience management process is to undertake a comprehensive analysis of a regulatory experience finding and to develop an action plan to address it.

The input to this part is the screened findings and information pertaining to the categorization. The output is the action plan to address it, which can range from no further action to the implementation of substantive changes to the regulatory process.

The analysis could be carried out by experienced staff with a comprehensive understanding of the affected regulatory functions and processes and who are able to account for the complex, multifaceted and often interlinked nature of the regulatory process in a country. A process-based approach may help understand the consequences and the impact of the finding beyond the specific context of the situation that generated the finding and it could also help identify possible remedial actions to avoid the repetition of the issue across all other functions and processes of the regulatory process. Similarly, when the finding is a good practice, a process-based approach could help replicate the practice in different contexts.

The review of the findings will progress across the organization involving, when necessary, experienced staff with wider responsibilities until it reaches senior management for decision making. The categorization of the finding performed during the screening and categorization part can help identify staff that need to be involved in the review. Each step in the analysis of

the finding has to add value towards ensuring that the scope of the analysis covers the wider scale of the institutional interest of the organization in the finding.

This publication assumes that the regulatory body has an institutional or corporate level management decision making authority to approve changes to the regulatory process. This authority can be exercised by an individual (i.e. the chairman or the director general of the regulatory body), by a group of designated senior staff (i.e. an executive board) or by a commissioner.

This publication therefore envisages a two step approach to complete the analysis of the regulatory experience findings. The first step is intended to assess the technical, legal, financial, organizational and managerial aspects of the finding and of the solution to address it. The outcome of the assessment is the proposed action plan and supporting documentation. The second step is the decision making itself.

It is acknowledged that the senior management of some regulatory bodies may be routinely involved both in the assessment, including preparation of the action plan, and in the decision making. In this case, the assessment and decision making steps in practice could occur as a single step of the regulatory experience management programme.

Likewise, the management with decision making authority may delegate certain responsibilities to designated senior management (e.g. a secretary general, a technical director or a board of directors) or may set criteria and/or tolerances relative to the implementation of certain actions for improving the regulatory process. For instance, the implementation of changes related to internal regulatory procedures or practices may be delegated, but still the competence for authorizing changes to publicly issued regulatory guidance retained. It is advisable to have documented criteria and thresholds of delegated functions in policy documents or in written procedures.

Some regulatory bodies may also call for the opinion of advisory bodies and of other stakeholders before taking a final decision on authorizing changes to the regulatory process. In such cases, this could also be documented in the regulatory experience management programme of the organization.

4.2.2.1. Assessment

One of the outcomes of screening and categorization of the illustrative regulatory experience management process is the identification of the owner or coordinator for the analysis of the finding, as well as recommendations about the individuals and/or organizational units that need to be involved (see Section 4.2.1.4). The owner or coordinator, once familiarized with the finding, will be in the position to confirm or to change the individuals and organizational units to be involved.

The assessment covers all the relevant elements of the regulatory process potentially affected by the finding, including, but not limited to, technical matters, legal and regulatory requirements, financial aspects, and managerial features of all processes of the management system affected.

The owner may decide to carry out consultations on an individual basis or to set up an open ended working group to coordinate the analysis. Depending on the complexity of the issue, the assessment may make it necessary to request feedback relative to the different regulatory functions and processes affected, as well as to consult with external players, such as license holders, other national authorities and stakeholders. In all cases, the owner retains overall responsibility for the successfully completion of the assessment of the finding.

Based on the feedback received from those involved in the assessment, the owner will prepare a proposed action plan, preferably jointly adopted by all those involved in the assessment. Dissenting opinions and/or alternative courses of action with the rationale could be reported in the proposed action plan, for the consideration of decision makers.

The conclusion of the assessment has to be documented covering topics such as:

— Information pertaining to the regulatory finding;

— Owner of the assessment and individuals and organizational units involved, including external consultations;

— Summary of activities carried out to complete the assessment (e.g., meetings, consultations, tests, investigation, inquiries, surveys);

— Proposed action plan: no further action/corrective actions, actions to share and disseminate lessons learned, including identified good practices, and timeframe for their implementation;

— Need to involve other competent authorities in the assessment of the finding before approval or of the need to refer the finding to other competent authorities for further action;

— Relevance of the finding and of the proposed action plan to:

    - Safety;

    - Impact on the organization and other affected bodies (resources, structure of the organization, operating procedures…);

    - Sharing domestically or internationally / information to stakeholders and existing appropriate channels for this finding;

    - Potential legal consequences for the regulatory body (at national or international level);

    - Positive/negative effects of the proposed action plan on existing arrangements;

    - Potential impact on reputation/credibility of the regulatory body/process, including matters such as insufficient effective independence, transparency or capacities.

— Consistency of solution adopted with other aspects of the regulatory process;

— Cost-benefit analysis;

— Assessment of the impact of the proposed solution on the stability of the regulatory process, on the licenses already granted, and on the regulatory burden on license holders;

— Measures to monitor progress on the implementation of the action plan;

— Measures to monitor the impact of the solution in improving the regulatory process;

— Lessons learned and guidance for sharing and disseminating lessons learned and the solutions adopted.

The documentation of the analysis has to provide decision makers with objective and, to the extent possible, quantitative information of matters such as safety relevance, urgency for implementation, cost-benefit and impact on the organization and/or regulatory process for them to take a well-informed decision about the proposed action plan.

For those findings for which the owner of the assessment has delegated authority to implement the action plan without seeking approval of the decision makers, the owner may need to inform the latter ones about the initiation of the action plan and to keep them periodically informed about progress and about the impact and benefits as for the effectiveness and efficiency of the regulatory process.

4.2.2.2. Decision making

The input to decision making of the illustrative regulatory experience management process is a document including the conclusion of the assessment and the proposed action plan. The output is the approved action plan for implementation.

In making decisions, the decision makers could consider factors such as:

— Need to involve or consult other state authorities or entities outside the regulatory body;

— Impact of action plan on the license holders, TSOs, etc;

— Balance of costs and benefits associated to the action plan;

— Resources needed, priority and timeframe;

— Compensatory actions when safety of facilities or activities might be impaired until full implementation of the action plan;

— Identification of the owner of the forward action;

— Follow-up of the implementation of the action plan and associated feedback/updating activities;

— Plan to share and disseminate lessons learned from regulatory experience.

The action plan could recommend actions ranging from the dissemination of lessons learned for the general knowledge of the staff of the regulatory body and license holders to the creation

of new or the revision of existing policies, regulations, regulatory guides or procedures to enhance the existing regulatory process.

Expectably, decision makers will thoroughly discuss the finding, its safety relevance and the proposed solution with the team that performed the analysis and with senior managers of the organization. This discussion may involve the staff who raised the finding, as well as external advisors. In particular, decision makers of the organization could make a conscious decision on whether the lessons learned have to be shared and disseminated, who the target audience could be, and which channels to use to share and disseminate relevant information within the regulatory body and through authorized parties, other regulatory bodies, international organizations and the public as considered appropriate.

Once decision makers have adopted the action plan to address the finding, which can be an area for improvement or a good practice to share, the implementation of the action plan can be assigned to the owner of the forward action.

It would be advisable to keep the conclusion of the analysis as a record for transparency and trending. The illustrative regulatory experience management process envisages to provide feedback to the staff that raised the regulatory experience finding for transparency and to motivate staff to use the process as part of their normal day-to-day activities when discharging regulatory duties.

4.2.3. Part 3: Implementing

This part of the illustrative regulatory experience management process covers all actions intended to implement the action plan approved by the decision makers of the organization, monitor progress and share and disseminate the les-sons learned from regulatory experience.

4.2.3.1. Implementation of the action plan

The owner of the forward action has the responsibility for coordinating the implementation of the plan and for carrying out associated tasks, such as:

— Monitor the implementation of the action plan;

— Ensure that sufficient resources are available for implementing the action plan and that assigned staff have the necessary competence to implement the action plan within the specified timeframe and, when necessary, request senior management or decision-making level management the allocation of more resources;

— Coordinate with other state authorities or relevant organizations outside the regulatory body when necessary;

— Assess the effectiveness of the action plan once completed;

— Ensure that sharing and dissemination of regulatory experience takes place timely;

— Provide periodic updates to senior management and decision-makers as envisaged in the approved action plan;

— When necessary, seek for the endorsement of changes to the approved action plan through the senior management and decision-makers to the extent necessary.

4.2.3.2. Sharing and disseminating lessons learned

The action plan approved by the decision making level management could identify whether the lessons learned from a regulatory experience finding are to be shared and disseminated. If they are to be shared and disseminated, regulatory bodies may consider possible target audiences and channels to that end.

The regulatory body may also consider the benefits of an open and transparent reporting culture when deciding about sharing and disseminating lessons learned. Both areas for improvement as well as good practices could be shared and disseminate. Criteria could be established to determine when a regulatory experience finding qualifies for sharing and disseminating, which channels could be used and who could be addressed.

The owner of the forward action could also be responsible for monitoring and supervising the implementation of the sharing and dissemination plan.

Appendix VI discusses measures to share and disseminate lessons learned to ensure that they reach those stakeholders and other organizations, either national or international, that could benefit from them.

4.3. CONTINUOUS IMPROVEMENT

This publication does not propose any specific metrics to evaluate active, proper and effective use of regulatory experience. It is up to the regulatory bodies to establish appropriate metrics suitable for the approach and the specific design chosen to build their regulatory experience management programmes.

In the illustrative process discussed in Section 4.2, regulatory experience is expected to play an important role as a driver for improving the regulatory process. As such, an appropriate governance could be established within the management system of the organization to monitor performance and effectiveness and to embrace a culture of continuous improvement in line with the IAEA safety requirements [14]. The objective would be to confirm the ability of the organization to achieve its intended goals, to correct weaknesses and proactively identify opportunities for improvement.

Likewise, the illustrative regulatory experience management process envisages regular monitoring of the programme to confirm that it is actively used by staff at all levels within the organization, that it is used properly and that lessons learned from regulatory experience are effective in improving the regulatory process.

Figure 6 shows the flowchart of the associated improvement process of the illustrative regulatory experience management process (for simplicity called REGEX in the figure). In accordance to it, the regulatory body periodically evaluates the degree of utilization and proper functioning of the arrangements to manage the illustrative regulatory experience management process to explore possible improvements. This can be done through management reviews, self-reflections/assessments or independent assessments. The outcome of these evaluations is

further assessed to confirm the effective and efficient use of the process or, where necessary, to identify and implement improvements. These evaluations could be documented as part of the documentation generated throughout the implementation of the illustrative regulatory experience management process.

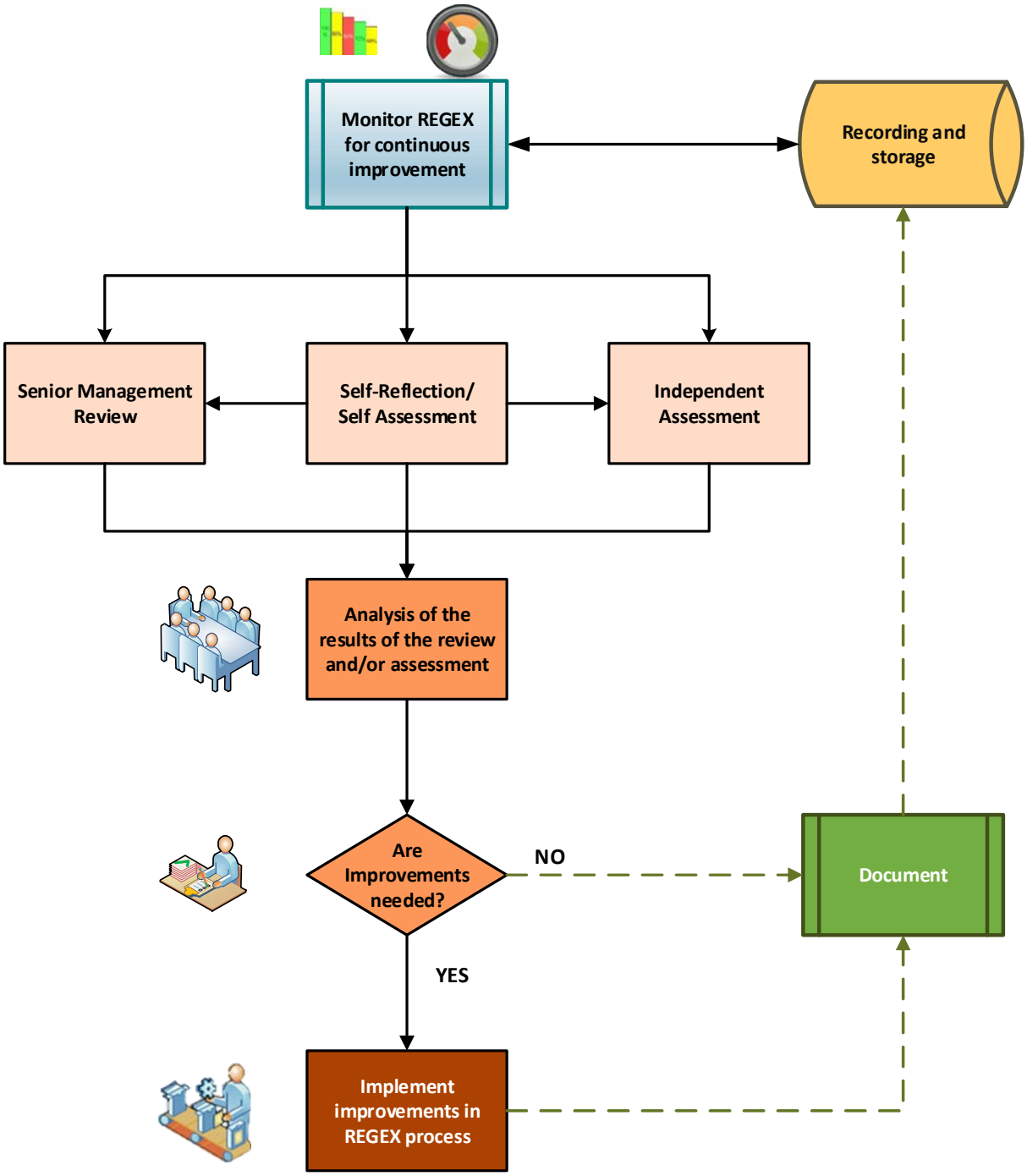

Fig. 6. The associated improvement process of the illustrative regulatory experience management process

4.3.1. Senior management reviews

Senior management of the organization could periodically review the effectiveness of the illustrative regulatory experience management process and, when necessary, agree on changes for improvement.

In reviewing the effectiveness of their regulatory experience management programme, senior management of the regulatory bodies could consider information about the performance of the system based on the results of monitoring and measuring, the lessons learned from evaluating performance and the actions taken to improve performance at all stages.

4.3.2. Self-reflection/Self-assessment

It is important that the regulatory body periodically reflects on the features, currency, and completeness of their regulatory experience management programmes to identify opportunities for making it more effective and efficient for its intended purpose.

In the illustrative regulatory experience management process, self-reflection is envisaged as a mechanism aimed at better understanding the way the programme functions in practice and the actual impact of it towards improving the effectiveness and the efficiency of the regulatory process. Self-reflection activities might not be limited to the discussion of regulatory practice, but could also aim at identifying and debating attitudes, values and beliefs held and shared by the staff to assess how they can positively or negatively impact on the effective management of regulatory experience. It could not only involve managers and staff with designated roles for the illustrative regulatory experience management process, but also a good representation of front end users. Where appropriate, external stakeholders that could be recipients of lessons learned could also be involved for a more comprehensive understanding of the way the illustrative regulatory experience management process functions.

In those organizations in which the functioning of their regulatory experience management programme has reached a maturity level compatible with defined set of goals or whenever there is available a set of normative requirements, the self-reflection could be transformed into formal self-assessment as appropriate.

Appendix VII contains a question set that can be used by regulatory bodies as an aid to self-reflect on the effective functioning of their regulatory experience management programmes.

4.3.3. Independent assessment

The regulatory body may also wish to conduct independent assessments of the effectiveness of its regulatory experience management programme. Those participating in the independent assessments (in-house or external) will need sufficient authority to discharge their responsibilities and to have direct access to senior management and staff.

To preserve the independent nature of the assessment, the organization may decide not to assign staff to review those parts of the programme within the responsibility of their management line.

The IAEA offers its Integrated Regulatory Review Service (IRRS) to strengthen and enhance the effectiveness of States' regulatory infrastructure for nuclear, radiation, radioactive waste

and transport safety. IRRS missions include a peer-review of compliance with Requirement 15 of GSR Part 1 (Rev. 1). The recommendations and suggestion from IRRS missions could also be valuable input for the host organizations to enhance their regulatory experience management system where appropriate.

4.4. SIGNIFICANT CHALLENGES TO SUCCESSFUL MANAGEMENT OF REGULATORY EXPERIENCE

The following paragraphs describe some of challenges identified by the regulatory bodies in their responses to the questionnaire sent to identify current practices for managing regulatory experience (see Section 3.1). Some of them are common to most regulatory bodies, whilst others are specific and depend on the characteristics of the organization and of its regulatory processes.

4.4.1. Insufficient Resources

Regulatory bodies need to find a good balance between the resources needed to operate a regulatory experience management programme and its added value towards enhancing the regulatory process.

Until the regulatory experience management programme is well established and effectively used, more resources could be needed. The negative impact of a high turnover of experienced staff to operate the regulatory experience management programme has also been identified as a challenge by some regulatory bodies, particularly during the initial stages of use until the programme is well established within the organization.

4.4.2. Complacency

Complacency is a challenge in at least two ways: i) the perception across the organization that everything works well and that the regulatory experience management programme does not add significant value, and ii) the perception that the existing management system of the organization already covers all what is needed to identify and incorporate lessons learned from regulatory experience.

The first challenge could be addressed by senior management through showing ownership and by promoting a questioning attitude and a continuous improvement mindset among staff. The second requires a comprehensive mapping of existing processes to ensure that all the essential elements to effectively manage regulatory experience are in place, operating effectively and contributing to the final objective. The regulatory experience management programme could contribute to achieving complementarity and completeness of existing arrangements rather than in lieu of existing arrangements.

4.4.3. Misuse

A regulatory experience management programme is not an appropriate mechanism to channel organizational or personal issues that could be handled through other existing processes or mechanisms (e.g., complaints, grievances or expression of personal or professional differences of opinion, promote or give visibility to achievements of individuals or organizational units). This could occur if staff believe there is no other way/channel and the regulatory experience management programme is issued as a last resort.

Likewise, the incorrect utilization of a regulatory experience management programme to address issues pertaining to other regulatory processes may also raise concerns. Examples of this could be the reporting of licence-holders' non-compliances identified during inspections or the reporting of safety concerns about the operation of facilities and activities that are not directly connected to the effectiveness of the regulatory process.

Staff would need appropriate guidance and training about the objective of the system and expectations on the way to use it. Likewise, staff would need clear expectations about the categories of findings to be collected and about the connection between the findings and the effectiveness of the regulatory process

4.4.4. Silo mentality

Silo mentality is an attitude that can emerge when individuals or organizational units do not want or are not able to share experience, including information, knowledge and know-how, which could be valuable for enhancing the regulatory process. This attitude has been identified as a serious barrier to ensure effective use of a regulatory experience management programme.

Management could demonstrate leadership by giving direction and ensuring that lessons learned from regulatory experience are easily shared across the organization as well as to and from other relevant organizations.

4.4.5. Fear of personal consequences

A blame-free working environment in the organization could foster identifying and submitting for further analysis regulatory experience findings.

Management could emphasize to staff that the active use of its regulatory experience management programme will not entail any negative consequence for them even if the findings are not screened in for analysis. Moreover, management could establish individual and institutional expectations towards regulatory experience management, reassuring staff that their contributions are not only wanted, they are also expected.

4.4.6. Demotivation

It is recognized that taking steps to submit regulatory experience findings may entail additional workload for the staff using the regulatory experience management programme. Lack of incentive may be a factor that could discourage and demotivate staff to become active contributors.

Management could consider options to encourage the staff to use regulatory experience management programme, for instance by acknowledging their contribution to effective regulation, by recognizing this competence in the evaluations of the staff performance, or by establishing a rewarding working environment for those who have a more active contribution to the management of regulatory experience, like encouraging staff to write articles or to participate in meetings where regulatory experience is shared.

The lack of feedback to those raising regulatory experience findings can be one of the most discouraging factors for engaging staff as active users of the regulatory experience management programme. Keeping those who have raised findings engaged throughout the process, in particular during the sharing and dissemination of the lessons learned, can be an effective way of acknowledging their contribution.

4.4.7. Overly bureaucratic or unsuitable design

While the regulatory body could benefit from a well documented regulatory experience management programme, every effort to ensure that the burden in processing the findings is the minimum necessary to ensure transparency and traceability is also necessary to maintain a reasonable balance between cost and benefit.

To the extent possible, tasks have to be streamlined and implemented following flexible and dynamic approaches. The design of a regulatory experience management programme could also include appropriate features so ensure that is user-friendly and the burden on the users is minimized.

The organization could pay attention to elements such as:

— Appropriate threshold for dealing with potential findings. A low threshold could lead to congestion of the process whereas a high threshold could prevent important lower level findings not being evaluated;

— Enough resources to prevent excessive delays in analysing findings. This could discourage staff from reporting;

— Management leadership and commitment to ensure that staff are available when requested to provide input for the analysis, decision making and follow up;

— Appropriate delegation arrangements for decision making authority to ensure fluid management of the regulatory experience management programme.

5. SUMMARY

Based on the review of the responses to the questionnaire sent to a number of Member State's regulatory bodies, the term regulatory experience does not have an official definition in the national regulatory frameworks of those countries that provided feedback. Also, very few regulatory bodies have policies in place specifically addressing the concept and management of regulatory experience.

There is no definition of regulatory experience either in the IAEA safety glossary [4] or in any IAEA publication. The adoption of a definition of the concept of regulatory experience could contribute to better understanding of the concept and a better management of the experience generated by the regulatory bodies from the exercise of their duties and from other sources, including the sharing and dissemination of the lessons learned.

Many regulatory bodies reported on existing processes and/or practices of their management system that address, to varying degrees, the management of regulatory experience. Creating a dedicated process or programme of the management system to manage regulatory experience is not viewed as essential; however, integrating key elements of the management of regulatory experience into existing processes of the management systems is viewed as beneficial for increasing the opportunities of learning lessons to enhance the regulatory process.

Few regulatory bodies have incorporated or are in the process of incorporating the management of the regulatory experience as a standalone core or support process. Incorporating the management of regulatory experience as a dedicated process or programme into their management systems is perceived by these regulatory bodies as beneficial to emphasize the importance of managing the interfaces among regulatory functions and activities.

A proactive approach to managing regulatory experience, supported by senior management leadership and coupled with strong individual commitment, could be beneficial for regulatory bodies to be more effective in enhancing their regulatory process.

There are many sources of regulatory experience. Most regulatory bodies routinely explore a wide range of internal and external sources in search of information and experience through different processes and following different approaches. However, very few have arrangements for managing the information from these sources in a more systematic and integrated way. Regulatory bodies could benefit from performing an analysis of the added value of available sources of regulatory experience to continuously improve the regulatory process and decide which of them can be of higher importance and interest for their organizations.

All regulatory bodies share regulatory experience routinely through local means and using international platforms. However, most of the time they do so on a case-by-case basis. Very few have a systematic approach to the sharing and dissemination of regulatory experience.

Currently there is no dedicated international reporting system to share regulatory experience. In the short term, exploring the possibility of enhancing existing international reporting systems and regulatory networks to promote and facilitate the reporting and sharing the regulatory experience could be the easiest approach.

In conclusion, this publication provides information that can be used by the regulatory bodies to reflect on their current arrangements for managing regulatory experience, learn about the practices of other regulatory bodies and explore possible measures to increase benefits from effective management of regulatory experience, as well as to address existing challenges.

APPENDIX I. SOURCES OF REGULATORY EXPERIENCE

I.1. PURPOSE

This appendix discusses possible sources of regulatory experience from which the regulatory bodies can learn lessons that could assist them in improving the regulatory process. It is not the intention of this appendix to provide an exhaustive list of potential sources of regulatory experience. Rather than this, the goal is to provide a sufficiently broad representation of the sources and encourage the regulatory bodies to self-reflect on the most appropriate arrangements to maximize the benefits from exploring those that are considered relevant for improving their regulatory process.

The sources have been arranged in two separate sets. The first set shows examples of activities associated to the conduct of regulatory functions and associated processes that can produce relevant regulatory experience. It is important to observe that lessons learned from regulatory experience collected from the implementation of a regulatory function or process might be of interest for enhancing other regulatory functions or processes. For instance, feedback from regulatory research intended to support the preparation of new regulatory guidance or to revise an existing one can also give place to lessons for enhancing the regulatory review and assessment function or associated process. Precisely the cross cutting review of collected findings of regulatory review is one of the factors that confers added value to the effective management of regulatory experience.

The second set contains external sources of experience not directly connected to the implementation of regulatory functions or processes for regulating domestic facilities and activities that may be relevant to identify lessons to be learned for enhancing the regulatory process. The external sources can be national or international.

Most of the examples shown in the table are multipurpose settings and forums that can generate a broad range of regulatory experience.

I.2. SOURCES ASSOCIATED WITH THE DOMESTIC REGULATORY PROCESS

REGULATORY FUNCTION/PROCESS	EXAMPLES OF ACTIVITIES THAT CAN GENERATE REGULATORY EXPERIENCE
Regulations and guides	• Issuance of new laws and regulations (National/Federal and Regional/States) on matters relevant to safety • Legislative proceedings • Regulations from other national regulatory authorities in matters with safety implications • Public consultations and hearings • Congressional committees • Standards of professional organizations (including non-nuclear organizations) • Reports and feedback from TSOs and advisory bodies • Reports and feedback from research organizations
Notification and authorization	• Issuance of authorizations • Regulatory review of modifications and process changes • Oversight of compliance with license conditions • Licensing appeals • Public consultations • White papers • Feedback from license holders
Review and assessment	• Safety evaluations • Benchmarking with other regulatory bodies • Lessons learned from operating experience feedback • Lessons learned from research • Technical meetings
Inspection of facilities and activities	• Inspection reports • Inspection findings • Operating experience feedback from activities and facilities • Operating experience feedback from relevant non-nuclear industries
Enforcement of regulatory requirements	• Enforcement appeals • Corrective actions • Enforcement procedures of other national regulatory bodies connected to regulated matters

REGULATORY FUNCTION/PROCESS	EXAMPLES OF ACTIVITIES THAT CAN GENERATE REGULATORY EXPERIENCE
Emergency preparedness and response	• Emergency drills and exercises, including interaction with participants and the public • Coordination committees involving local, regional and state authorities • Interaction with other national authorities directly linked with the preparation and response to emergencies
Integrated management system	• Quality management audits • Independent assessments • Self-assessments • Government audits • Peer review reports and findings • Findings from Management System reviews
Staffing and competence of staff	• Interaction with national authorities responsible for resourcing government bodies, including the regulatory body • Interaction with regional authorities with transferred or entrusted regulatory competences • Interaction with educational and research centres

I.3. EXTERNAL SOURCES OF REGULATORY EXPERIENCE

TOPIC	EXAMPLES OF ACTIVITIES THAT CAN GENERATE REGULATORY EXPERIENCE
Cooperation with national authorities not linked to the regulatory process	• Exchanges with other national regulatory bodies to discuss general matters of common interest (i.e. operating experience, inspection and enforcement practices and experience…) • Lessons learned from national non-safety research and technology programmes conducted by other regulatory bodies
Production and use of international safety standards	• IAEA Safety Standards and associated documents (e.g. TECDOC and Safety Reports) and participation in their elaboration • Meetings of the IAEA Safety Standards Commission and Committees

TOPIC	EXAMPLES OF ACTIVITIES THAT CAN GENERATE REGULATORY EXPERIENCE
Activities of international organizations specialized in nuclear energy and associated matters.	• International conferences, meetings and seminars hosted by international organizations, in particular those focused on sharing experience from regulating facilities and activities. • Committees, working groups and task forces of international organizations • Exercises promoted by international organizations (e.g. ConvEX, INEX, etc.). • Technical documents and policy guidance published by international organizations and participation in the elaboration of them (i.e. IAEA TECDOC and Safety Reports, reports of the IAEA advisory committees, OECD/NEA policy documents and technical reports, etc.). • Activities of the technical cooperation programmes operated by international organizations such as training courses, fellowships and scientific visits, workshops and expert missions. • Peer reviews and advisory missions (e.g. IRRS, EPREV, OSART, SALTO, etc.).
International convention, treaties and agreements	• Governing bodies and diplomatic conferences • Contracting parties review meetings • National reports • Multilateral implementing regulations and agreements
International codes of conduct on safety	• Technical Meetings • Guidance and technical reports
International cooperation settings among regulatory bodies	• Bilateral and multilateral cooperation agreements among regulatory bodies • Technical exchanges under the umbrella of bilateral and multilateral agreements (e.g. benchmarking, combined exercises, shared intelligence, etc.)
Standards, codes of practices and publicly available technical reports of the industry	• National and international standards from the industry (e.g. ANSI/ANS, ASME, IEEE, ISO, etc.). • Codes of practice (Code of Ethics for Nuclear Operating Organizations, Principles of Conduct of NPP and Reactor Exporters, etc.). • Technical reports (INPO, WANO, EPRI, WENRA...)

TOPIC	EXAMPLES OF ACTIVITIES THAT CAN GENERATE REGULATORY EXPERIENCE
International reporting systems and databases	• IAEA data bases (e.g. INES, INIS, PRIS, etc.) • Incident reporting systems (e.g. IRS, FINAS, IRSRR, etc.) • Other databases (e.g. NEA nuclear databases, ICSBEP database on criticality safety benchmarks, etc.)
International research	• International research programmes or projects (e.g. INPRO, Horizon 2020, IAEA coordinated research project, CABRI water loop project, ITER, etc.) • Cooperative research projects
Regulators' associations, forums and networks	• Associations of regulatory bodies (e.g. ENSREG, WENRA, FORO, INRA, etc.) • Forums of regulators (e.g. SMR Regulators Forums, WWER Regulators Forum, CANDU Forum, TSO Forum, etc.) • Networks of regulators and of safety related activities: (ANSN, GNSSN, REGNET, GSAN, etc.).
International non-nuclear sources	• International events from non – nuclear industries with instructive value • Activities and documents of other no-nuclear international organizations (WHO, OECD/IEA, IATA…)

APPENDIX II. RESEARCH AND DEVELOPMENT

II.1. PURPOSE

The purpose of this appendix is to discuss how to integrate feedback gained from research, either own or external research, into the regulatory experience management process of a regulatory process.

II.2. RESEARCH AS A SOURCE OF REGULATORY EXPERIENCE

Specific Research and development (R&D) programs are continuously conducted in order to help clarify and solve some nuclear safety or radiation protection issues.

For instance, in the field of power reactors, long standing R&D efforts have been devoted to accidents like the loss of coolant or core melt accidents. These efforts have resulted in modification of safety regulations and guidance in several countries. Similarly, long lasting studies have led to the revision of radiation exposition standards. Thus, R&D is a key factor in the enhancement of the regulatory process and an important source of regulatory experience as shown in Fig. 5 of Section 4.2.1.1.

This contribution from R&D to the management of regulatory experience has, however, some peculiarities, that make its use different from that of the other sources.

Firstly, R&D programmes last long, spanning sometimes over decades, and, in most cases, their results are obtained progressively. The confidence in their results and lessons is also built gradually. So, R&D conclusions that could be of significance for the regulatory process rarely appear suddenly. This has two consequences:

— Regulatory bodies cannot always wait for the definitive conclusions and may have to decide whether some parts of the regulatory process have to be amended while the R&D is still going on; and

— Results and new knowledge of some R&D programmes become available at a slow pace and without breakthroughs that could attract the attention of the licensees and/or of the regulatory bodies.

Secondly, R&D actions may reveal that some risks are different from what was anticipated. For instance, an accident scenario which was considered as extremely unlikely may prove plausible (this was the case of certain reactivity accidents on pressurized water reactors); consequences that were strongly feared may turn out to be limited (this has been the case of seismic vibration of pipe systems). R&D may also show that the provisions against certain risks are not appropriate. Thus, R&D outcomes (experimental or theoretical results, computing code and databases) may give rise to questions on the regulatory process like:

— Is it still necessary to require/ban this particular practice, since studies performed with R&D computing codes show that it has negligible (or manageable) consequences?

— What has to be introduced into the regulatory process to better address this particular problem that a recent R&D result has shown to be more serious than believed?

— When ongoing R&D is directed towards addressing a particular issue, what temporary measures need to be adopted until comprehensive results become available?

Thirdly, regulatory bodies often have a limited relationship with ongoing research programs. Some of them directly administer or participate in R&D programmes while others receive only indirect information through specialized literature or congresses. As a consequence, evaluating the significance of R&D outcomes as regards the regulatory process may prove to be difficult. To cope with this challenge, the following points could be considered:

— Fields of the regulatory process which are potentially impacted;

— Potential impact on safety of concerned facilities or activities;

— Degree of confidence in the results;

— Availability of practical measures allowing to limit the consequences or avoid the problem; possible consequences of these measures on other safety issues;

— Degree of maturity and complexity of the existing regulatory process in the concerned area;

— The margin of time available for action before a safety or regulatory issue will be faced as a result of phenomena or risks revealed by the R&D.

Even if the regulatory body does not follow directly the research programs, it could establish and maintain a monitoring mechanism of these programs allowing it to be aware regularly of the results and lessons learnt. This can take various forms: establishing a scientific committee, maintaining regular links with research organizations, participating in international organizations or cooperation, having consultants prepare state of the art reports, etc.

Another aspect of R&D is that when field activities are conducted in nuclear test facilities, for instance with the purpose of simulating accidental conditions, the safety of these test facilities sometimes may raise specific questions. The tests may lead to findings that are not directly related to the safety issue that is being addressed by the experimental program, but to the safe operation of the test facility itself. These finds could also be analysed on their own value.

II.3. CONCLUSION

R&D is an important source of regulatory experience and, as such, regulatory body need to explore how better use lessons learned from R&D in keeping their regulatory process up to date and suitable. Regulatory bodies, though, may need to establish arrangements to address the specific characteristics of this source of regulatory experience, such as those mentioned above, to effectively utilize information and knowledge generated from R&D.

APPENDIX III. REGIONAL OFFICES AND SHARED REGULATORY FUNCTIONS

III.1. PURPOSE

The purpose of this appendix is to discuss the challenges associated with management of regulatory experience in situations in which:

a) The regulatory body delegates some responsibilities to regional offices or authorities; or

b) The regulatory responsibilities are shared between several institutions.

III.2. DIFFERENCES AND SIMILARITIES

In this appendix the two situations laid out in III.1 are seen as two ends of a spectrum with varying amounts of independence of offices/institutions and their responsibility for regulatory functions.

Regional Offices

Some regulatory bodies with competence to exercise all regulatory functions within the State also have regional offices or divisions distributed across the country to organize the regulatory work in certain geographical areas or regions.

There are other States with legislation allowing the central government or the regulatory body to transfer or entrust certain regulatory functions to regional authorities of self-governing states or autonomous regions of the country through agreements. In some countries states with delegated regulatory competences are known as ‘agreement States’.

Despite the important statutory differences between these two situations, for simplicity in this annex they are referred to as ‘regional offices’ because in both situations they operate under the auspices of a single regulatory organization with assigned responsibility for establishing the overall regulatory policy.

Shared Regulatory Functions

In some States the responsibilities for different parts of the regulatory framework, such as legislation, licensing of facilities and activities or authorizing transports could be shared or split between different organizations. In this case, none of these institutions can be identified as ‘the regulatory body’. Instead, the different institutions together that are responsible for all regulatory functions make up ‘the regulatory body’. In this appendix shared or split responsibilities are referred to as ‘shared regulatory functions’.

On the one end of the spectrum are the regional offices that might be seen as mere part of the overall organization which is located in a geographical area away from the headquarter for operational reasons. On the other end of the spectrum, regulatory functions might be fully

separated and given to different institutions that fulfil them within their own mission and mandate. However, in accordance with IAEA Safety Standards, “where several authorities are involved, the government shall specify clearly the responsibilities and functions of each authority within the governmental, legal and regulatory framework for safety” (paragraph 2.6 of GSR Part 1 (Rev. 1) [2]). Likewise, “where several authorities are involved in the authorization process, the regulatory requirements shall apply, and they shall be applied consistently and without undue modification” (paragraph 2.12 of GSR Part 1 (Rev. 1) [2]). This comes with the need for close collaboration and coordination in all cases.

On both ends of the spectrum, either regional offices or shared regulatory functions, much of the experience in implementing the regulatory framework resides where the implementation occurs, whether in different regions across the country or by different institutions. It is important that the experience generated from these regional offices or institutions could be integrated into a single global regulatory body’s regulatory experience management process. However, managing regulatory experience in both situations can pose some unique challenges.

III.3. CHALLENGES

III.3.1. Regional offices

One of the biggest challenges that regulatory bodies with regional offices face in the context of regulatory experience management is ensuring consistency in the application of the regulatory process across the regional offices in the country. Therefore, it is particularly important for these regulatory bodies to have an effective and well integrated regulatory experience management programme or arrangements.

Several factors can result in inconsistent application of the regulatory process, for instance:

— Difficulty ensuring that regulatory experience is captured and disseminated across regional offices;

— Geographic distance might result in regional offices developing slightly different attitudes and approaches (cultures) in implementing the regulatory process;

— Regional offices may be subjected to different external factors (public perception, political pressure, additional media scrutiny) that can influence how they implement the regulatory process.

In practice, in regulatory bodies with regional offices many regulatory processes are managed by the central organization (i.e. headquarters) but require input from the regional offices. However, since the central organization can be somehow detached from the field implementation of those regulatory processes conducted by the regional office, the owners of these processes in the central organization may have limitations to understand the intricacies and details of their implementation at the regional level. These potential limitations make even more important to build effective arrangements to make sure that the regulatory experience generated in the regional offices is not lost (i.e. reaches the headquarters and it is shared with other regional offices).

III.3.2. Shared regulatory functions

For regulatory functions that are shared or split between institutions, there are similar challenges. However, an important difference is that different attitudes and approaches might not be perceived as an issue because of the authority is distributed. What is important though is that the overall goal to ensure nuclear safety is reached to the same level regardless of the specific regulatory process. The ways to achieve this can differ, within reason, but it is important to harmonize the approaches towards this goal.

Another important difference is the necessity to coordinate and share information between organizations/institutions rather than within one institution. Within a regulatory body with regional offices, there is a clear assigned hierarchy between the regional offices and the headquarters when establishing policy and guidance to implement the policy. This can be different with shared regulatory functions. As organizations/institutions with shared regulatory functions fulfil the given regulatory functions within their own mission and responsibility, the exchange and interaction among the institutions sharing regulatory experience is more collaboration on equal terms than collecting experience.

III.4. KEY TOOLS

III.4.1. OWNERSHIP

In the case of regional offices, regulatory bodies need to ensure cohesion across entire organization, while allowing regional offices to adapt to their local environment. They need to establish ownership of programs and processes at the appropriate levels and ensure that they are being implemented as intended in each region. In order to accomplish this, the regulatory processes that are to be implemented by the regional offices need to be clearly prescribed in procedures and other documents, and expectations and responsibilities need to be clearly described and understood. Regulatory bodies could also provide the regional offices with some autonomy so that decisions can be made at the appropriate level and with commensurate effort and resources. Regulatory bodies can use previous regulatory experience to establish these thresholds.

In case of shared regulatory functions, institutions might be completely autonomous, but it is still important to emphasize the necessity to define the ownership of the whole regulatory body system.

III.4.2. COLLABORATION

Regulatory bodies are expected to develop and maintain their regulatory process in collaboration with the regions or institutions. They could build processes in their organizations that encourages employees in the regional offices or institutions to identify and communicate issues regarding the regulatory process, as well as possible improvements to the regulatory process, to program owners so that these can be addressed at the organizational level. This also requires the regulatory body to foster an environment where issues, concerns, and ideas can be raised without fear of retaliation and that these are evaluated and acted upon appropriately and where outcomes are communicated appropriately.

Regulatory bodies with regional offices could coordinate with the regions to plan and provide for compatibility in regulatory approaches. They could also continuously review the adequacy of such programs and provide technical support for training of regional licensing and inspection staffs.

For regulatory bodies with shared regulatory functions it is important to establish and maintain effective communications and working relationships between the different institutions. An effective way to coordinate is to set up a committee structure with subordinate working groups. This allows sharing experience on implementing the regulatory functions and harmonization as well as enhancing the application of the regulatory process.

Regulatory bodies can benefit from engaging with other States and associated regulatory bodies, as well as with other industries with regional offices or shared regulatory functions to understand how they manage their organization. They can look at how others implement their regulatory process, and if there are any improvements that can be made in how they implement their own regulatory process. Possible questions to ask include:

— How do other countries manage and implement their regulatory functions (e.g., licensing, inspection)?

— What differs from your own methods?

— What do you perceive to be beneficial to incorporate into your own processes?

Conversely, regulatory bodies could be proactive in sharing any lessons learned from regulatory experience. They could strive to make as much information as possible accessible to other regulatory bodies, including having the information available in English.

III.4.3. PERIODIC ASSESSMENT

In the case of regional offices, regular assessment of the implementation of the regulatory process by each regional office is important to ensure that regulatory experience is being managed appropriately. Regulatory bodies can conduct periodic surveys and self-assessments to ensure that the regulatory process is being applied consistently across the regions. For example, organizations can compare actual performance with planned or expected results throughout the organization and across regions and analyse any significant differences. Additionally, regulatory bodies may conduct periodic evaluations and alignment of resources to ensure the most effective allocation of resources. Audits and reviews from parties external to the regulatory body, such as oversight bodies, can also help in identifying issues.

In cases of shared regulatory functions, while there is not a central authority establishing the approaches to be followed, still the different institutions that together are responsible for all regulatory functions can carry out intercuspations or benchmarks of their practices towards achieving

III.4.4. TRAINING AND KNOWLEDGE MANAGEMENT

Regions or institutions of the regulatory body can hold conferences and counterpart meetings to foster the exchanging of regulatory experience. It is also important for regulatory bodies to

maintain communications and access to information within an organization and across to external organizations, and to establish the appropriate tools and infrastructure to do so.

In order to promote consistency across regions, regulatory bodies with regional offices could implement an effective training program to ensure that staff is qualified to the same level. Regulatory bodies can encourage resource sharing across the regions through, for example, staff rotations and exchanges. This might incur some costs but can be beneficial since it allows experience and insight to be shared across the regions.

Regulatory bodies with shared regulatory functions can for example establish a countrywide training program to ensure a similar level of training and knowledge across the regulatory body system and to foster informal exchange.

APPENDIX IV. TECHNICAL SUPPORT ORGANIZATIONS

IV.1. PURPOSE

Some regulatory bodies complement their own capabilities relying on studies, assessments, reviews or inspection work performed by outside organizations generally termed TSOs in the nuclear terminology.

The purpose of this appendix is to discuss the role and involvement of Technical Support Organizations (TSOs) in supporting the regulatory body to manage regulatory experience.

IV.2. INVOLVEMENT OF TSOS IN THE MANAGEMENT OF REGULATORY EXPERIENCE

These TSOs have various statutes, roles and functions depending on the national legal and regulatory framework, such as:

— Scientific or technical institutes like universities, engineering schools or research centres;

— Private or public organizations specialized in technical verification, including nuclear technology matters;

— Consultancy organizations or experts specialized in nuclear safety;

— Advisory expert groups.

They carry out a variety of tasks, including:

— Scientific or technical studies;

— Technical assistance (for instance measurements) to inspections;

— Technical/scientific assessment of safety documentation submitted by licensees;

— Partial or full safety assessment of safety analysis submitted by licensees;

— Assistance in preparing regulations or guides;

— Issuing advice or recommendations on practices or specific safety cases.

Hence, these TSOs participate in the implementation of some of the regulatory functions mentioned in Section 3.2.1 as sources of regulatory experience. A common point to the abovementioned activities is that, when performing them, TSOs are in direct contact with files prepared by the licensees. Because of their technical/scientific mission, they often have extended interaction with the licensee's staff and reach a good understanding of their reasoning. This gives them opportunities to notice points of interest to the regulatory body like incorrect or unsatisfactory application of regulations and guides, inappropriate use of technical codes and standards, discrepancies with recognized practices or use of knowledge that is not state of the art.

For instance, assessing an accident analysis performed by a nuclear operator applying for a license may lead the TSO staff to notice various facts:

— The licensee applied inappropriate safety criteria and there is an ambiguity on this point in the available guidance documents;

— The licensee used a computing code that is not fully qualified for the analysis, but the regulatory body did not express its expectations about code qualification for this type of study;

— The licensee considered hypotheses on some physical phenomena involved in the accident that are no longer accepted by the specialists; but this new state of accepted knowledge has not been properly communicated to the licensee;

A TSO employee, participating in an inspection, may notice the following:

— The licensee uses an outdated measuring technique, but the regulations and guidance documents do not clearly exclude such a technique;

— A certain part of the inspected facility complies with a past version of a code or standard that is normally no longer in use, but the regulations or decisions of the regulatory body have not clearly excluded the use of this version;

— During a first of a kind operation, something unexpected happens, like significant vibrations, temperature elevation or unusual noise that the TSO employee judges potentially detrimental and there is nothing in the regulation or guides addressing these phenomena.

On the occasion of assisting the regulatory body in preparing a new regulation or guide, the TSO may give indications such as:

— It is necessary to define more accurately a certain notion (for instance, importance to safety) because it has been noted when analysing safety cases that the licensee used it in an unexpected way;

— The qualification of the computing code used in certain analyses has to be improved because TSO's own counter-studies have shown that there is a great sensitivity to the models included in the code;

— A high-level regulatory provision, setting only a general goal, need to be replaced by a more specific one, since it has been noted there was some doubt and hesitation on how to comply with the high-level provision.

These items may differ from the ones ordinarily found by the regulator's staff in that they are often more technical in nature, but they may be as relevant to the regulatory experience. In particular, they may reveal:

— Misinterpretation or poor understanding of regulations and guides because of obscurity or lack of detail in these documents;

— Improper practices due to lack of regulation or guidance in unusual areas;

— Risks not appropriately covered by existing regulations or guides, because of ignorance of new facts.

Therefore, these items need be conveyed to the regulatory body's regulatory experience management system in order to induce the necessary changes.

Several means can be used to achieve this, for instance:

— A specific chapter or paragraph may be devoted to these points in the reports or advices prepared by a TSO for the regulatory body; this chapter or paragraph could be filled out by TSO's staff and reviewed at an appropriate level of its hierarchy; this review has to exclude facts that are outside the scope of the regulatory experience;

— Regular meetings gathering appropriate representatives of the TSO and the regulatory body may be set up; during these meetings, significant findings arising from the work performed by the TSO could be presented and discussed for possible introduction in the regulatory experience management system;

— Periodic reports on the significant facts found by the TSO may be prepared;

— A direct entry point into the regulatory experience management system of the regulatory body may be provided for TSO staff.

In order to ensure that TSO staff feed the system with relevant items (either directly or indirectly through regulatory body's staff), it is necessary that they receive appropriate information about the importance of regulatory experience as a prominent means to improve the regulatory process and as a consequence, the quality and relevance of the licensee's documents or activities they examine. They could also benefit from an appropriate training programme. Information and training could be the same for the staff of the regulatory body or, if necessary, can be adapted to the specificities of TSOs' staff.

Expert committees or advisory groups are sometimes established to give opinions or advices to the regulatory body on specific questions related to:

— Regulations and guides under preparation, like giving an advice on drafts of these texts;

— Safety cases prepared by a licensee, like before granting a construction or operation license;

— Safety policy and strategy, like debating and revising safety principles or priorities after an accident.

In the course of their work, these committees or groups may arrive at conclusions related to the regulatory process, in a similar way as traditional TSOs, but on subjects considered at policy level. Thus, it is important that a proper way of conveying these conclusions to the regulatory body be provided for.

In a way similar to other TSOs, the members of these groups could receive appropriate information on the importance of regulatory experience.

APPENDIX V. IDENTIFICATION OF REGULATORY EXPERIENCE FINDINGS

V.1. INTRODUCTION

The identification of potential regulatory experience findings is the primary driver of the regulatory experience management programme. Without findings there are no lessons to be learned.

Managers of the regulatory bodies at all levels could instil positive traits in the staff through training and coaching them, as necessary, and by providing them with appropriate tools to document and channel potential findings. Depending on the policy of the organizations, some can be inclined to use fully documented means, including IT based solutions, while others may opt for flexible approaches, including oral reporting.

Regardless of the specific approach followed by the organization, the very first step is the judgement of individuals to decide if it is worth allocating time and effort of others in the organization to assess a given situation with a broader perspective. This may not be a simple decision, particularly for individuals who focused on the conduct of specific regulatory tasks. It is, therefore, in the interest of streamlining the resources of the organization to provide appropriate guidance and training to staff to ensure that only relevant regulatory experience is captured and to avoid as much as possible spending resources of the organization in assessing findings which are not suitable for the regulatory experience management programme.

V.2. TEMPLATES TO HELP IDENTIFY REGULATORY EXPERIENCE FINDINGS

The regulatory bodies might consider the benefits from designing templates, check lists and other means to guide staff in self-assessing about the relevance of potential finding before triggering the assessment of them through the regulatory experience management programme.

When designing these tools, the regulatory body could identify suitable questions to help staff identify weaknesses that need to be addressed as well as strengths that could be disseminated and replicated across the organization and elsewhere, as appropriate, taking into consideration the three basic dimensions of a problem under consideration and the interrelation between these dimensions:

— The regulatory function or process: aspects related its ‘fabric’, structure and constituents of the process subject to assessment, including, but not limited to, fundaments and methodology, regulatory objectives and criteria, technical soundness, currency and accuracy;

— The staff: aspects related to the individuals in charge of the implementation of the function or process, including, but not limited to, qualifications, available resources, availability of guidance and support;

— The organization: aspects related to the conditions under which the regulatory process is conducted, including, but not limited to, working environment, leadership and involvement of management, interfaces and safety culture of the organization;

Table 1 shows an example of a checklist that could be used for building tailor made aid tools to support staff in deciding whether there are lessons to be learned to improve the regulatory process, including the identification of good practices.

ASPECTS RELATED TO REGULATORY FUNCTIONS AND PROCESSES	
Opportunities for improvement	**Strengths**
▪ The regulatory process (as implemented) does not fully meet the policy, strategy and goals of the organization ▪ The methodology of the process is not well-informed/technically sound and has not been sufficiently tested ▪ Interfaces between the regulatory process and other regulatory processes are not considered or properly covered ▪ There are not enough regulatory criteria or a consistent framework to implement the regulatory process ▪ The frequency and depth of the regulatory process do not fit the purpose and regulatory criteria ▪ The process (as implemented) has not been updated to cover all known regulatory experience ▪ The regulatory process does not minimize the use of resources and/or gives place to excessive interference in the operation of the facility or activity	▪ The regulatory process sets best example of how to foster principles and goals of the organization ▪ The implementation methodology of the regulatory process could be replicated as a best practice for other processes ▪ The regulatory process creates strong synergies with connected processes ▪ The regulatory process is a good example of effective and efficient compliance with regulatory criteria ▪ The regulatory process represents a good practice to achieve objective and meet requirement with the minimum frequency and burden ▪ The process has been well-informed with existing regulatory experience and has brought significant enhancements ▪ The regulatory process introduces novelties that minimize resources and interferences that could be worth sharing
ASPECTS RELATED TO THE STAFF	
Opportunities for improvement	**Strengths**
▪ Staff have not available appropriate procedures to implementing the process ▪ Staff have not available appropriate training and guidance to understand the fundamentals and goals of the process ▪ There are not enough resources and means (human and technical) to implement the process ▪ Staff do not have access to specialized support and advice to implement the regulatory process and reach the regulatory objectives	▪ The organization has put in place and revised procedures and arrangements to keep them up-to-date with new knowledge and experience ▪ The organization has in place exemplary capacity building programmes, including coaching of fresh staff by experience staff ▪ Appropriate mechanisms are in place to ensure that there are enough Staff available to implement the regulatory process in an effective and efficient way ▪ The organization has set up appropriate arrangements to ensure availability of

	external expert support to ensure effective delivery of the regulatory process
ASPECTS RELATED TO THE ORGANIZATION	
Opportunities for improvement	**Strengths**
▪ The management of (at the correspondent level) is not appropriately informed of and involved in the process ▪ There is not a guilt-free environment to foster a questioning attitude in the implementation of the regulatory process ▪ The outcome of the process, as implemented, is not taken into consideration as part of the broader regulatory oversight process of the organization	▪ The outcome of the process is taking into consideration for learning lessons and disseminate them as appropriate within and outside the organization ▪ There are appropriate mechanisms to raise concerns and regulatory experience findings regarding its implementation ▪ The process is well integrated within the management system and there is a multidisciplinary and complementary approach in assessing the outcomes of it

Table 1. Example of a check list to support the identification of regulatory experience findings

V.3. STAFF MOTIVATION

It has been pointed out several times in this publication that staff or regulatory bodies play a fundamental role in achieving successful utilization of regulatory experience. Regardless of the specific source of regulatory experience, whether internal or external to the organization, the important point is that at the end of the day an individual staff member or a group of staff members will have to take the initiative to document and submit a finding for screening and analysis.

Expectably all staff could be willing to do so based on their individual commitment to the organization and to continuous improvement (see Section 3.2.8). Nevertheless, the management of the organization can explore opportunities to motivate staff, for example by:

— Providing feedback about the conclusions of the screening, analysis and implementation of lessons learned from the findings raised by individual staff members;

— Involving staff who raise finding along the process as convenient;

— Emphasizing to staff the relevance of individual contributions to the safety objective of the organization in the policy statements and in staff training;

— Organizing meetings with the staff periodically to collectively discuss examples of improvements in the regulatory process achieved from lessons learned of regulatory experience findings;

— Reflecting the improvements in the regulatory process in the annual report of the organization or in internal newsletters or circulars to acknowledge involvement of staff and further promote the utilization of the system.

V.4. STAFF TRAINING

The analysis of the responses to the questionnaire sent by the IAEA to regulatory bodies shows that the concept of regulatory experience and the arrangements to manage it are not uniform across the organizations that responded to the questionnaire. It is, therefore, expectable that something similar had happened if a similar questionnaire would have been distributed to the staff of any of these regulatory organizations.

Although there is relatively straightforward intuitive meaning of the concept of regulatory experience, with all certainty different interpretations would be given about its fundamentals, such as the definition, the purpose, the means available in the organization, the expected benefits, the relationship with other regulatory concepts with similar end, etc.

The obvious conclusion is that appropriate materials and programmes to educate staff about the concept and to train them on the use of the means available is prerequisite to ensure effective management of regulatory experience.

The regulatory experience management programme of a regulatory body needs be tailored to the specific characteristics of the organization, account being taken of the features of its management system. The corollary of this statement is that the education and training programme of the staff also needs be tailored to fit the specific modality of its regulatory experience management programme. Though this limitation is acknowledged, the content of a sound education and training programme aimed at the effective management of regulatory experience has to cover essential subjects, as those identified in table 1. Regulatory bodies can use the list of topics in this table to identify those specific aspects that they consider appropriate for the objective of their specific training programme.

TOPICs	PURPOSE
Section 1: Fundamentals	
▪ Concept and definition of regulatory experience ▪ Objective ▪ International standards ▪ National regulations ▪ Mission and policy statements ▪ International commitments and contribution to the global safety regime ▪ Structure of the regulatory body ▪ Interaction and coordination with other national regulatory bodies ▪ Liaison with license holders ▪ Liaison with advisory bodies and TSOs ▪ Liaison with other regulatory bodies and involvement in international programmes and activities ▪ Connection and differences between operating and regulatory experience	This section is intended to provide trainees with insights about the concept of regulatory experience and how it relates to the organization of the regulatory body and to the regulatory process, including liaison with other national authorities and stakeholders.
Section 2: Benefits from effective management of regulatory experience programme	
▪ Added value of the management of regulatory experience for enhancing the regulatory process ▪ Examples of situations in which regulatory experience has given place to enhancement of the regulatory experience	This section seeks to provide evidence of the added value of the effective management of regulatory experience by showing practical examples.
Section 3: Sources of regulatory experience	

TOPICs	PURPOSE

▪ Internal sources:
  ▪ Core regulatory processes and functions
  ▪ Other regulatory functions and processes
  ▪ Management system
  ▪ Operating experience
  ▪ Regulatory research
  ▪ Advisory bodies and TSOs
▪ External sources:
  ▪ National:
  o Non-nuclear legislation and policy
  o Non-nuclear regulatory bodies
  o Non-nuclear industries
  o Industry standards
  ▪ International
  o International safety standards
  o International industry standards
  o International nuclear research
  o International organizations
  o Associations, forums and networks of regulators
	This section is intended to guide the trainees throughout the most common sources of regulatory experience and to help them identify those sources that could have priority attention by the staff of the organizations.

Section 4: Arrangements for managing regulatory experience	

▪ Approach and modality
▪ Roles and responsibilities
▪ Integration within the management system and interfaces among relevant processes
▪ Management of external sources of regulatory experience
▪ Arrangements for collecting regulatory experience:
  ▪ Identification: templates, means, advice and practical examples
  ▪ Collection: channels for reporting and organization
  ▪ Storage: type of information stored, means, access to and retrievability of information
▪ Arrangements for analysis of regulatory experience:
  ▪ Screening: criteria and thresholds
  ▪ Assessment and elaboration of action plans to address findings of regulatory experience
  ▪ Decision making
▪ Arrangements for Implementing action plans and sharing lessons learned:
  ▪ Monitoring the implementation of action plans
  ▪ Monitoring impact in the regulatory process
  ▪ Criteria for sharing and dissemination of regulatory experience
	This section is the bulk of the programme and its purpose is to provide step-by-step information on how to complete a sound analysis of the regulatory experience findings identified by the staff of the regulatory body, including findings from external sources of experience.

TOPICs	PURPOSE
Section 6: Leadership and management	
▪ Management commitment to the management of regulatory experience ▪ Management reviews of the regulatory experience management system	This section is intended to illustrate how the management of the organization commits to an effective and efficient management of regulatory experience
Section 7: Engaging staff	
▪ Roles and responsibilities ▪ Expectations from staff ▪ Blame-free working environment ▪ Staff involvement throughout the analysis of regulatory experience findings and feedback ▪ Recognition of staff contributing to the management of regulatory experience ▪ Means available to staff for handling and channelling regulatory experience findings	This section is intended to foster and encourage staff of the regulatory body and associated organizations to actively use the regulatory experience management programme and to acknowledge the contribution of individuals in enhancing the regulatory process
Section 8: Continuous improvement of the arrangements for managing regulatory experience	
▪ Self-reflection/Self-assessment ▪ Benchmarking and peer reviews	This section discusses the process for reviewing the effectiveness and efficiency of the existing arrangements and to enhance them as necessary
Section 9: International forums for reporting on lessons learned from regulatory experience	
▪ Existing international forums for reporting operating experience and how they relate to reporting regulatory experience. ▪ Advantages and disadvantages of existing international systems to share regulatory experience	This section illustrates how to use existing incident reporting systems to share regulatory experience.

APPENDIX VI. SHARING AND DISSEMINATING LESSONS LEARNED

VI.1. PURPOSE

The purpose of this Appendix is to provide information that could be used to effectively share and disseminate lessons learned from regulatory experience.

VI.2. SHARING AND DISSEMINATION EFFORTS

Consistent with the purpose of Requirement 15 of the GSR Part 1 (Rev. 1) [2], the action plan proposed by the management and approved by the decision makers of the regulatory body to address regulatory experience findings could also include specific instructions for sharing and disseminating the lessons learned from the analysis of such a finding. The owner of the action plan could develop a sharing and dissemination plan accordingly.

In preparing such plan, the owner of the action plan would decide about the best approach to reach target recipients and organizations taking into consideration factors such as:

— Purpose:

- Lessons learned are disseminated for information only; or
- Follow-up actions and/or feedback from recipients are requested (either within the regulatory body or by authorized parties).

— Target recipients, such as:

- Staff of the regulatory body;
- License holders;
- Other national authorities;
- Regulatory bodies of countries with bilateral relationships or potentially interested in the regulatory experience;
- International organizations and forums for further dissemination of the lessons learned;
- Academy and research organizations;
- TSOs;
- General public.

— Means to share lessons learned:

- Dedicated meetings, workshops or seminars organized to address the target institutions and organizations;
- Through established interfaces, such as:
    - International event reporting systems;

        - National reports to international conventions;
        - Reporting channels foreseen in bilateral/multilateral agreements;
        - International or regional cooperation associations, networks and forums.
    - Taking advantage of relevant events where reporting can contribute to reach target audiences:
        - National/international meetings, conferences, workshops or seminars;
        - International benchmarking and other co-operation exercises.

— Means and channels to disseminate lessons learned:

- Within the organization, for instance through:
    - Internal notices or announcements;
    - Staff bulletins;
    - Newsletters.
- Outside the organization, for instance through:
    - Regulatory information notices;
    - Annual report and/or other official publications of the organization;
    - Web site of the regulatory body;
    - Articles or reports in specialized magazines, web sites or media.

— Monitoring mechanisms in place to:

- Ensure that the addressees timely implement follow-up actions and provide feedback;
- Evaluate effectiveness of the sharing and dissemination efforts;
- Identify additional follow-up actions when needed (e.g. when there is an insufficient or late response from the recipient or when the feedback received is not enough to evaluate the effective implementation of lessons learned).

The owner of the action plan could retain his responsibility for the overall monitoring and supervising the effective sharing and dissemination of the lessons learned from regulatory experience findings regardless of the involvement of other staff of the regulatory body tasked to accomplish specific information and/or communication tasks. He or she could keep management timely informed about the results of the sharing and dissemination efforts.

VI.3. INTERNATIONAL FORUMS TO SHARE REGULATORY EXPERIENCE

There are several international systems in use for analysing operating experience of nuclear installations, such as the International Reporting System for Operating Experience (IRS), the IAEA Incident Reporting Systems for Research Reactor (IRSRR) or the Fuel Incident Notification and Analysis System (FINAS). These systems are primarily focused on the assessment of events with safety significance in nuclear facilities.

The use of the term event in the context of the reporting system is quite broad and covers events, issues, and operating experience information, such as good practices, lessons learned or other findings. Therefore, in principle these systems could provide also an adequate space to share regulatory experience findings. For instance, reporting category 8 of the IRS include: "New perspectives, industry initiatives, and lessons learned information gained from the results of analysis, research, or benchmarking/review of events and issues in other industries" [19]. Likewise, category (f) of the IRSRR covers events of potential safety significance and reporting [20] and category 6 of FINAS covers events of potential safety significance [21]. In spite of it, in practice, regulatory experience on issues not directly connected to operational occurrences are seldom reported through these systems.

Possible reasons for the limited reporting of this regulatory experience could be:

— Regulators may not be willing to report and discuss about possible weakness of their regulatory processes in an open forum;

— Limited interest to discuss issues that could be perceived by the members as of low safety significance for the reporting system;

— Difficulties to report non-event related regulatory experience issues using the existing reporting forms that are oriented to report events;

— Limitations of the use of traditional analysis techniques for the assessment of non-event related regulatory experience issues.

There are other international forums that could also be used for sharing lessons learned from regulatory experience. For instance, the annual meeting of the senior regulators during the IAEA's General Conference in September every year, the plenary meetings of the Global Nuclear Safety and Security Network or during the meetings of the various regulatory associations and forums (e.g. WENRA, ENSREG, the Ibero-American Forum of Nuclear and Radiological Regulatory Agencies, CANDU Forum, etc.). Specific international conferences organized periodically to exchange information and knowledge could also serve as a platform to share and further disseminate lessons learned from regulatory experience, like the International Conference on Effective Regulatory System.

All these international forums could be used to enhance the current level of sharing of regulatory experience and even to make reporting more systematic and frequent; however, trying to reach the level of systematization and maturity of event-related operating reporting systems would be very challenging for the international community. First, the international community of regulators would need to be convinced of the benefits from increasing and enhancing the current level of reporting of lessons learned from regulatory experience in order

to justify the commitment to additional reporting duties and the deployment of resources to sustain new or enhanced reporting systems. Second, there need to be consensus on the definition of the term regulatory experience and regulatory experience findings, as well as on the categories for reporting these findings.

Enhancing the existing international reporting systems of operating experience for nuclear installations instead of creating new reporting systems could be a reasonably step forward towards enhancing and systematizing the reporting of regulatory experience. For instance, creating suitable reporting forms to make easier the reporting and assessment of regulatory experience and establishing appropriate mechanisms to assess and discuss regulatory experience in closed meetings are some ideas that could be considered to foster the sharing of regulatory experience in international reporting systems. It is up to the membership of the reporting systems to decide about the advantages and disadvantages of it.

The situation for sharing and disseminating lessons learned from regulatory experience in relation to activities involving radioactive sources only is even more challenging. Currently the only global-scale forum in which operating experience of facilities and activities is systematically assessed are the working groups associated to the International Nuclear Event Scale (INES) administered by the IAEA [22]. However, the INES aims at the classification of operational occurrences, including potential events[8], through the assessment of the potential and actual consequences of the events for the public. It is, therefore, unlikely that issues related to non-event related regulatory experience issues are reported at an international scale, for instance for INES assessment.

[8] Potential events are situations that increase likelihood of a postulated event

APPENDIX VII. QUESTION SET FOR SELF-REFLECTING

VII.1. PURPOSE

Bearing in mind that the guidance available in IAEA safety standards in relation to the effective management of regulatory experience, at this stage it is not practicable to design a question set for performing a normative self-assessment of compliance with requirement 15 of GSR Part 1 (Rev. 1).

Nevertheless, this appendix put forward a question set that can be used by a regulatory body to self-reflect on the arrangements in place for identifying, collecting, analysing, sharing and disseminating lessons learned from regulatory experience.

Requirement 15 of the GSR Part 1 (Rev. 1) involves two concepts: operating experience and regulatory experience. As discussed in Section 2.2, these concepts are closely related and share the same objective, but at the same time with distinct features. The scope of this question set only covers the assessment of the arrangements for identifying and disseminating regulatory experience.

The question set in this annex is based on the questionnaire that the IAEA sent to a representative number of regulatory bodies in June 2017 (see Annex I). The questions of the original questionnaire have been reworded for clarity and the question set has been expanded to cover subjects that were not considered formerly.

VII.2. QUESTION SET

Q1: Does the organization have a definition of the term regulatory experience in any official document of the regulatory framework, such as in regulations, regulatory guidance, policy statement or internal procedures?

Q2: Do the management at all levels and the staff of the organization share a common understanding of the term regulatory experience?

Q3: Does the mission or any policy statement of the organization acknowledge the need to identify lessons to be learned from regulatory experience, for instance by encouraging staff to proactively collect regulatory experience?

Q4: Has the organization made available to staff guidance and establish expectations for individual and organizational units in relation to the collection of regulatory experience?

Q5: Does the organization have arrangements in place to promote a questioning attitude, for instance through encouraging staff to raise concerns about the effectiveness of the regulatory process?

Q6: Does the organization have arrangements to encourage a blame free organizational environment and to ensure that staff who raise concerns about the effectiveness of the regulatory process is protected against any form of retaliation?

Q7: Has the organization identified the most relevant sources of information for identifying lessons to be learned from regulatory experience and has directed staff to proactively identify lessons to be learned from these sources?

Q8: Has the organization made available to staff criteria and/or thresholds against which to screen issues of potential interest for identifying lessons to be learned from regulatory experience?

Q9: Does the organization have any approaches, practices, methods, or tools specifically intended to conduct the collection, analysis and sharing of regulatory experience from regulating facilities and activities?

Q10: If the answer to question 9 is no, does the organization use other arrangements to ensure that issues of potential interest for identifying lessons to be learned from regulatory experience are collected, analysed and shared?

Q11: Do the staff of the organization routinely identify issues of potential interest for identifying lessons learned from regulatory experience?

Q12: Does the organization have arrangements in place to ensure that relevant issues of potential interest for identifying lessons learned from regulatory experience are timely and comprehensively analysed and to act upon the lessons learned?

Q13: Does the training programme for the staff of the organization discuss the identification of lessons to be learned from regulatory experience and provide guidance on the arrangements of the organization to conduct the collection, analysis and sharing of it?

Q14: Does the organization routinely discuss the benefits obtained from the identification of regulatory experience and the impact of forward actions taken towards enhancing the regulatory process within the organization, with the license holders and with other stakeholders?

Q15: Does the organization routinely share lessons learned from regulatory experience?

Q16: Has the organization selected suitable mechanisms to share and disseminate lessons learned from regulatory experience internally and externally or is the decision taken on a case-by-case basis?

Q17: Does the organization periodically discusses the arrangements in place for identifying lessons to be learned from regulatory experience with advisory bodies, technical support organizations or other national authorities?

Q18: Are there appropriate arrangements to ensure that information relative to issues of potential interest for identifying lessons to be learned from regulatory experience is timely received from or shared with advisory bodies, technical support organizations or other national authorities?

Q19: Are there appropriate arrangements to ensure that information from safety research programmes conducted, supported or followed by the regulatory body are timely analysed for identifying lessons to be learned from regulatory experience?

Q20: Does the regulatory body periodically analyse available information about safety projects that may raise relevant information for identifying lessons to be learned from regulatory experience?

APPENDIX VIII. REGULATORY EXPERIENCE FROM NON-NUCLEAR DOMAIN

VIII.1. INTRODUCTION

Efforts to achieve better regulation exist in all domains where modern government tries to reduce the cost and assure benefits. Regulatory experience from all different domains has potential universally-applicable value related to all parts of regulation (policy, legislation, enforcement, inspections and experience feedback practice). Applicability and usefulness of regulatory experience from other domains to nuclear industry increases when major regulatory issues are safety or risk for people and environment. This is the case for sectors like transportation, process and food industry.

This appendix briefly explores potential sources of regulatory experience from non-nuclear industry which could be useful to nuclear regulation and ways to use it. Beneficial regulatory experience exchange between different sectors seems to be at the same time highly promising and challenging.

The next Section describes three important sources of regulatory experience knowledge from different domains: 1) research; 2) international organizations; and 3) other hazardous industries.

The final Section concludes with remarks about potential opportunities and challenges to realize benefit from regulatory experience of non nuclear domains.

VIII.2. SOURCES OF REGULATORY EXPERIENCE OUTSIDE THE NUCLEAR INDUSTRY

VIII.2.1. Research on regulation

Research about regulation policy, implementation, inspection and about the regulatory process itself can be found in all industry domains. Some of the lessons learned from that research could also be applicable and beneficial for the nuclear industry. Some specific examples of general research on effectiveness and efficiency of regulation that could also be of interest to nuclear regulation are:

— Methods for assessing cost and benefits of regulation. These studies are used by many developed governments and sometimes are also applied in the nuclear industry. The outcome of these studies can be useful for deciding when to introduce explicit regulatory requirements or choosing alternative approaches. Reference [23] in one example of these studies.

— Identifying and explaining best practice regulation features can help improve regulation to follow systematic approaches. It is always challenging to measure efficiency and effectiveness of regulation and to interconnect the impact of co-existing regulatory features, e.g.: communication, consultation, consistency, flexibility, independence, accountability and transparency. Reference [24] presents a general approach that can also be applied to nuclear regulation.

— Comparison of regulatory framework designs can also contribute to regulatory decision making. Reference [25] presents a piece of research illustrating a reality with abundant mixed regulation design types. The publication emphasizes the final objective of effective regulation, which is the ability to enforce compliance in an effective an efficiency manner, as well as the importance of efficiency gains base on cooperation with the subjects of regulation.

Actually, there is wide room for exploring the added value from systematic empirical research of existing regulatory frameworks in different domains. The above-mentioned reference [25], which is a joint report of the U.S. national academies of Sciences, Engineering and Medicine about designing safety regulations for high-hazard industries, also concludes that there is a lack of systematic empirical research exploring the applicability and effectiveness of various regulatory regimes regulating different domains with certain commonalities and under different conditions.

VIII.2.2. International organizations as a forum for regulatory experience exchange

International organizations are facilitating various ways of regulatory experience exchanges. Here are provided several examples of regulatory experience feedback exchanges facilitated by OECD and the European Commission (EC):

— The EC promotes cross sectoral regulatory experience feedback exchange by bringing different sectors together. One example of it is an EC workshop attended by regulatory experts from shipping, aviation and nuclear industry [26]. These exchanges allow better understanding of similarities and potentials to exchange applicable best regulatory practices from different hazardous industries.

— OECD provides regulatory experience feedback for various regulatory aspects in different domains by preparing reports and facilitating exchange:

  - The Council on Regulatory Policy and Governance issued a report [27] with 12 recommendations addressing performance and tools for effective and efficient regulatory policy, management and governance to achieve social and environmental goals;

  - The report Regulatory Enforcement and Inspections [28] provides guidance on improving regulatory enforcement and inspections and provides some examples of good practices. Eleven universal principles are identified: evidence-based enforcement, selectivity, risk focus and proportionality, responsiveness, long-term vision, transparency, information integration, fairness, compliance promotion, and professionalism.

  - The OECD has developed indicators of regulatory policy and governance in order to cover three principles: stakeholder engagement, regulatory impact assessment and ex-post evaluation and provided a baseline measurement to track status and progress. The evaluation of these indicators for 2015 and 2018 can be found in reference [29].

International organizations have significant potential to collect and exchange regulatory experience from different domains.

VIII.2.3. Regulatory experience from other hazardous industries

Nuclear industry is already using operating experience feedback from other hazardous industries exchanging lessons learned related to technical and human aspects. It is therefore logical to extend this exchange to regulatory experience feedback.

Two examples are mentioned here as illustration of potential sources:

— Like nuclear industry, other hazardous industries are also learning greatly from major accidents. Findings from these investigations could be included within the scope of the nuclear regulatory experience feedback. In reference [30] the role of the regulator was assessed for offshore safety in the wake of the Macondo disaster.

— Specific novel activities from other hazardous industries could be considered as something applicable to nuclear industry either to be adopted or as a source for lessons learned. In reference [31] process industry regulators from different countries organized a mutual joint visit programme on inspections in order to exchange lessons learned and best practice.

Lessons learned from regulatory experience feedback of other hazardous industries are potentially applicable to nuclear industry and, as such, could be periodically reviewed.

VIII.3. CHALLENGES AND OPPORTUNITIES

As presented above it is clear that there is huge potential for additional regulatory experience feedback from outside nuclear industry. Existing activities and available information could help nuclear regulation at all levels from policy, through enforcement, inspection and all other operational aspects.

There are many challenges to fully utilize all these potential opportunities related to applicability of findings, uncertainties of results, and need for additional resources.

International organizations like the IAEA and the NEA could consider establishing arrangements to periodically scrutinize regulatory experience feedback made available by appropriate international organizations of non-nuclear industries (e.g. aviation, chemical industry and others) to benefit from that experience and, when relevant, disseminate lessons learned across the nuclear industry.

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ANNEX I. QUESTIONAIRE ON METHODS AND PROCESSES FOR COLLECTING, ANALYSING AND SHARING REGULATORY EXPERIENCE

I-1. INTRODUCTION

In June 2017, the IAEA sent a questionnaire to a wide number of regulatory bodies to receive feedback on existing practices for collecting, analysing, implementing and sharing regulatory experience.

The questionnaire was sent to 43 regulatory bodies of different sizes and characteristics to draw well-informed conclusions about the current situation. A total of 27 regulatory bodies provided written responses to the questionnaire[9]. The good percentage of responses (62% out of those approaches) gives good evidence of the interest raised by the questionnaire.

I-2. TAXONOMY OF RESPONDERS TO THE QUESTIONNAIRE

Among the 27 regulatory bodies that provided responses to the questionnaire, there are:

— 19 countries with nuclear power plants in operation.

— 1 country in the later stages of commissioning a nuclear power plant

— 4 countries have other types of nuclear installations or nuclear power plants in decommissioning.

— 3 countries do not have nuclear installations, only activities.

The majority of the responders to the questionnaire operate different types of nuclear installations. Therefor the conclusions arising from the analysis of the responses could be biased towards countries with larger and medium size regulatory bodies.

Annex II of this publication summarizes the conclusions of a connected workshop organized under a project of the IAEA´s Technical Cooperation Programme involving countries of Europe region, the majority of which do not have nuclear installations. The participants in the workshop were requested to reply to a questionnaire with questions similar to the ones sent out by the IAEA in June 2017. In spite of the different taxonomy of the participants in the workshop, the overall conclusions achieved in the workshop confirmed, in essence, the conclusions drawn from the assessment of the responses to the questionnaire discussed in this Annex.

[9] The regulatory bodies of the following countries provided written responses to the questionnaire: Argentina, Armenia, Bulgaria, Canada, Chile, China, Cuba, Czech Republic, Finland, France, Georgia, Germany, Hungary, India, Ireland, Japan, Kazakhstan, Lithuania, Pakistan, Russian Federation, Slovak Republic, Spain, United Arab Emirates, United States, United Kingdom, and Zimbabwe. The regulatory body of Slovenia reported to the IAEA in a meeting to that end.

I-3. ANALYSIS OF THE RESPONSES

The questionnaire was prepared by the participants in the first meeting of consultants to elaborate an IAEA publication on methods and process for collecting, analysing, implementing and sharing regulatory experience[10].

The following ad-hoc definition of the term was proposed for responding to the questionnaire:

Regulatory experience is knowledge and skills gained from regulating safety of facilities and activities as feedback resulting from the implementation of regulatory functions and their processes.

The analysis of the responses given to the 10 questions of the questionnaire are summarized below.

Question 1. Is your organization's understanding and use of the term regulatory experience consistent with the proposed definition (i.e. regulatory experience is knowledge and skills gained from regulating safety of facilities and activities as feedback resulting from the implementation of regulatory functions and their processes)? Please, explain your response.

All the responders stated that there is not an official definition of the term regulatory experience in their regulatory framework. Some underlined that the underlying objective of term regulatory experience is implicitly covered by some of the processes of their management system, namely the quality and knowledge management processes.

A good number of responders are of the opinion that the proposed fits well with their understanding of the meaning of the term; however, several responders would like to extend the definition as follows:

— Underline the importance of operating experience,

— Include nuclear security and safeguards in the scope of the term,

— Underline the importance of nuclear research.

Question 2. Please, explain your organization's policies and practices that foster the use of regulatory experience for the continuous improvement of the regulatory process. Does your organization have documented processes to manage regulatory experience in its management system?

The majority of the responders stated that they do not have policies or practices specifically focused on collecting and analysing regulatory experience for the purpose indicated in the definition. On the other hand, many responders reported on existing processes that contribute

[10] The meeting took place 8 to 12 May 2017 in the IAEA´s Headquarters. The contributors for the preparation of the questionnaire were: H. Khouaja (Canada), Z. Pastory (Hungary), J. Robles-Alcaraz (USA), D. Senior (UK), Z. Simic (EC/JRC), O. Veyret (France), N. Vlahov (Bulgaria) and T. Bilic, A. Nicic, M. Recio and I. Shadad from the IAEA Secretariat.

to identify regulatory experience and benefit from lessons learned to enhance their national regulatory process.

Very few responders reported on specific processes of their management systems specifically focused on managing regulatory experience (one of them under development) and one responder provided an example of a process with similar objective but with a very high threshold to trigger it, which prevents the consideration of findings with lower safety significance.

Question 3. Which are the sources of regulatory experience that your organization systematically captures from the implementation of regulatory activities and processes (e.g. inspections, review and assessment, licensing, emergency preparedness and response oversight or exercises…)?

The majority of the Regulatory Bodies scrutinize a wide range of internal and external sources of information in search of information and experience using different processes and approaches. However, the majority do not have in place an integrated process for managing regulatory experience obtained from the many internal and external sources of information.

The responders mention many examples of sources of information for internally generated regulatory experiences (see Annex 3 of this publication for more information)

— Regulatory inspection reports;

— Licensing of new technologies;

— Assessment of operating experience feedback;

— Audits, evaluations and self-assessments;

— Emergency drills;

— Monitoring regulatory processes through performance indicators;

— Research projects initiated by the regulatory body;

— Assessments carried out by Technical Support Organizations on behalf of the regulatory body;

— Feedback from interested parties and the public during the elaboration of new regulations or guidance;

— Analysis of reports submitted by the licensees in response to conditions of the licenses;

— Feedback from licensees (e.g. feedback obtained from standing or ad-hoc committees or resulting from licensing processes);

— Feedback from staff (either individuals or staff panels/committees).

Likewise, the responders provided many examples of sources of externally-generated regulatory experience that is considered for the purpose of maintaining effective and efficient regulatory process:

— Standards, technical and policy documents produced by international organizations relevant for the regulatory process and participation in the elaboration of them;

— Standards from the nuclear industry and from other relevant industries;

— International reporting systems of operating experience;

— Lessons learned from the operating experience of other relevant industries (e.g. aviation, chemical and petrochemical, mining, other energy generation industries…)

— National Committees involving regulatory bodies of industries with characteristics similar to nuclear energy;

— National and international research and technical cooperation projects;

— Participation in international conventions and codes of conduct, including review and technical meetings and national reports;

— External peer reviews and advisory missions;

— Benchmarking with other national or international regulatory bodies:

— Bilateral and multilateral cooperation with other regulatory bodies;

— International associations and forums of regulators; and

— Committees, subcommittees and working groups of international organizations.

Question 4. Which processes or tools in your organization are available to collect and document regulatory experience? What criteria does your organization use to screen and review it?

The majority of responders do not have single process for collecting and documenting regulatory experience, they collect regulatory experience through individual processes focused on specific regulatory functions, like the inspection process, the assessment of operational feedback or the evaluation of periodic reports produced by the licensees in response to conditions of the licenses.

One responder reporting on a guideline meant to integrate findings major regulatory processes and take appropriate action and another on a process meant to evaluate and improve performance.

Question 5. How does your organization ensure that positive and negative feedback, including staff feedback, gained from the implementation of different regulatory activities and processes is integrated and analysed throughout all levels and across all the disciplines in the organization?

Very few responders reported on processes specifically designed to integrate regulatory experience gained by the regulatory bodies from different internal and external sources of information.

Some reported about groups of specialists regularly monitoring and analysing feedback from on-going regulatory activities and incorporate findings into the planned regulatory activities. Others have in place a global regulatory oversight process that collect and integrate findings, primarily of operating experience and inspection, to decide on corrective and follow up actions, including possible enhancements of the regulatory process.

Other responders stated that integration is achieved as part of the comprehensive consultation process undertaken before issuing new regulations and guidance. Normally a committee or an organizational unit drives regulatory process priorities and ensures that it continues to benefit from lessons learned and strives for continuous improvement of the regulatory process.

Several responders also reported on electronic databases and IT based data collection systems to capture regulatory experience gained from the implementation of regulatory functions and processes. These databases and systems are accessible to all staff and use a range of criteria to prioritise and determine the nature of associated actions and oversight required. A few also mentioned the establishment of communities of practice to capture knowledge and experience and to share best practices and lessons learned.

A few responders reported on specific processes that allow individual staff members provide feedback about the regulatory process or to report on potential regulatory experience findings. Some gather feedback from staff through periodic surveys and internal audits. Others have enabled feedback mechanisms in the webpages of their internal webs (intranets) to give staff the opportunity to submit comments with respect to the content of the page or to propose improvements to policy and processes featured in those pages.

Several responders underlined existing efforts towards improving regulatory safety oversight culture by providing an environment where staff feel free to raise issues or concerns without fear of reprisal.

Question 6. How does your organization use this feedback to maintain and improve the effectiveness of the regulatory process? Please describe how your organization uses this information to improve the effectiveness of the regulatory process (e.g. corrective action, lessons learned, action plans…)

The majority of the responders have in place several programmes of corrective actions, lessons learned, and actions plans which are used to benefit from regulatory experience and drive action towards maintaining and effective and efficient regulatory process.

Furthermore, many responders also highlighted that core processes for development of regulations instruct those involved in the process to consider feedback from different sources when determining he need for a new or amended regulation.

Question 7. What are the barriers that your organization has experienced to effectively manage and implement lessons learned from regulatory experience?

The responders identified a wide array of challenges and barriers to fully benefit from regulatory experience. For the sake of simplicity, they have been categorized in five groups as follows:

— Related to the architecture of the process:

  - Lack of a systematic and structured process for receiving feedback from the regulatory experience and its review and analysis;
  - Challenges to capture and implement lessons learned to formalizing good practices; and
  - Setting too high thresholds to review or take action for each regulatory process or function.

— Related to staff:

  - Lack of experienced staff to lead the process;
  - Rapid turnover of staff and continued changes in the demographics, experience, and knowledge of the workforce;
  - Resistance to change;
  - Insufficient time available to report about regulatory experience;
  - Unawareness of the concept of regulatory experience due to lack of guidance; and
  - Limited involvement of staff in the management of regulatory experience and restraint to raise regulatory experience findings due to:
    - Lack of motivation
    - Fear of retaliation
    - Fear of blaming others
    - Excessive bureaucracy and burden

— Related to management:

  - Lack of commitment and leadership;
  - Taking immediate decisions instead of making effort to manage and implement lessons learned from experience;
  - Acknowledge and accept that the issuance of a letter/decision/regulation does not close the matter and future findings may require additional actions;
  - Put more efforts to analysis the root cause of non-satisfactory implementation of a regulation or decision;
  - Changes in management leading to the adoption of different priorities;

— Related to the organization:

  - Lack of resources;
  - Competing interests and priorities of different stakeholders;
  - Size and breadth of the regulatory body, which makes challenging the implementation of corrective actions consistently across the organization as well as the dissemination of lessons learned; and
  - Challenges associated to the effective transfer of knowledge and experience between organizational units in organization using a matrix structure

— Related to information technology solutions:

  - Lack of appropriate IT solutions to capture, track, analyse and use regulatory experience feedback and an associated management platform;

Question 8. What information from other regulatory bodies and international organizations does your organization use to improve the regulatory process? How does your organization receive/obtain and use this information? Please describe any specific arrangements for managing the information provided by other regulatory bodies and international organizations.

The responses to this question show a very active involvement in multiple international activities that are considered sources of regulatory experience, such as:

— Committees and activities arranged by international organizations (e.g. the International Atomic Energy Agency (IAEA), the Nuclear Energy Agency (NEA) of the OCDE, the International Commission on Radiation Protection (ICRP), the World Health Organization (WHO), committees and activities of the European Union institutions under the EURATOM treaty, the European Technical Safety Organisations Network (ETSON), the Heads of the European Radiological Protection Competent Authorities (HERCA), the European Association of Competent Authorities (EACA)…);

— Technical exchanges and standards and guides of associations of the industry (e.g., Institute of Electrical and Electronics Engineers (IEEE), the American Society of Mechanical Engineers (ASME), the World Association of Nuclear Operators (WANO), the Institute of Nuclear Power Operations (INPO), the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC)…);

— Forums of regulators (e.g. the International Nuclear Regulatory Associations (INRA), the Western European Nuclear Regulators' Association (WENRA), the European Nuclear Safety Regulators Group (ENSREG), Ibero-American Forum of Radiological and Nuclear Regulators (FORO), CANDU Senior Regulators´ Group, VVER Regulators Forum, SMRs Regulators Forum…);

— International conventions review meetings and national reports;

— Meetings to discuss experience with the Codes of Conduct;

— IAEA Safety Standards Committees and Commission meetings;

— Operating experience reporting and review systems and international reports on lessons learnt from accidents;

— International peer review and advisory missions;

— Bilateral and multilateral agreements;

— Benchmarking exercises with peer regulatory bodies;

— International research and cooperation projects, particularly those aiming at transferring experience in regulating nuclear activities;

— Webpages of international organizations and other regulatory bodies;

— Technical meetings, seminars and conferences;

— Lessons learned from other industries;

— European Association of Competent Authorities for the Safe Transport of Radioactive Material where there is an open an honest sharing of information and experience, regulator to regulator; and

— Fellowship programmes.

Some responders reported on mechanisms established to screen, analyse and share external regulatory experience for the purpose of enhancing the regulatory process; however, the majority follows ad-hoc approaches. A few regulatory bodies have established practices for staff to share the knowledge gained from the participation in international activities. The majority channels the experience learned within their organization units and through their line managers.

Question 9. Please describe formal, as well as informal means, by which your organization receives external feedback from interested parties for improving the regulatory process? How does your organization receive/obtain and use this information? Please, describe any specific arrangements for managing this information?

The responders identified a large number of mechanisms to receive feedback from interested parties about their regulatory process:

— Official interaction with licensees (e.g. as part of authorization processes, including authorization of changes and license renewal) and daily regulatory activity;

— Regular meetings and consultations to share experience with licensees;

— Official consultations with interested parties and public hearings before issuing regulations and guides;

— Solicitation of public comments and surveys;

— Recommendations from advisory committees and TSOs;

— Meetings with non-governmental organizations and professional associations;

— Reporting to congressional committees and liaison with government offices;

— Statutory public information committees;

— Feedback from interested parties during and after emergency response exercises;

— Hot lines open to regulated and interested parties and the general public to report on safety issues.

The majority of the responders assign staff to assess the feedback and propose a response or course of action, in particular to address possible non-conformances and enhance the regulatory process.

Some responders underlined that the provision of feedback to all consultations from the public in relation to its regulatory and legal competences is a statutory obligation.

Question 10. How does your organization decide which regulatory experience to share externally with interested parties and with other regulatory bodies and international organizations? Please, describe any specific criteria and process to do this. Which type of information relating to regulatory experience is regularly posted in your web site? Is this information regularly made available in English?

The majority of the responders regularly share regulatory experience through their institutional web sites or through official documents such as annual reports, national reports to international conventions, reports shared through international event reporting systems, as well in technical meetings and conferences.

A few responders conduct an annual general meeting at which feedback on regulatory performance is provided to interested parties is provided as a statuary obligation.

Many responders have bilateral and multilateral agreements with other regulatory bodies and periodically arrange meetings to exchange regulatory experience.

A few responders periodically share regulatory experience connected to the competence of other government organizations through interoffice letters and/or in meetings organized to that end.

A few responders have in use comprehensive electronic reading rooms to make publicly available most of the official documents handled by the regulatory bodies.

Decisions on sharing regulatory experience externally are mostly done on a case-by-case basis. Information sharing is decided based on expert judgement and commensurate with the arrangement, mechanism, and /or the venue in question, but normally no specific criteria have been established.

I-4. GENERAL CONCLUSIONS

— The term regulatory experience does not have an official definition in the national regulatory framework of the countries that replied to the questionnaire. However, there is

a general understanding that the term is basically consistent with the definition provided in the feedback request.

— Very few regulatory bodies have policies in place specifically addressing the management of regulatory experience. On the other hand, many reported on existing processes and/or practices of their management system that address, to varying extents and degrees, the management of regulatory experience.

— Most regulatory bodies routinely explore a wide range of internal and external sources in search of information and experience through different processes and following different approaches. However, very few have integrated arrangements for managing regulatory experience.

— Few regulatory bodies have incorporated or are in the process of incorporating the management of the regulatory experience into their management systems as a stand-alone core or support process.

— Incorporating the management of regulatory experience as a dedicated programme into an Integrated Management System is perceived as beneficial by some regulatory bodies to emphasize the importance of managing the interfaces among regulatory functions and activities.

— All regulatory bodies share regulatory experience routinely through local means and using international platforms. However, most of the time they do it on a case by case basis. Very few have a systematic approach to decide about the dissemination of regulatory experience.

ANNEX II. CONCLUSIONS OF AN IAEA REGIONAL WORKSHOP ON MANAGING REGULATORY EXPERIENCE

II-1. BACKGROUND

From 21 to 25 August 2017, the IAEA organized a workshop in Ljubljana, Slovenia, to discuss possible approaches to establish effective and efficient methods and processes for managing the regulatory experience gained from the regulation of facilities and activities, as well as from other national and international external sources of experience.

This workshop was one of the activities of the IAEA´s Technical Cooperation (TC) project RER/2/013 "Enhancing Energy Planning, Nuclear Power Infrastructure Development and Nuclear Safety Regulatory Oversight" and was specifically designed to complement the on-going IAEA´s efforts to elaborate a publication on process and methods for collecting, analysing, implementing and sharing regulatory experience.

14 staff members of European regulatory bodies and technical support organizations (TSO) of 13 countries of the IAEA's TC Europe region, 2 international experts and 2 IAEA staff members participated in the workshop.

Before the workshop the IAEA sent to the participants a questionnaire to collect opinion and recommendation on how to provide better assistance to Member States to enhance the management of regulatory experience. The responses to the questionnaire were presented by the participants at the beginning of the workshop and served as background information for further discussion.

Four working groups were arranged to discuss in detail and provided recommendations to the IAEA in relation to:

— Methods for identifying, collecting and storing regulatory experience findings;

— Methods for screening and assessing regulatory experience findings;

— Acceptance, implementation and follow up of action plans and decision-making in relation to sharing regulatory experience;

— Enablers/barriers and crosscutting elements to ensure effective management of regulatory findings.

II-2. RESPONSES TO THE QUESTIONNAIRE

Table II.1 shows the questions and the responses provided by the participants to the questionnaire sent by the IAEA before the workshop.

QUESTIONNAIRE ON RECOMMENDED APPROACHES TO THE IAEA IN RELATION TO REGULATORY EXPERIENCE MANAGEMENT	YES	NO	NOT SURE
Should the IAEA develop a new safety standard to address management of regulatory experience?	9	2	1
Should the scope of existing IAEA safety standards on operating experience feedback be widening to cover regulatory experience management?	7	2	3
Should the current scope of the International Reporting System (IRS) for operating experience feedback be broaden to facilitate/foster reporting of regulatory experience?	2	1	9
Should the IAEA develop technical guidance on processes to collect, analyse and share regulatory experience?	10	1	1
Should the IAEA provide theoretical training on processes to collect, analyse and share regulatory experience?	11	1	0
Should the IAEA provide hands-on training on processes to collect, analyse and share regulatory experience?	10	1	1
Should the IAEA create and administer a specific collaborative space (e.g. in RegNet) to facilitate sharing regulatory experience?	8	0	4
Should the IAEA organize periodically events to discuss and share regulatory experience?	10	0	2
Should the IAEA organize safety review missions specifically focused on regulatory experience management?	6	3	3
Should the IAEA strengthen the review of regulatory experience management at IRRS missions?	9	0	3

Table II.1 Responses to the questionnaire on recommended approaches in relation to regulatory experience management

The responses to the questionnaire were discussed by the workshop participants with the following conclusions:

— The majority of the participants stated that there is a clear difference between regulatory experience and operating experience and between the processes to manage one or the other.

— The majority of the participants were in favour of developing a new IAEA Safety Standard on regulatory experience management. A second option could be reviewing one existing IAEA Safety Standard on regulatory management processes to provide specific recommendations and guidance on regulatory experience management.

— The majority of the participants considered that broadening the scope of the IAEA-NEA International Reporting System (IRS) is not the best approach to foster regulatory experience sharing.

— The majority of the participants strongly supported IAEA capacity building on regulatory experience management as well as periodically organizing meetings to share best practices.

— The participants did not consider a priority to develop a new IAEA safety review service on the matter of regulatory experience. The preferred approach was to enhance SARIS self-assessment questionnaire and strengthen the review of regulatory experience practice during the IRRS missions.

— The majority of the participants supported the operation of a collaborative space in RegNet but recommended postponing action until there is a clear understanding and support by the international community and IAEA has developed specific guidance.

II-3. WORKSHOP CONCLUSIONS

— The workshop acknowledged that, while there are IAEA safety requirements addressing regulatory experience (e.g., Requirement 15 of the GSR Part 1 (Rev. 1)), there is not specific guidance in the IAEA Safety Standards regarding the management of regulatory experience. Until specific IAEA guidance is available, the workshop supports the preparation of an IAEA's publication (e.g. a TECDOC series publication) to collect feedback on existing practice and propose approaches to enhance it.

— The workshop also underlined that the publication should provide a range of methodologies and practices to be used by the regulatory bodies at their own discretion. This approach would be better than proposing an overly complex and elaborated methodology that many regulatory bodies will not have the resources and capabilities to implement it.

— The workshop acknowledged that the differences in size and complexity of the national nuclear programmes – in particular, the types of facilities and activities in the country – condition the optimum approach to establish an effective and efficient regulatory experience management system.

— The workshop underlined that the simple issuance of a publication will not be enough drive to promote the sharing of regulatory experience outside the regulatory body, including internationally. To progress in this objective, the importance and benefits of sharing regulatory experience have to be recognized and taken as a priority by the leadership of the regulatory bodies and agreed at international level (e.g. during the review meetings of the Convention on Nuclear Safety and other high- profile international conferences).

— The workshop agreed with the definition of regulatory experience but recommended to also include the term ‘attitudes’ in the definition and to define the meaning of the term ‘regulatory process’ for the sake of clarity.

II-4. WORKSHOP RECOMMENDATIONS

General

1. The regulatory experience management process of a regulatory body has to fit well the features of the regulatory process and the context of the specific country. The publication should offer an array of possible solutions to build a suitable management process on the basis of the specific situation of the country. For instance, for some new and less developed regulatory bodies the priority is completing the legal aspects of the regulatory process (i.e. laws and regulations). These regulatory bodies can gain regulatory experience primarily from international standards and guidance and from the cooperation provided by other regulatory bodies.
2. The publication should be mindful about the level of resources in smaller regulatory bodies to put in place complex regulatory experience management processes.
3. The publication should include clear explanation of the meaning of the terms used to facilitate good understanding and ensure consistent use of the practices described in it.

Identifying, collecting and storing regulatory experience

4. The regulatory experience management process should consider interfaces between the regulatory body and other players with a role in establishing and maintaining the regulatory process (e.g. different authorities, TSOs, political institutions…)
5. The process has to provide room for involving and receiving feedback to improve the regulatory process from the licensees and other interested parties. Depending on the specific regulatory approach of the country, TSOs may also need to engage licensees and other interested parties when considered necessary and as agreed by the regulatory body.

Methods for screening and analysing findings

6. The workshop recommended monitoring and reviewing the effectiveness of the regulatory experience management process in accordance with the management system of the regulatory body.
7. The publication should recognize that regulatory experience can also be withdrawn through unformal settings (e.g. meetings, discussions…). This regulatory experience should be entered when appropriate into a formal process.

Acceptance, implementation and follow up of action plans and decision-making in relation to sharing regulatory experience

8. The workshop suggested strengthening SARIS self-assessment question set used to review compliance with Requirement 15 of the GSR Part 1 (Rev. 1) considering the

good practices identified in the publication. The guidance could be further enhanced through the wider knowledge gained from the lessons learned of IRRS missions.

9. Staff of the regulatory body should be provided with appropriate guidance and easy-to-use tools. The staff should receive training on the concept and objectives of the regulatory experience management process and on the use of the tools for that purpose.

Enablers/barriers and crosscutting elements to ensure effective management of regulatory experience

10. The publication should promote that interfaces with other processes of the management system of the regulatory body (e.g. knowledge management, safety culture, competence management, organizational and human elements…) are properly managed.
11. The publication should acknowledge that staff motivation is an essential element of the regulatory experience management process. The mission and policy statements of the organization should motivate and encourage staff to embrace its regulatory experience management process. Senior management should take leadership and ensure appropriate resources for its effective implementation.
12. The workshop recommended the IAEA provide assistance (e.g. through the TC programme) to regulatory bodies for the establishment or improvement of the regulatory experience management system.

List of participants in the workshop

Chichinadze, D.	Ministry of Environment and Natural Resources, Georgia
Ivanovic, Z.	Agency for Environmental Protection, Montenegro
Karmirmirukyan, A.	Armenian Nuclear Regulatory Authority, Armenia
Kiteski, D.	Radiation Safety Directorate, North Macedonia
Milea, D.	National Commission for Nuclear Activities Control, Romania
Paci, R	Radiation Protection Office, Albania
Petrocz, T.	Hungarian Atomic Energy Authority, Hungary
Pashayev, R.	Nuclear and Radiological Activity Regulations Agency, Azerbaijan
Renev, I.	Fsue VO "Safety", Russian Federation
Serenaite, D.	Radiation Protection Center, Lithuania

Tulegenov, M	Ministry of Energy, Kazakhstan
Vene, B.	Slovenian Nuclear Safety Administration, Slovenia
Wlostowski, M.	National Atomic Energy Agency, Poland
Zakharov, O.	Scientific and Engineering Centre for Nuclear and Radiation Safety, Russian Federation
Vlahov, N.	Bulgarian Nuclear Regulatory Agency, Bulgaria
Senior, D.	Office of Nuclear Regulation, United Kingdom
Kobetz, T.	International Atomic Energy Agency
Recio, M.	International Atomic Energy Agency

ANNEX III. USE OF A QUALITY MANAGEMENT SYSTEM TO COLLECT REGULATORY EXPERIECE (RSC, LITHUANIA)

III-1. REGULATORY FRAMEWORK

The Lithuanian Radiation Protection Centre (RSC) was established in 1997 and has obligations to coordinate actions of state and municipal institutions in the area of radiation protection, to exercise the state regulation and supervision of both radiation protection in respect of exposure of members of the public and the environment and the practices involving sources of ionising radiation.

A national framework for the radiation safety has been established. It consists of primary and secondary legal acts. The main primary acts are:

a) Law on Radiation Protection;

b) Law on Radioactive Waste Management.

These Laws determine, inter alia, functions and responsibilities of governmental bodies, policy makers, state institutions and regulatory bodies. Safety principles, regulations and oversight of the activities in field of radiation safety are also addressed.

A national framework for the radiation safety covers practices in medical, industry, science and educational facilities and activities involving sources of ionising radiation except the practices in the area of nuclear energy involving sources of ionising radiation.

III-2. QUALITY MANAGEMENT SYSTEM

The Lithuanian Law on Public Administration requires that quality management of public administration at state level and at the level of an entity of the public administration should be implemented.

Considering that, RSC has established and developed a comprehensive management system in line with standard ISO 9001:2008, which is in force since 2009. The RSC Quality Management System is certified. RSC Quality Management System is based on a process approach, which is described in the Quality Management System documentation, consisting of a vision, a mission, a quality policy, a quality management manual and 29 procedures describing processes. The implementation of the processes is supported by 67 working instructions, which explain how the work is to be prepared, reviewed, carried out, recorded, assessed and improved. Processes are divided into management, executive and supporting processes. RSC has prepared a schematic process map. Each process has a designated processes owner.

RSC senior management commitment to the establishment, implementation, assessment and continual improvement of the Quality Management System is expressed by developing the Quality Policy, organizational goals and processes and in providing adequate resources for the development of Quality Management System.

RSC management responsibility for the Quality Management System is defined in the Management Manual. A management representative for quality within advance defined responsibilities and who directly reports to the senior management is appointed.

The documentation of the Quality Management System is readily accessible by intranet. Formal training on access, use and familiarisation with its functions is given to all new staff. All RSC employees use approved Quality Management System documents, when performing their activities.

RSC performs measurement, assessment and review processes through internal audits, external audits, collection of information from interested parties, self-assessments, and by Quality Management System reviews. RSC prepares a yearly plan for internal audit. Each year at least 21 internal audits are organized.

III-3. NEXUS BETWEEN THE REGULATORY EXPERIENCE PROCESS AND QA BASED ON ISO 9000

Despite the fact that the definition regulatory experience is absent from Lithuanian legislation or regulatory documentation, the concept is well known for the staff of RSC and is widely used while performing its regulatory activities such as authorization, inspection, emergency preparedness and response, etc.

Currently there are no stand-alone regulatory experience management process in the Quality Management System, but the essential elements of such a process covering collecting, analysing, implementing and disseminating of regulatory experience are spread across the other processes and are being well managed. It is recognized that regulatory experience is a powerful tool for improvement of existing regulatory process.

All regulatory functions and activities of RSC are the sources of regulatory experience that are being systematically captured from the implementation of regulatory activities and processes, i.e.:

- management of State Register of sources of ionising radiation and occupational exposure;
- authorization of activities with the sources of ionizing radiation;
- review and assessment;
- inspection and enforcement;
- emergency preparedness and response;
- public, occupational and environmental exposure monitoring and expertise;
- radiation protection education and training.

Beside the regulatory experience gained from regulatory activities, RSC is obtaining information from external national and international sources relevant for regulating facilities and activities. That includes various sources of information such as:

- exchanges with other national or international regulatory bodies to discuss matters of interest;
- publications of international organizations (IAEA, the European Commission, the Heads of European Radiological Protection Competent Authorities (HERCA), etc.) and

publication of other regulatory bodies (annual reports, regulatory decisions, recommendations and guides, etc.);

- international conferences, meetings and seminars, committees or working groups hosted by international organizations, training courses, scientific visits and fellowships;
- IAEA's peer reviews and advisory missions (i.e. Integrated Regulatory Revise Service (IRRS), Emergency Preparedness Review (EPREV), Education and Training Appraisal (EduTA), International Physical Protection Advisory Service (IPPAS);
- information obtained on request or based on bilateral agreements;
- web-resources or databases managed by international organizations;

Despite the fact that RSC is using many different sources for collecting of the regulatory experience, the formal process for collecting and documenting regulatory experience together with criteria to screen and review is not available yet and will be developed in nearest future.

RSC ensures that positive and negative feedback, including staff feedback, gained from the implementation of different regulatory activities and processes is integrated and analysed throughout all levels and across all the disciplines in the organization.

The RSC procedure 'The Management of the Non–conformances' is dedicated to the reporting of non–conformances affecting RSC processes and activities, determining the causes of the non–conformances and taking corrective actions (assessment of the effectiveness of the corrective actions). Non-conformances can be reported by each RSC employee.

Besides that, weekly senior management meetings and units meetings, also quarterly organised meetings with all RSC staff are exploited as a frame for positive and negative feedback to be presented and discussed. Every RSC employee has a right to propose the topic for such discussion.

Also, the information obtained and the experience gained by RSC employees during the seminars, training courses, scientific visits or fellowships is presented to all RSC staff during such quarterly meetings. Later on, the resolutions of the meetings serve as a basis for improvement of regulatory processes or amendments of legal acts.

External feedback from interested parties for improving the regulatory process is received by through formal and informal means, like RSC website, seminars, conferences, trainings, fellowships, publications, meetings with public, work with school children and students from universities and colleges.

RSC also collects the feedback on its performance as a regulatory body by sending the questionnaires to the licensees. Feedback is analysed once a year. Responsible persons prepare a report on analysed feedback, and the report is later evaluated by senior staff and later presented to all employees during quarterly meeting. RSC uses feedback information and implements corrective measures. Additionally, RSC organizes annual surveys on various issues arising from regulatory activities for interested parties.

RSC recognises that it is important not only to collect and analyse regulatory experience gained from various sources but also share valuable pieces of experience with other national regulatory

bodies and national and international organisations. RSC shares its regulatory experience externally with interested parties. Usually such decision is made by senior management on case-by-case basis. Also, the information related to authorization, inspection or other regulatory activities and regulatory experience is posted in RSC website periodically, if information could be important to another country, information is made available in English.

III-4. SUMMARY

The external and internal auditors' reports confirmed that the Quality Management System of RPC successfully operates and is a daily working tool the staff performs everyday tasks according to the system procedures and work instructions.

Implemented quality management system improves operational efficiency, performance and quality of performance of public services and contributes to the formation of positive public attitude towards the activities of state institutions.

There is no stand-alone regulatory experience management process in the management system, but the essential elements of such a process covering collecting, analysing, implementing and sharing of regulatory experience are spread across the other processes and are being well managed.

ANNEX IV. USE OF AN ELECTRONIC INFORMATION SYSTEM TO SUPPORT THE MANAGEMENT OF REGULATORY EXPERIENCE (HAEA, HUNGARY)

IV-1. REGULATORY FRAMEWORK

The Hungarian nuclear industry covers a diverse park of existing facilities, including:

- Paks Nuclear Power Plant: 4 VVER 440/213 units of 507 MW(e);
- Training Reactor of Budapest University of Technology and Economics: light-water cooled and moderated pool-type reactor, 100 kW;
- Budapest Research Reactor: light-water cooled and moderated tank-type reactor with beryllium reflector, 10 MW;
- Interim Spent Fuel Storage Facility (ISFS): dry chamber modules for storage of nuclear spent fuel;
- National Radioactive Waste Repository in Bátaapáti for disposal of solid and liquid low and intermediate level waste produced during the operation of the NPP; and
- Radioactive Waste Treatment and Disposal facility in Püspökszilágyi, for the disposal of waste of institutional origin.

In addition, Paks II nuclear power plant, with 2 units of VVER-1200/AES-2006 reactor design, is expected to submit a construction license application which is the next license application in the licensing phase.

Activities using radioactive sources in Hungary are also widespread, including research, industrial and medical applications.

The Hungarian nuclear energy legal framework assigns the regulatory functions to the Hungarian Atomic Energy Authority (HAEA). Its responsibilities and duties are regulated through the 1996 Atomic Energy Act and through the 2016 Act on the General Public Administration Procedures. Several Government Decrees implements the legal provisions as follows:

- 112/2011. Government Decree on the scope of authority of the HAEA in relation to European Union obligations and international obligations in connection with atomic energy, on the designation of co-authorities contributing to the regulatory proceeding of the HAEA, and on the scientific council assisting the work of the HAEA;
- 118/2011. Government Decree on the nuclear safety requirements of nuclear facilities and on related regulatory activities; and
- 155/2014. Government Decree on the safety requirements for facilities ensuring interim storage or final disposal of radioactive wastes and the corresponding authority activities

The last two decrees contain the 10 Volumes of Nuclear Safety Codes for nuclear facilities and the 2 Volumes of Safety Codes for storage and disposal facilities as annexes.

In summary, the Hungarian regulatory framework is composed of a set of acts, government decrees, ministerial decrees, safety codes, safety guidelines and applicable local regulations. HAEA has full empowerment to exercise all regulatory functions.

Regulatory oversight consists of 4 main instruments: licensing, inspection, assessment and enforcement. Licensing is the regulatory instrument used prior to the commencement activity: the authority judges before the commencement of the activity whether its implementation will comply with the requirements, and if necessary specifies additional conditions and respective tasks. Inspection typically takes places during the realization of the activity; it reveals the facts and circumstances of the activities and, in addition, it gives opportunity for intervention in the implementation phase. The authority performs the assessment typically after termination of an activity or a process, so the conclusions are drawn subsequent to the completion of the activity or the process, the feedback therefore is an essential part of this regulatory instrument, by which the failures revealed can be avoided next time. Licensing, inspection and assessment are not fully separate instruments: they may and frequently need to supplement each other for the appropriate oversight of a certain case. Enforcement means fine for most of us, however in the nuclear field the fine is the ultimate instrument. The authority has a lot of opportunities for the intervention before imposing a fine to enforce the compliance with a legal requirement or regulatory decision.

HAEA has tasks in the area of regulatory oversight of nuclear facilities, radioactive waste repositories and new NPP units, supervision of the peaceful purpose of applications and security of nuclear facilities, nuclear and other radioactive materials, safety supervision of transport packages, radiation protection, emergency response, international relations and technical support.

IV-2. PROBLEM STATEMENT

Given the diverse park of nuclear facilities and the widespread use of applications regulated by HAEA, sharing knowledge and regulatory experience within the organization has been identified as a strategic priority of the organization.

In 2008 HAEA decided to initiate a project to establish an electronic system aimed to facilitate sharing of regulatory knowledge and experience.

The objective of the project was to establish a unified mechanism, including a process and an electronic system, to be used across the organization to collect regulatory experience and facilitate its analysis.

We expected several benefits from the establishment of the mechanism. We wanted to develop a uniform approach for the collection and the utilization of regulatory experiences. We considered, that a reliable system for storing relevant information and a user-friendly database to help the utilization are the essential parts of it. We wanted to centralize recording and categorize findings received from different sources. We knew that a traceable system and clear process with separation of responsibilities and prioritization of findings based on urgency and importance help implementation of action plans. We take into consideration what are the main

steps (subprocesses) of the process. As it is discussed later, the first step is monitoring information sources and collecting experiences. Evaluation of information, suggestion for utilization, evaluation of proposal, issue of tasks and designating the responsible are the next steps. After implementation, evaluation of results and utilization are the final steps of the process.

IV-3. SOLUTION

As it is written in Section IV-2, HAEA developed a procedure and a database for the utilization of regulatory experience in 2008. The lookout of potential information sources, collecting of experiences and suggestions for the utilization is the responsibility of HAEA's employees and managers. First, the proposer – typically a nuclear safety inspector - makes an entry in the database and describe the substantive information related to the finding. After that, the Head of Department of the proposer accepts or refuses the finding for further evaluation. In the case of acceptance, the finding is discussed in the weekly executive meeting. A competent leader will be designated as responsible for assigning tasks and checking implementation and utilization. He is also responsible for assigning staff who are responsible for implementation as well as for informing the proposer of the action taken or of the docketing of the finding if the proposal is finally rejected. The inspectors who are responsible for implementation are not necessarily the same as the proposers. After they finished the tasks, the competent leader makes an evaluation and send a notice to all the managers and also share the results of the evaluation within HAEA. Finally, the designated competent leader investigates whether the utilization process is complete or other complementary tasks need to be undertaken before closure of the proposal.

Sources of information monitored are diverse. First, information gained from international activities, such as international events, working groups arranged by international organizations (EU, FINAS, INES, IRS, IRSRR, NEA, VVER Forum), bilateral and multilateral regulatory authority meetings, professional cooperation contacts, technical books and journals. Communication exchanges with international organizations and co-authorities or announcement of foreign professional organizations are also great sources of information. Another group of sources come from the supervisory activity of HAEA, namely those which are mentioned in Section IV-2: licensing, inspection, enforcement and assessment. Information we gain from the licensees through ad-hoc reports, event reports, periodic reports (annual reports, quarterly reports) and operator's announcements are very important as well. The third group consists of experiences based on the operation of HAEA, like results of investigations, experiences gained from the involvement in international and domestic missions, results of target oriented task and individual suggestions initiated by inspectors.

We have developed 3 categories for prioritization of findings based on urgency and importance. According to that, a proposal for utilization of experience can require urgent action, mid-term action or just a reminder for starting utilization process. In addition to this, we can add specific deadline to the proposals.

There are different kind of roles and responsibilities for the participants in the process: competent leader, Head of Department, Technical Division staff, manager of the database, staff who are responsible for the implementation.

The finding (gained experiences or proposals made from them) can be related to the operation of some department, HAEA's activities, Technical Support Organization's (TSO), nuclear facilities or application of technologies.

The relevant areas of expertise are wide-ranging: emergency preparedness, suppliers, safety culture, safety analysis, human factor, earthquake, operation of the authority, training and examination, storage of spent fuel, corrosion, nuclear safety, TSO's activity, quality management, nuclear fuel, ageing management, treatment of radioactive waste, radiation protection, probabilistic safety assessment, lifetime extension, anticipated operational occurrences and accidents. These areas can be selected for the proposal in the program.

The ways of implementation are also widespread. A proposal may lead to target inspection, target task, request for amendment of a document, individual task, enforcement, legislation, training, discussion (department meeting, directorate meeting or joint meeting with the licensee), project work, TSO's activity or participation in an event.

The system has a user friendly interface that allows the users retrieving key information about the findings, such us: priority and deadline, explanation of the findings, proposals to address them and implementation elements (i.e. planned actions, conditions…), as well details about the department which affected by the proposal and details about responsibilities in the implementation phase. The system can also display information sources, state of proposals (accepted or not) and task status which can be open, archive, implemented or some tasks can require further attention. It is also possible to change the finding or the proposal if some new information is available or if the management decides to change responsible staff or the deadline. The system also helps investigate the possible connection between findings and proposals which already exist in the system. After implementation, or when the process phase has changed, designated leaders and responsible staff are automatically notified.

The schematic Fig. IV-1 below shows the HAEA's process for managing regulatory experiences.

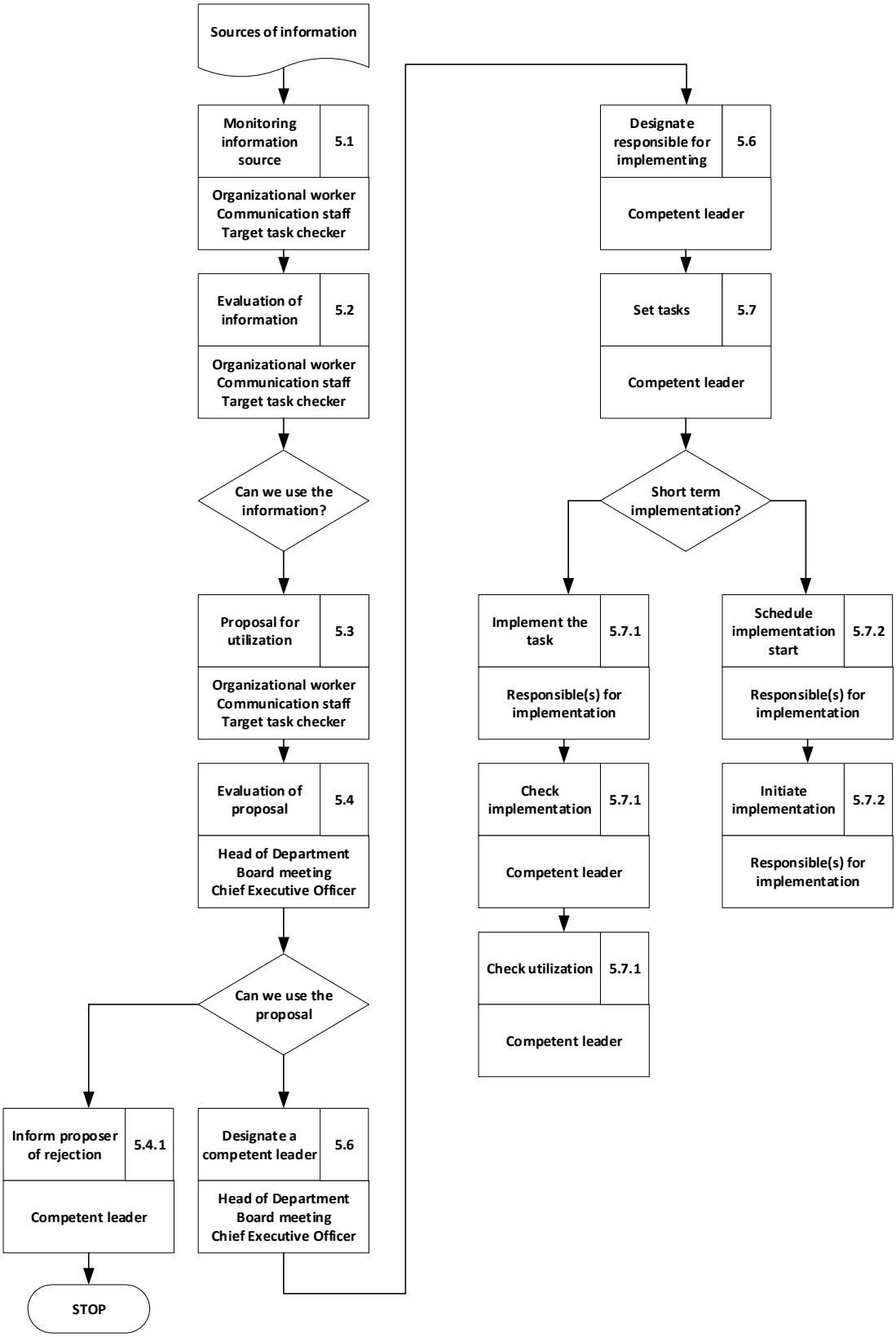

Fig. IV-1. HAEA's process for managing regulatory experiences

IV-4. CHALLENGES

HAEA's system for managing regulatory experiences was actively used by staff between 2008 and 2012. Between 2014 and 2017 the regulatory body's staff doubled and the priorities shifted towards the regulatory oversight of the expansion programme of Paks II nuclear power plant.

HAEA's organization structure has been recently changed in 2018 and renewed attention is being given to the management of regulatory experiences as an important element of the regulatory oversight process. A revision of the regulatory experience management procedure and IT system is on-going to adjust it to the new structure. HAEA will reactivate the procedure and the use of the regulatory experience system once the update has been completed.

In parallel, HAEA managers will intensify efforts to increase staff's motivation to enter findings in to the system and make proposals to benefit from regulatory experience.

Time has passed from the original development of the system, including the procedure and the database. Technology changes, as well as current needs and expectations have to be taken into account. HAEA's intent is to develop a more user friendly interface for the system, among other things to upload documents and other resources into the proposal directly.

ANNEX V. THE CANADIAN NUCLEAR SAFETY COMMISSION'S HARMONIZED PLAN PRO-GRAM (CNSC, CANADA)

V-1. CONTEXT

Overall, the Canadian Nuclear Safety Commission (CNSC) draws on more than 70 years of regulatory experience in the nuclear sector. Established in May 2000 under the Nuclear Safety and Control Act (NSCA), the CNSC replaced the Atomic Energy Control Board, which had been in force since 1946 under the Atomic Energy Control Act.

V-1.1. REGULATORY FRAMEWORK

As a result of its extensive regulatory experience, the CNSC has established an effective and flexible regulatory framework comprising the regulatory instruments by which the regulator achieves its mandate. As the enabling legislation for the CNSC, the NSCA is at the top of the framework. The following set of regulations sit under the NSCA, providing further legislative authority:

▪ *General Nuclear Safety and Control Regulations* ▪ *Radiation Protection Regulations* ▪ *Nuclear Security Regulations* ▪ *Packaging and Transport of Nuclear Substances Regulations, 2015* ▪ *Nuclear Non-proliferation Import and Export Control Regulations* ▪ *Administrative Monetary Penalties Regulations* ▪ *Class I Nuclear Facilities Regulations*	▪ *Class II Nuclear Facilities and Prescribed Equipment Regulations* ▪ *Uranium Mines and Mills Regulations* ▪ *Nuclear Substances and Radiation Devices Regulations* ▪ *Canadian Nuclear Safety Commission Cost Recovery Fees Regulations* ▪ *Canadian Nuclear Safety Commission Rules of Procedure* ▪ *Canadian Nuclear Safety Commission By-laws*

The Commission makes independent, objective and risk-informed decisions, taking into consideration all of the information provided by applicants, stakeholders, Indigenous peoples, and staff. CNSC staff make recommendations to the Commission based on thorough assessment of factual evidence. The Commission recognizes the role of professional judgment, particularly in areas where no objective standards exist.

The CNSC's regulatory framework (see Fig. V-1) consists of the Nuclear Safety and Control Act (NSCA) and other laws passed by Parliament that govern the regulation of Canada's nuclear industry, as well as regulations, licences and documents that the CNSC uses to regulate the industry.

Fig.V-1. Key elements of the CNSC's regulatory framework

V-1.2. FACILITIES AND ACTIVITIES COVERED

The CNSC has exclusive jurisdiction over nuclear-related matters in Canada, as shown in Fig. V-II below.

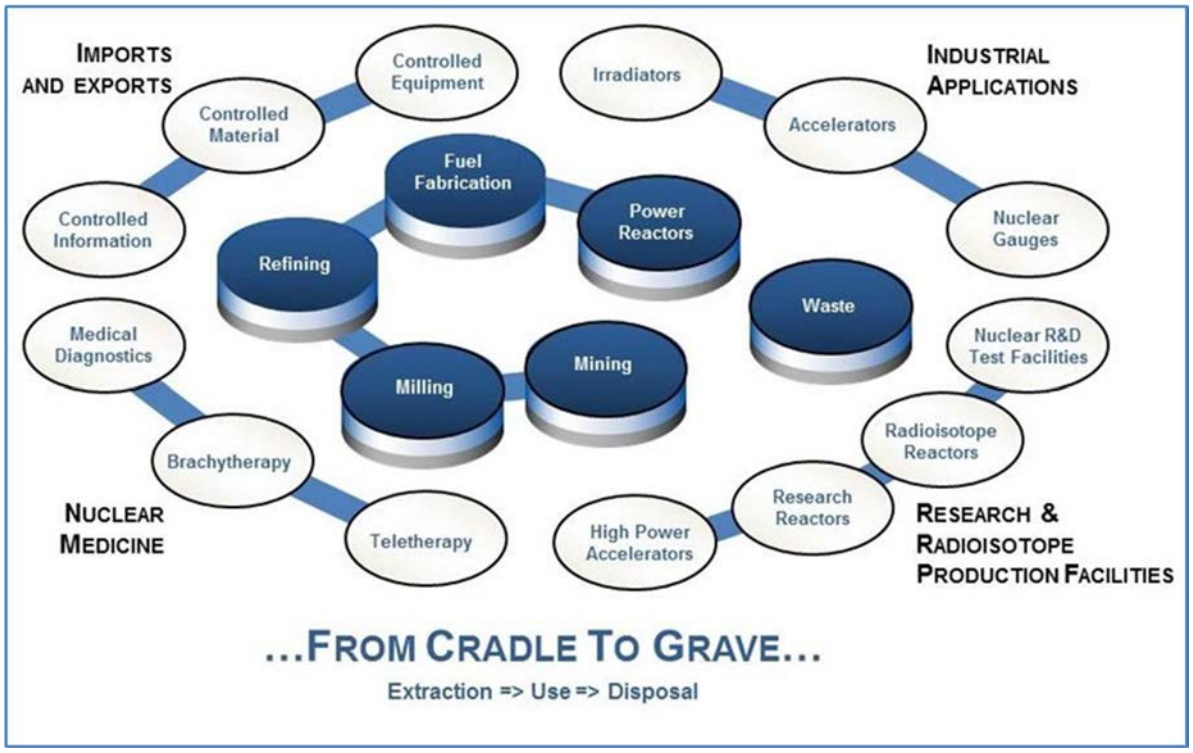

Fig. V-II. Scope of CNSC jurisdiction

V-1.3. Management of Regulatory Experience

The CNSC has implemented its regulatory functions and the related processes for more than seven decades. During that time, the regulator has consistently collaborated with domestic and international organizations to strengthen approaches to nuclear regulation, share related information and continuously improve oversight of the use of nuclear power and activities. In addition, the CNSC continuously monitors the external environment to ensure that the organization is ready to adapt to and influence changes that may impact its priorities. Of particular focus are changes brought about by the nuclear industry and through domestic and international political contexts. The result is a significant and evolving body of knowledge, skills and expertise, which the CNSC regards as a tangible resource in continuously improving both its outward-facing regulatory framework and internal-facing management system.

V-2. PROBLEM STATEMENT

This case study describes how the CNSC is meeting the challenge of harmonizing the wide spectrum of processes by which the organization fulfils its mandate. The primary catalyst for the 2008 inception of the CNSC's Harmonized Plan Program for Improvement Initiatives (HP) was a series of independent and internal reviews that identified opportunities to improve consistency and effectiveness in how the CNSC was carrying out the work that cuts across the organization. Previous initiatives to undertake these improvements had missed the mark, never quite gaining the global buy-in across the organization that is so vital to the success of a wide-reaching solution that needs to endure and evolve over time.

The first wave of HP projects was related to improvement opportunities identified in an independent review carried out by Talisman International in 2007. Early successes with these initiatives helped establish a strong foundation for moving forward with the HP by giving both staff and management tangible, sustainable examples of the benefits of harmonizing their work. Furthermore, this early success let the CNSC refine the terms and conditions necessary for ongoing success of this approach to continuous improvement.

The HP's initial promise – prioritizing, coordinating and aligning initiatives; nurturing consistency and collaboration; providing staff with the right tools; holding managers and staff accountable; and continuing to evolve the HP approach overall – has been met on all counts.

V-3. SOLUTION

The HP has evolved over the past 10 years into a comprehensive program with a dedicated governance structure, clearly defined roles and responsibilities, and a disciplined approach to integrating and aligning all cross-functional CNSC improvement initiatives into a single, prioritized, corporate improvement agenda. The HP maximizes the effectiveness and efficiency of the CNSC's corporate objectives for continuous improvement by leveraging commonalities between initiatives, and then streamlining and prioritizing the work for more effective distribution of resources. Having the right people working on the right priorities at the right time helps managers work together to address gaps and reduce redundancy. The continued success of the HP in applying this principle has served to inspire all levels of management to continuously endorse the initiatives by committing the appropriate resources and accepting ownership as appropriate.

The HP activities are captured in a document that provides details about the status, timelines, resource commitments, deliverables and interfaces for all improvement initiatives under the HP and is updated regularly to reflect current priorities. Through the HP, critical changes are made first. Initiatives are triaged against established criteria, and initiative progress is monitored by the Harmonized Plan Steering Committee (HPSC) and reported directly to senior management on a quarterly basis. HP priorities are then revisited at least twice each year. In general, highest priority is assigned to initiatives that deliver immediate improvement to address strategic gaps while drawing on a minimum commitment in time and resources.

To deliver its mandate, the CNSC seeks feedback from employees and other organizations to continuously improve its capacity to identify and correct issues or enhance attributes that affect how it meets its mandate through continuous improvement, learning and knowledge management:

— staff are encouraged to develop and apply a questioning attitude and to hone their analytical and technical skills and competencies;

— formal feedback programs, self-assessment tools, and oversight mechanisms are geared toward corrective action, including self-assessments of the harmonized plan program itself;

— the HP integrates and aligns all cross-functional CNSC improvement initiatives into a single prioritized plan for action.

The HP is also the subject to self-assessments to ensure continuous improvement and confirm that the program continues to meet its objective.

V-3.1. Process Overview

The diagram in Fig. V-3 outlines the flow of activities and decision points that make the HP work:

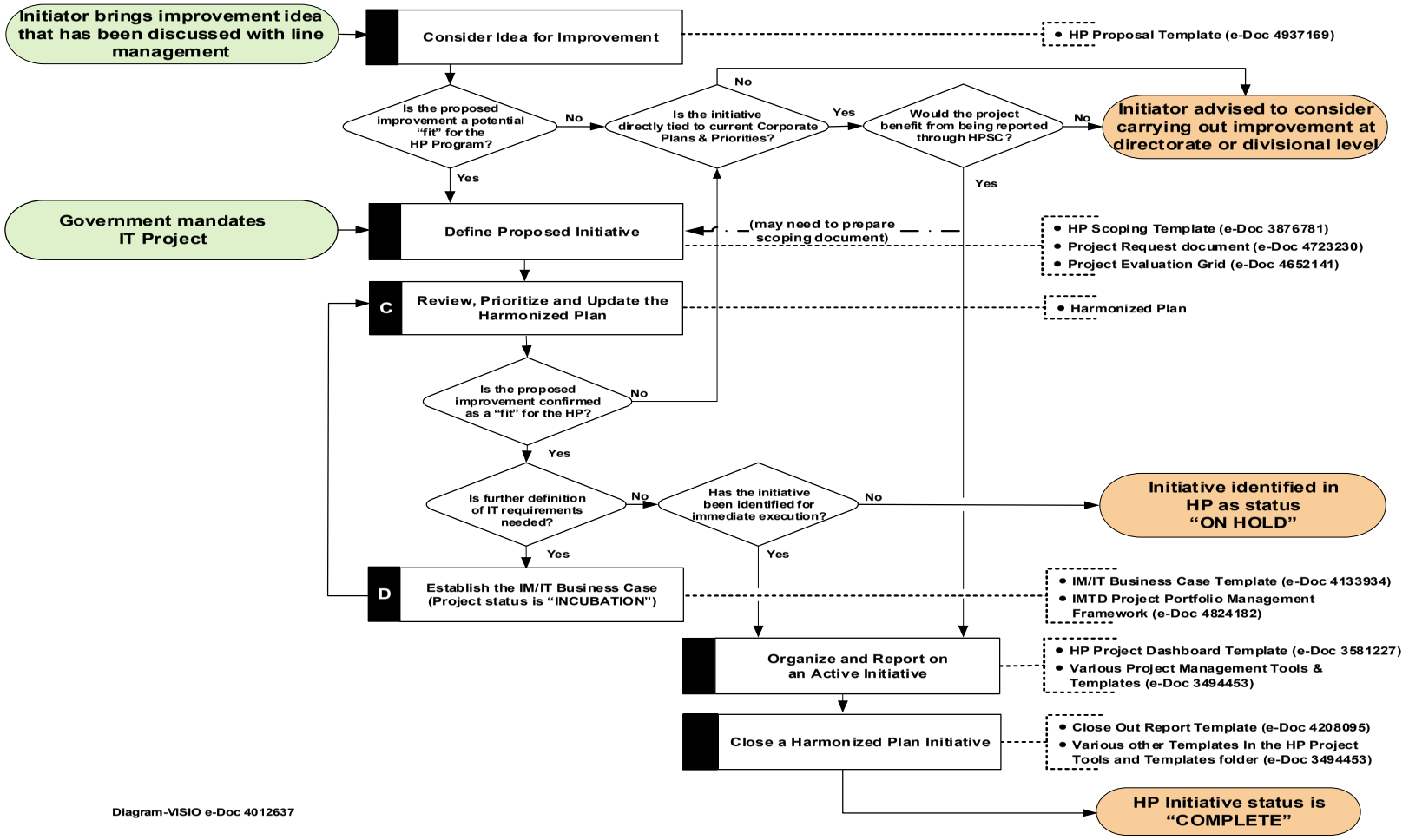

Fig.V-3. HP Program Process Overview

V-3.2. Typical HP Profile

The HP typically comprises about 25 priority initiatives of varying size, scope and duration, with approximately 15 projects underway at any given time. Each improvement initiative is expected to have an impact on multiple directorates. It has an approved scope and is 'owned' by an 'initiative champion' at a senior management level. Any HP initiative might entail policy development, process improvements, information technology improvements, amendments to legislation, or all of the above.

V-3.3. Governance

The HP functions within a framework of leadership, direction and support that provides a single-line reporting structure to facilitate communication, reporting and decision-making. The diagram in Fig. V-4 illustrates the governance structure of the HP.

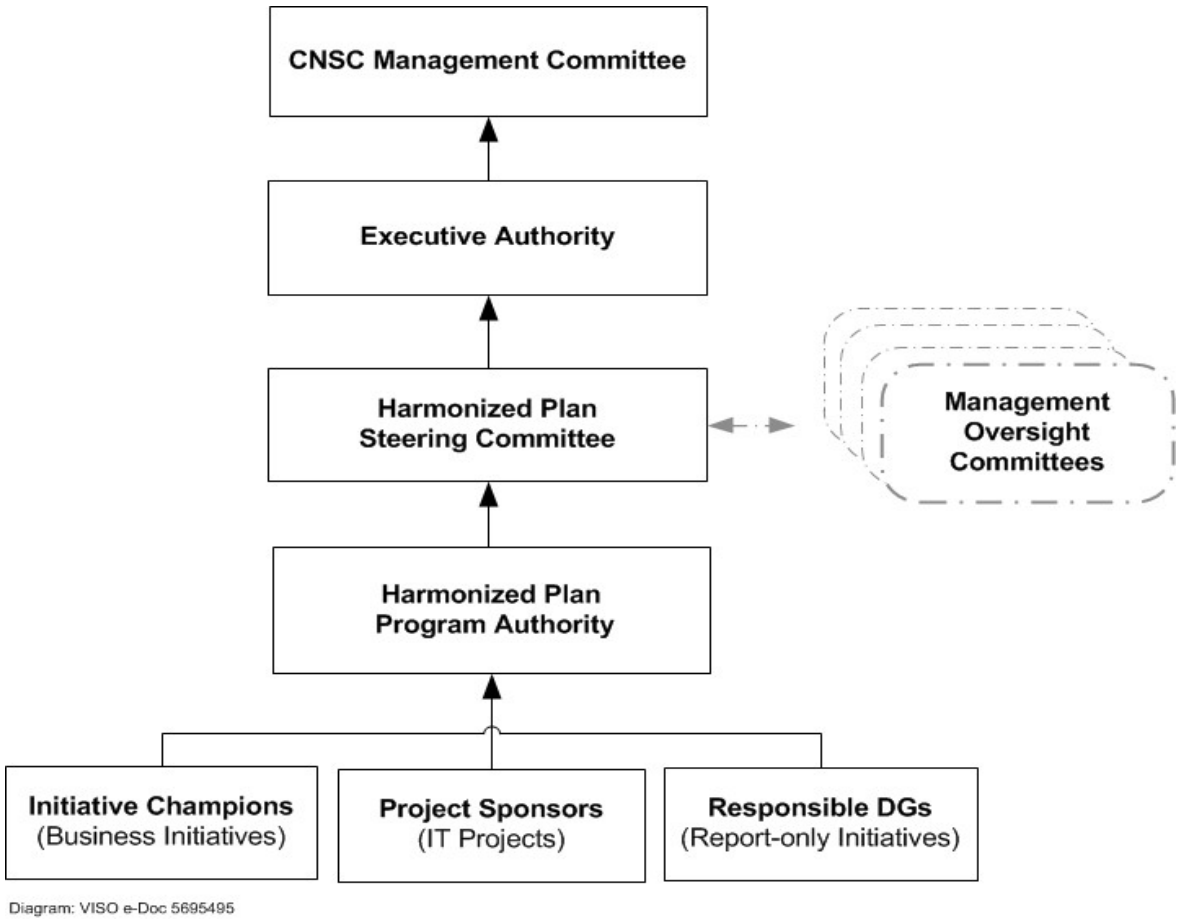

Fig.V-4. HP Program Governance

The HP's streamlined project reporting structure has proven extremely effective in keeping management apprised of the progress of improvement initiatives across the CNSC, and in engaging senior management when approvals or direction are needed.

The HPSC reports directly to the CNSC Management Committee and provides senior management oversight for the HP. The HPSC meets regularly to review the progress of ongoing HP initiatives, and to prioritize and integrate new initiatives.

V-3.4. Collaboration

HP improvement initiatives consistently reflect the horizontal contribution of experts from all applicable areas of the organization. This factor is a cornerstone of HP success to date. When the people who will be most affected by a change have a voice in its development, the change becomes more tangible and sustainable.

V-3.5. Sample Success Stories

As a result of early and ongoing commitment, engagement and follow-through by top management and the active participation of staff, the CNSC has realized many improvements through the evergreen HP approach. Some of those with the broadest and deepest impact include the following initiatives:

— The Conduct of Inspections (COI) initiative corrected a history of inconsistencies in the way inspections were carried out by the different service lines. Through the HP approach, the HPSC brought together representatives from all applicable groups to develop, document and implement a common framework for conducting inspections which ultimately enhanced the effectiveness, consistency, uniformity, transparency and professionalism of CNSC compliance oversight activities;

— The Inspector Training and Qualification Program (ITQP) initiative complemented the COI project by establishing common training and qualification for all inspectors. The ITQP curriculum comprises three types of learning: core training, on-the-job training and service-line-specific training, ensuring that CNSC inspectors have the broad knowledge, hands-on skills and service-line experience they need for performing their jobs effectively, which in turn helps ensure quality and consistency in CNSC inspection practices;

— Administrative Monetary Penalties (AMPs) are civil sanctions imposed by the regulator, without court involvement, for the violation of a regulatory requirement. The AMPs initiative established a program by which the CNSC can impose penalties for non-compliance, deterring violation of regulatory requirements and thereby promoting compliance. The project was completed under the HP in three phases: 1) amendment of the legislation, 2) development of the new AMPs Regulations, and 3) development of the AMPs program and enabling tools (such as processes, templates and governance);

— The Knowledge Management (KM) initiative, entails developing KM strategies, objectives and activities, and then processes for carrying them out.

V-4. LESSONS LEARNED

V-4.1. Lessons learned at the HP Program level

Lessons learned at the HP program level include:

— Single-line reporting: The HP's streamlined project reporting structure has proven extremely effective in keeping management apprised of the progress of improvement initiatives and engaging senior management when approvals or direction are needed;

— Initiative Champions: Each assigned initiative needs an accountable Champion to support and oversee the initiative from beginning to end;

— Initiative close-out reports: Close-out-reports capture the highlights of each initiative including lessons learned, what went well, and what could have gone better. They also include information on implementation and maintenance of the deliverables and are a good knowledge management practice.

V-4.2. Lessons learned from HP initiatives

Table V-I reflects general lessons learned from previous HP improvement initiatives.

	BEST PRACTICES	DESCRIPTION
1	Project scoping is clear and accurate	The parameters of the project (what is and what is **not** included), and target outcomes, are clearly articulated.
2	Risks are taken into account	Measures are in place to ensure that priorities, external risks, interdependencies, constraints, and any other factors that might have an impact on project timelines, are identified, understood and communicated at all levels.
3	The impact of dependency on external groups and agencies is recognized and mitigated	If deliverables depend on external group or agency participation, those parties are identified and engaged as early as possible in the project.
		Any conflicting priorities that could have a direct impact on project timelines have been identified in the scoping document and in the project plan.
		Any necessary contingencies are incorporated into the project plan before communicating timelines to senior management.
		Measures are in place to ensure that any unmitigated impact will be immediately and clearly communicated to management.
4	Business needs guide the solution	Business needs are clearly defined before the technical solution is considered.
		Continuous alignment is maintained between business needs and priorities, and the technical solution(s).
		When Information Management and Technology Directorate involvement is anticipated, the IMTD is included early in planning discussions, and IMTD communicates technical options to the business representative(s) before a solution is recommended.
5	The right people are participating	Appropriate representation on the project team is key to getting things done in a timely manner. Any and all directorates that will be affected by the change should be represented as contributors on the team.
6	Participants can make decisions	In order to effectively represent their directorates, each participant is permitted, expected and prepared to make decisions on behalf of his or her directorate.

	BEST PRACTICES	DESCRIPTION
7	Representation is continuous	For related initiatives, the same directorate representatives either participate directly or commit to effective knowledge transfer.
8	Management is actively engaged	Management buy-in, commitment, collaboration, engagement and support have been confirmed to provide decision-making authority to directorate representatives, assist in effectively resolving issues and competing priorities, and ensure continuity.
9	Participants are actively and effectively engaged	Engagement, flexibility and collaboration of participants are primary contributing factors to success. Therefore, contributors on an HP project team ☐ stay actively involved throughout the project ☐ keep their respective directorates apprised of project status and developments ☐ immediately raise issues, concerns and requirements on behalf of their directorates ☐ transfer their knowledge of the project to a directorate colleague where there is a reassignment or if a colleague is assigned to a linked initiative ☐ are prepared to attend /participate in presentations to senior management
10	All elements of the project have been appropriately organized	To enable the initiative lead to quickly find and coordinate project elements, and to reinforce team inclusiveness, a project workspace has been created for storage of Index Card, HP Dashboard, draft deliverables, reports, presentations, etc. Refer to the *How to: Organize and Report on an 'ACTIVE' HP Initiative document, or the Quick Tips for Organizing and Reporting on an 'ACTIVE' HP Initiative reference page for guidance.*
11	Quality control is built into planning	Quality checks are incorporated into the project plan from beginning to end, including after any revision to drafts and deliverables.
12	Communication activities and healthy dialogue	Effective communication at all levels is vital to project success. Therefore: ☐ expectations, roles and responsibilities are communicated at project outset ☐ decision-making authority is clearly defined in the Project Charter ☐ governance is clearly established, particularly for cross-functional projects ☐ contributors are willing to consider and challenge differing views ☐ participants are kept informed as to when and how decisions are made ☐ participants actively make decisions for and speak to their directorates ☐ regular communication is maintained between initiative champion and lead ☐ senior management gets realistic updates ☐ contributors are given the opportunity to review updates to senior management ☐ records of decision for the project are documented and communicated to all
13	Iterative approach to IT solutions	An iterative approach is in place for development and incremental delivery of technological solutions to meet business needs.

	BEST PRACTICES	DESCRIPTION
14	Timely updates	Scheduled updates are reported in a timely manner to ensure that the appropriate parties get the information they need at predictable times.
15	Appropriate escalation	Issues and risks are escalated to the appropriate decision makers, particularly during critical points in the project, to ensure that concerns are addressed in a timely manner while minimizing impact on the project schedule.
16	Implementation and maintenance planning	The work and resources that will be needed to transfer the finished improvement for implementation in day-to-day operations is well defined and planned before going to senior management for final approval.

TABLE V-1. General lessons learned from previous HP improvement initiatives

Table V-II shows the criteria used for inclusions in the HP and the prioritization of the initiatives.

CRITERIA FOR INCLUSION IN THE HP	CRITERIA FOR PRIORITIZATION OF HP INITIATIVES
A proposed improvement is considered for inclusion in the HP when it meets one or more of the following criteria: ▪ Senior management has identified the HP as the vehicle for the improvement ▪ The initiative can reasonably be expected to result in a tangible and sustainable improvement ▪ The idea is 'cross-cutting' (that is, the work of carrying out the project itself, and the resulting improvement, would have an impact on multiple divisions, directorates and/or branches of the organization) ▪ The initiative would benefit from consistent management attention ▪ The improvement would correct a gap, or correct a duplication or inconsistency that is currently in multiple areas ▪ The improvement would tie in with or be part of corporate plans and priorities ▪ The improvement would apply to or have an impact on an existing process or application ▪ The DG who would 'own' the improvement has been identified and consulted, and has indicated interest in and agreement with the proposal ▪ The initiative is being managed by another steering committee, but would support the strategic planning framework or other continuous improvement	The HPSC prioritizes improvement initiatives against established criteria to identify which initiatives will be (or will continue to be) 'ACTIVE' and which ones will be kept or shifted to 'ON HOLD' status. The resulting list of 'ACTIVE' initiatives is confirmed by the Management Committee. In addition to applying the inclusion criteria above, prioritization of proposed improvements takes the following into consideration in a weighting system that assigns scores to each proposed project: ▪ The strategic importance of the initiative ▪ The feasibility of the work necessary to deliver the improvement; that is, the organization's ability to provide the resources and management attention needed to complete the project (doability) ▪ The likelihood of successful implementation given the breadth and depth of the associated organizational change(s) In general, initiatives that can be expected to deliver immediate improvements to address strategic gaps while drawing on a minimum commitment in time and resources receive the highest priority. The prioritization criteria are set out in the Project Evaluation Grid in the *HP Scoping Template*, along with the score values associated with each.

TABLE V-I1. Criteria for inclusion in the HP and for prioritization of initiatives

ANNEX VI. REGULATORY EXPERIENCE IN THE FRAMEWORK OF AN INTEGRATED MANAGEMENT SYSTEM (NNSA, PEOPLE'S REPUBLIC OF CHINA)

VI-1. BACKGROUND

The Nuclear Safety Act of the People's Republic of China came into effect since 1 January 2018. Article 35(2) of the Act requires that the nuclear safety regulatory body establish experience feedback system, deal with the licensee's reporting information related to nuclear safety in time and share the information.

National Nuclear Safety Administration (NNSA) of the People's Republic of China established the integrated management system. In 2016, NNSA published Integrated Management System Manual for Nuclear and Radiation Safety Regulation (IMS) taking into account IAEA GS-R-3 Management System for Facilities and Activities and its guideline. With regard to improving regulatory process continuously by making use of regulatory experience, IMS 2.3(4) Assessment and improvement describes as follows: Based on the self-assessment of managers at all levels, internal and external independent assessments and experience feedback, the monitoring and assessment system and self-improvement mechanism are established for the integrated management system to create a learning organization, through which continuous improvement can be achieved by identifying the problems and deficiencies in the management system in a timely manner. In guideline of experience feedback for nuclear and radiation safety, the regulatory experience process is documented.

IAEA conducted a follow-up IRRS mission in September 2016 to review the national regulatory framework for nuclear and radiological safety in China, and specifically the measures undertaken following the recommendations and suggestions of the 2010 IRRS mission. The IRRS team concluded that the MEP (NNSA) is an effective and credible regulatory body. The IRRS team also recognized that significant progress had been made in the regulatory process since 2010, and fruitful work has been carried out in drawing lessons learned after Fukushima Daiichi accident.

VI-2. PRACTICE OF NNSA

NNSA senior management attached great importance on collecting, analysing, implementing and sharing of regulatory experience. NNSA administrator holds topical meeting on regulatory experience, encouraging all members summarizing lessons learned, contributing to the enhancement of regulatory process and capability. NNSA holds semi-annual and annual management meeting, communicating and promoting the good practices of regulatory experience.

In 2017, NNSA initiated a project to develop and revise its guidelines, programs, instructions and procedures. According to the project plan, the documents are classified into 4 levels. The top level is IMS. The second level documents consist of three categories: administrative guidelines, management guidelines and technical programs. Guideline of experience feedback, ranked as a second level management guideline, together with the core processes identified in IMS which include regulations and standards development, safety review and licensing, safety inspection and enforcement, accident emergency and radioactive environment monitoring, personnel qualification, compose the second level management guidelines. The project, combining current documents in effect and over 30 years of regulatory experience of NNSA,

identifying and supplementing the weakness, developing and revising the documents under the unified standard, aims to continuously improve the regulatory process.

NNSA systematically captures regulatory experience from the implementation of regulatory activities and processes. Information notice, regulatory suggestions and regulatory requirement, are announced accordingly in light of analysing results.

Guideline of experience feedback for nuclear and radiation safety indicates some source of regulatory experience, which includes:

— Review and investigation on the events of concerns and significant non-conformance items.;

— Developing, monitoring and analysing of performance index for nuclear facilities and activities;

— Establishment and maintenance of internet-based experience feedback platform;

— Analysing the feedback provided in relation to important information in nuclear and radiation safety.

NNSA establishes bilateral and multi-lateral mechanism with other regulatory bodies and international organizations, communicates periodically. Experience feedback meetings focusing on various disciplines and topics are held annually for nuclear facilities. For significant regulatory experience, experience feedback meeting is convened timely. For operating nuclear power plant, thematic experience feedback meeting was held quarterly, the theme of meeting arises from the result of biweekly screening meeting. Experience feedback platform sends emails automatically to registered users about the events briefings.

VI-3. SUMMARY

In general, NNSA implements internal and external experience feedback extensively, collecting, analysing, implementing and sharing lessons relevant to nuclear and radiation safety learned domestically and internationally. NNSA enhances regulatory effectiveness through identifying the priorities and optimizing regulatory resources, thus continuously improves the nuclear and radiation safety regulation in China.

ANNEX VII. ONR´S ASSURANCE FRAMEWORK AS A DRIVING FORCE FOR ENSURING EFFECTIVE REGULATION (ONR, UNITED KINGDOM)

VII-1. PURPOSE

The purpose of this Appendix is to describe the assurance framework that the UK Office for Nuclear Regulation (ONR) has developed in recent years, and in particular how this framework supports the collecting and sharing of regulatory experience.

VII-2. OVERVIEW OF ONR AND THE IMPORTANCE OF REGULATORY EXPERIENCE

Set up by the Energy Act 2013 as a stand-alone public corporation, ONR independently regulates safety and security at 37 licensed nuclear sites in the UK. These include the existing fleet of operating reactors, fuel cycle facilities, waste management and decommissioning sites and the defence nuclear sector. In addition, ONR regulates the design and construction of new nuclear facilities and the transport of nuclear and radioactive materials. ONR also works with the international inspectorates to ensure that nuclear material safeguards obligations for the UK are met. ONR co-operates with international regulators on safety and security issues of common concern, including associated research.

The responsibility for delivering a safe and secure nuclear industry rests with the nuclear industry itself. ONR's mission statement is, "To provide efficient and effective regulation of the nuclear industry, holding it to account on behalf of the public" [1]. ONR uses a wide range of regulatory tools and processes (such as inspection, permissioning and enforcement) to influence those it regulates, and to encourage the achievement of sustained excellence and continuous improvement in safety and security performance across the nuclear sector.

The legal framework for the UK nuclear industry is based around The Energy Act 2013, The Nuclear Installations Act 1965 and The Health and Safety at Work etc. Act 1974 (HSWA). HSWA places duties on all employers, including those in the nuclear industry, to look after the health and safety of both their employees and the public. However, because of the particular hazards associated with the nuclear industry, including the potential for accidents to cause widespread harm and social disruption, further legislation is also in place, specifically the Nuclear Installations Act 1965. This Act requires nuclear sites to have a nuclear site licence and there is a standard set of 36 Licence Conditions attached to each licence covering design, construction, operation and decommissioning phases.

Within ONR, the collection and sharing of regulatory experience are key elements that underpin the mission statement to be an efficient and effective regulator. In addition, ONR works to five core regulatory principles of Proportionality, Accountability, Transparency, Targeted and Consistency, and regulatory experience is fundamental to ONR demonstrating that it is working to these principles sustainably.

Put simply, where ONR's practices and behaviours have proven to deliver successful safety and security outcomes, this experience needs to be captured to help ensure future success. Where practices have been less effective, regulatory experience also needs to be captured and used to help prevent reoccurrence and to continuously improve regulatory performance. ONR has

grown rapidly and the current headcount is 630 staff (including 400 technical staff) working out of three offices in Liverpool, London and Cheltenham. The number of technical staff has more than doubled in the last decade, and the capture and share of regulatory experience is an important part of the training and development of this increased capacity.

VII-3. WHY ONR INTRODUCED AN INTEGRATED ASSURANCE FRAMEWORK

ONR was established under law by The Energy Act 2013 (TEA13) and has operated as a stand-alone public corporation since April 2014, regulating nuclear safety, security, conventional safety, transport and safeguards in the UK. ONR was previously an agency within the UK Health & Safety Executive (HSE) and at the point of separation established its own corporate and executive governance arrangements including a Board comprising Chair and a blend of Non-Executive and Executive Directors.

ONR also introduced its own arrangements to provide assurance to its new Executive and Board that ONR is regulating the industry efficiently and effectively in line with its mission statement. This assurance was in the form of a combination of operational assurance reviews (delivered internally) of ONR's regulatory processes, along with audits of ONR's corporate functions (provided by the UK Government Internal Audit Agency).

ONR leadership challenged that these arrangements needed to be refined and improved in order to move to a more integrated approach, providing an authoritative and coherent source of assurance that ONR is regulating effectively and efficiently, by harnessing its regulatory experience. ONR leadership advised that the assurance framework should be informed by relevant good practice nationally and internationally and this led to benchmarking activities with other high hazard regulators.

ONR leadership also wanted to demonstrate an organisational learning culture, open to challenge and a real hunger for continuous improvement. The assurance framework operates on the principles of collect, assess and implement regulatory experience and therefore helps to drive effective regulation, as well as providing assurance that ONR is operating effectively.

VII-4. THE STRUCTURE OF ONR'S ASSURANCE FRAMEWORK

ONR's assurance framework follows a *defence in depth* structure using a number of layers of defence. The approach described in this Section is informed by UK government guidance on assurance frameworks, and also national and international nuclear industry guidance on Internal Oversight. ONR also meets periodically with other UK high hazard regulators including the UK Health and Safety Executive and the UK Civil Aviation Authority; this helps to continuously benchmark and help refine the model.

Figure VII-1 below provides a visual of ONR's *three tiers of defence* integrated assurance approach. Within the model, the collection and use of regulatory experience is the fundamental source of both assurance and improvement.

TIER ONE – IN-LINE ASSURANCE AND OVERSIGHT

— This comes direct from those responsible for delivering ONR's core regulatory processes such as inspection, assessment, permissioning, investigation and enforcement. It provides

assurance that regulatory performance is monitored, risks identified and addressed and objectives are being achieved. This type of assurance may lack full independence, but its value is that it comes from those who know the business, culture and day-to-day challenges.

— ONR's regulatory processes are captured within a regulatory management system called HOW2 which is managed centrally and process ownership is dispersed throughout the ONR technical community.

— ONR maintains a suite of inspection and assessment guides and these are periodically updated based upon regulatory experience. All of this guidance is publically available via ONR's internet site.

— ONR employs a *review, learn improve* process within the front line to capture learning associated with specific regulatory activities such as significant regulatory decisions associated with permissioning or enforcement.

— In order to share regulatory experience across the business and with non-technical staff, ONR runs regular *learn about* sessions to complement its comprehensive communications activities. The philosophy behind all of ONR's communications is open engagement so that staff are fully involved and can share their experience to benefit the organisation.

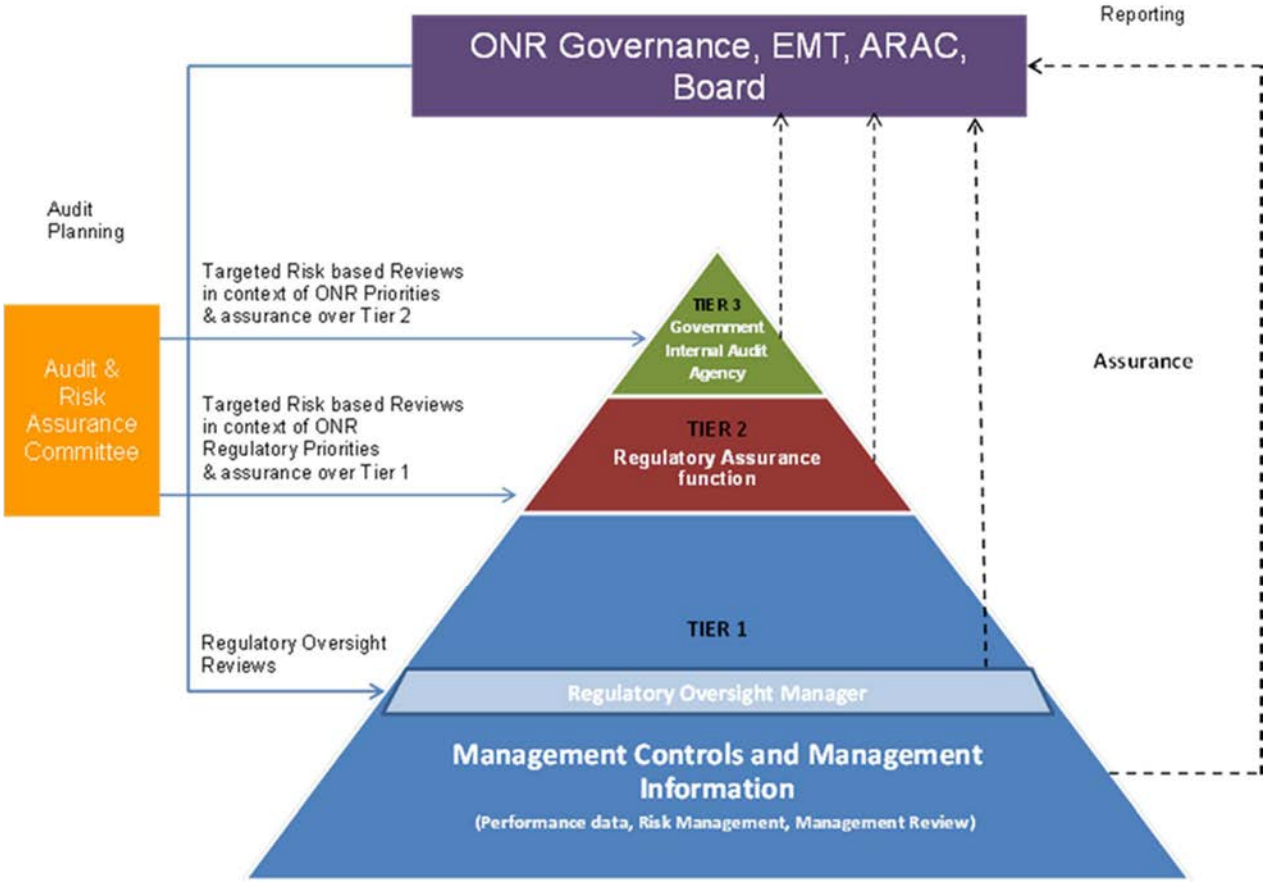

Fig. VII-I. ONR's Integrated Assurance Framework – harnessing Regulatory Experience

— In order to extract more value from front line regulatory experience, ONR has also invested in a Regulatory Oversight Manager (ROM) within this first line of defence. The ROM delivers a structured plan of risk-informed live reviews of regulatory activities in order to capture inspection practices and provide continuous improvement and learning.

— The ROM acts a *critical friend* to the business and generates both tactical and strategic improvements. The ROM gathers regulatory experience through live observations (sitting in on inspections, emergency exercises etc.) and provides balanced feedback to ONR inspectors to directly improve regulatory efficiency and effectiveness.

— The ROM also reports a thematic review of ROM activities to the business and this identifies cross organisational good practices and improvement opportunities – all geared towards improved regulatory effectiveness.

TIER TWO – INDEPENDENT REGULATORY ASSURANCE FUNCTION

— ONR has invested in a Regulatory Assurance function that is independent of front line regulation and other Tier One assurance activities. The function conducts risk-informed strategic reviews across ONR's regulatory processes and decisions. The process is again built upon regulatory experience principles; reviews are undertaken through the collection of evidence via interview and documentation review. This information is analysed (comparison with ONR's processes and relevant standards and good practice) in order to produce an assurance rating and identify good practices and recommendations for implementation in the business to improve regulatory effectiveness.

— A structured plan of approximately 12 strategic reviews is developed at the start of the year with senior leadership engagement. The plan is endorsed at ONR Board committee. Figure VII-1 shows that Performance against the plan is subsequently reported to the Executive Management Team (EMT) and the Board's Audit and Risk Assurance Committee (ARAC) throughout the year. Recommendations are also tracked and reported at this level, demonstrating senior leadership support.

— The function is resourced by experienced staff with a combination of regulatory experience and audit skills. The function maintains a small core team and other inspectors join the team for one to two years to refresh the function. This approach also helps to spread the philosophy of continuous improvement throughout the organisation.

— In addition to planned reviews, the function also conducts reactive reviews at the request of ONR leadership and especially the Chief Nuclear Inspector who has accountability to the ONR Board for efficient and effective regulation of the industry.

— Whereas the Tier One Regulatory Oversight Manager operates within the front line and observes live inspections to improve regulatory effectiveness, the Tier Two Regulatory Assurance function is independent of the front line and reviews regulatory activities retrospectively and more strategically. The net effect is complementary assurance.

TIER THREE – UK GOVERNMENT INTERNAL AUDIT AGENCY (GIAA)

— The Government Internal Audit Agency (GIAA) provides ONR (under contract) with professional and fully independent risk-informed audit coverage across its other corporate functions such as Finance, Human Resources, IT, Policy & Communications etc.

— For operational (regulatory) assurance, GIAA places reliance upon the assurance activities conducted in Tiers One and Two. This integrated approach is cost-effective and helps to ensure that the right skills are deployed to the right areas of assurance.

— In order to ensure that assurance planning is integrated and effective, the leads from each Tier work closely together routinely and also meet on a formal basis quarterly.

— ONR also takes assurance from other independent assurance providers operating in the third line, such as those provided by independent regulators, other government agencies and IAEA international peer review services

VII-5. LEARNING AND BENEFITS OF THE ASSURANCE FRAMEWORK

Leadership support from the top is paramount in implementing, maintaining and realising the benefits of the integrated approach. Organisational attitude and culture to internal challenge are also key. ONR sees assurance findings as an opportunity to drive continuous improvement and to improve regulatory efficiency and effectiveness.

Commitment and investment in the form of dedicated and experienced resource to each Tier of the assurance framework delivers the process of collecting and assessing regulatory experience and driving regulatory effectiveness and organisational improvements.

Independence is key and in ONR, all assurance activities are delivered independently into ONR's corporate and executive governance arrangements with an authoritative voice. At the same time, each Tier of assurance has clear accountability to deliver its component of the integrated assurance plan whilst ensuring close working to prevent duplication and ensure coherent and consistent assurance coverage for the organisation.

Sustainability is supported by having all of ONR's assurance processes mapped within ONR's management system (HOW2). In addition, two levels of training on assurance are delivered into the business – a detailed half-day course for ONR managers and a bite-size course delivered as a routine component of general refresher training and for new starters.

Organisational buy-in has to be secured and maintained and this is helped by regular feedback on findings and improvements to all layers of the organisation. In ONR, the Executive and Board Committees receive regular updates, and in addition to this, all assurance findings are reported in staff briefings and are available on the ONR intranet.

Benefits of operating the integrated assurance framework (return on investment) -

— Fundamentally the integrated approach provides coherent assurance coverage, in line with ONR's risk appetite, to the Executive and Board in the manner with which ONR is discharging its statutory responsibilities.

— Based upon regulatory experience principles, the integrated approach helps to ensure that ONR is driving to be an efficient and effective regulatory in line with its mission statement, as assurance findings are used routinely to drive continuous improvement.

— Assurance findings also support wider learning needs to ensure that staff have sufficient technical and regulatory competence to perform their role.

— The approach provides confidence to duty holders that ONR does not rest on its laurels but strives to improve efficiency and effectiveness in its regulatory and support processes.

— Assurance acts as a critical friend to the organisation so that opportunities for learning and improvement are captured and implemented in a non-confrontational manner.

— In the spirit of sharing good practice, ONR's investment in assurance has attracted interest from other industry regulators and nuclear regulators internationally. In doing so, ONR has also significantly benefited from shared learning in these exchanges.

— Self-evaluation is a cornerstone of the International Atomic Energy Agency (IAEA) peer review missions and ONR's approach is a clear demonstration of how it strives to meet expectations in this area.

VII-6. SUMMARY

ONR's mission statement is to provide efficient and effective regulation of the UK nuclear industry, holding it to account on behalf of the public. In order to help achieve this, ONR has invested resource to formally collect and assesses regulatory experience and implement associated improvements via a defence in depth assurance process. The process is based upon Three Tiers of Assurance and aligns with international practice on internal oversight, learning and assurance.

Along with the investment in resource, leadership within ONR, and an open learning culture, have been key enablers in implementing and sustaining the integrated assurance approach. This enables the assurance function to operate and report its findings with independence. Improvements are tracked at Executive and Board committee and this helps to ensure that they are implemented effectively and to schedule.

At a time of rapid change and growth, ONR has placed regulatory experience at the heart of its assurance processes and is using it to help drive and demonstrate effective regulation.

REFERENCES TO ANNEX VII

[1] OFFICE FOR NUCLEAR REGULATION, Framework Document Between the Department for Work and Pensions and the Office for Nuclear Regulation. October 2019.

ANNEX VIII. REGULATORY EXPERIENCE MANAGEMENT IN A COUNTRY WITHOUT NUCLEAR INSTALLATIONS (RPAZ, ZIMBABWE)

VIII-1. REGULATORY FRAMEWORK

The Radiation Protection Authority of Zimbabwe (RPAZ) was established as the competent authority to regulate the use of ionizing radiation in the country through the Radiation Protection Act [Chapter 15:15] of 2004. The mandate of RPAZ is to protect people and the environment against the harmful effects of ionizing radiation through the application of international safety standards. The national framework that exists is made up of the primary legislation and secondary legislation in the form of regulations issued from time to time taking into account changes in the international safety standards.

VIII-2. FACILITIES AND ACTIVITIES

The scope of applications in Zimbabwe is limited to radiation sources only as there are no nuclear applications. These are used in practices in the medical, industrial, security, education and research. Further, controls are in place for the control of activities giving rise to NORM.

VIII-3. REGULATORY EXPERIENCE

RPAZ values continuous improvement of regulatory processes and the management system stresses the importance of feedback as a way of initiating improvement. A number of initiatives have been established to collect regulatory experience aimed at improving effectiveness. These include:

— Client feedback platforms: Licensees and applicants have an opportunity to comment or raise issues regarding any aspects of the regulatory processes. Anonymous submissions can be done either online through the Authority website or through the Suggestion box at the Authority offices. Additionally, the Authority Clients Charter allows for a transparent engagement with all interested parties who are encouraged to raise any issues of concern directly. This can be done verbally, official letters or during inspections or meetings;

— Surveys: Periodic surveys are conducted to solicit feedback from licensees on the performance of regulatory processes. These are done during External Audits, as well as the review of Strategic Plans. The information obtained is used as an input in developing strategies for the new planning period;

— Process based: Feedback is collected during the implementation of the various regulatory experience such as licensing, development of regulations, inspection and enforcement. This is highly dependent on the ability of staff to identify issues of interest that can be used to improve the processes. Individual process owners have the responsibility to identify such issues that can be helpful during implementation of the processes;

— Management Reviews: Process owners have an opportunity to present feedback gathered for consideration during management meetings. This will enable issues to be deliberated and decisions taken on changes that can be actioned to improve the processes.

— Performance Reviews: RPAZ employees a performance management system at individual, departmental and organisational level. The review and final performance assessment provide valuable feedback that can be used to improve performance. Good practices from individuals, and departments can be collected for the benefit of others in the organisation. Similarly, opportunities for improvement are identified to remedy areas of weakness.

— Conferences and Workshops: Reports from staff after attending conferences and workshops also present valuable feedback that is useful for improvement of processes.

VIII-4. BENEFITS

— Incremental improvements;

— Improved stakeholder relations;

— Continual staff development.

VIII-5. CHALLENGES

— Although feedback is collected, there is no dedicated process or guidance for such activities. It is left to individual process owners on how such feedback is collected;

— Collection of feedback is at irregular intervals/ erratic as it is not a priority;

— Lack of skills and poor attitude on importance of regulatory experience;

— Lack of manpower leading to lower prioritization of feedback collection;

— Absence of electronic tools for collection and analysis of feedback;

— Limited stakeholder interaction activities such as workshops, trainings and seminars.

ANNEX IX. SHARING AND IMPLEMENTING REGULATORY EXPERIENCE BETWEEN COM-PETENT AUTHORITIES (BMU. GERMANY)

IX-1. CONTEXT

Germany is a republic with a federal structure and is composed of 16 federal states. Within the governmental structure, the responsibility for nuclear safety and radiation protection lies with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU). The licensing procedure for operation and decommissioning and the continuous regulatory supervision of German nuclear power plants lie within the responsibility of the individual federal states. To preserve legal uniformity for the entire territory of the Federal Republic of Germany, the BMU is responsible for issuing legislation. It also acts to harmonize the licensing and supervisory activities of the state authorities regarding legality and expediency.

In order to fulfil its statutory responsibilities related to the safe utilization of nuclear energy, the BMU's role is to clarify fundamental issues that are relevant to the safety of nuclear facilities. The German Atomic Energy Act and the ordinances based on it are – with some exceptions – implemented by the federal states on behalf of the federal government.

The Atomic Energy Act includes the general national regulations for protective and preventive measures, radiation protection as well as for radioactive waste and spent fuel management in Germany and is the basis for any associated ordinances.

As of 2018, authorized facilities under supervision are 7 nuclear power reactors in operation, 23 nuclear power reactors undergoing decommissioning, 7 research reactors in operation and 7 research reactors undergoing decommissioning. Additionally, a number of associated activities is also covered by the Atomic Energy Act and under supervision of the federal states or at the federal level.

There is no specific regulatory experience management programme prescribed. Tools for the collection, analysis and implementation of regulatory experience are implemented in different ways and used by the different responsible institutions.

The core processes of supervision of nuclear installations and the interfaces between nuclear regulatory supervision of the Federation and the federal states are defined in a handbook on cooperation between the Federation and the federal states in nuclear law.

IX-2. PROBLEM STATEMENT

With Germany being a state with a federal structure, the execution of federal laws is basically the responsibility of the federal states. This also applies to the implementation of the national Atomic Energy Act and related laws and regulations regarding nuclear power plants and research reactors. The regulatory body as a whole is therefore composed of the nuclear licensing and supervisory authorities of the Federation and the federal states. This situation requires a high level of interaction between the different institutions.

Sharing experience in this case is a question of sharing between different institutions and ensuring the same level of safety in all federal states.

IX-3. SOLUTION

For cooperation between the federal government and the federal states (Länder), the Länder Committee for Nuclear Energy (LAA) with its sub-committees and working groups is of particular importance.

The first meeting of the LAA took place in 1982. The committee integrated a number of committees, some of which had already been in existence since the 1960s, in one single body. It is a permanent Federation-Länder committee composed of representatives from nuclear licensing and supervisory authorities of the federal states and the BMU. It serves the purpose of preparatory coordination of activities of the federation and the federal states. All kinds of questions in connection with the execution of the Atomic Energy Act, the preparation of amendments or the further development of legal and administrative provisions can be discussed. In the interest of an execution of nuclear law that is as uniform throughout Germany as possible, the competent nuclear licensing and supervisory authorities of the federal states and the BMU draft regulations in consensus for the uniform handling of nuclear law. These regulations are then promulgated by the BMU. The BMU chairs the LAA and also manages its affairs. The LAA's decisions are usually taken by mutual consensus.

The LAA (Fig. IX-1) consists of four Technical Committees for issues relating to legal matters, nuclear safety, radiation protection and fuel cycle matters. Furthermore, working groups are assigned to these Technical Committees for special permanent tasks. If needed, the Technical Committees may set up ad hoc working groups for special and, in particular, urgent individual issues. The Technical Committees and the permanent working groups convene at least twice a year and more frequently if necessary. The General Committee convenes at least once a year.

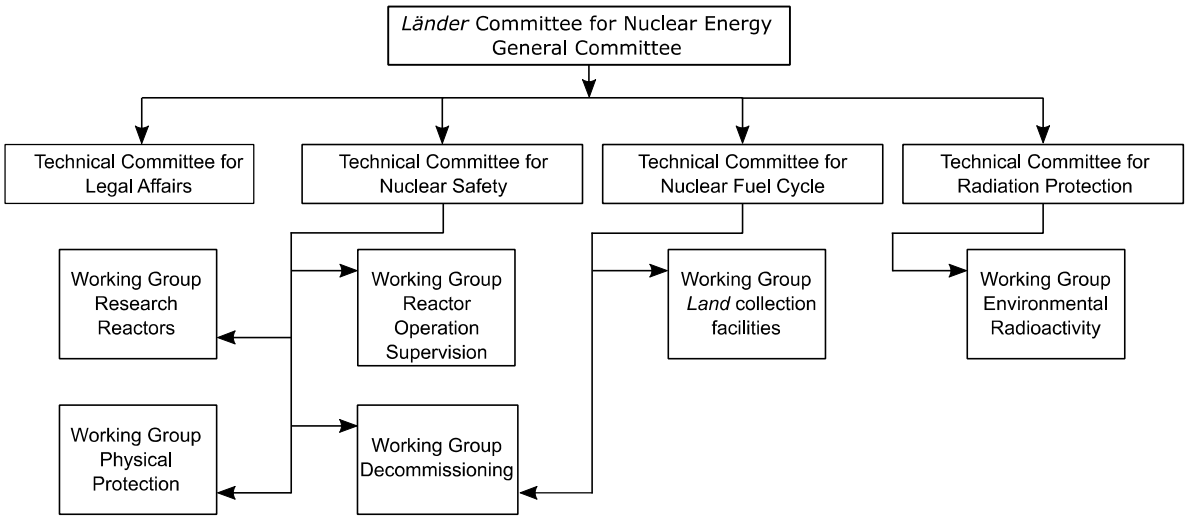

Fig.IX-1.: Structure of the Länder Committee for Nuclear Energy (LAA)

The BMU organizes the meetings and sends the invitations and the agenda for the meetings of the General Committee of the LAA. The supervisory authorities of the Länder may register agenda items and the meetings are held in accordance with the coordinated agenda. In some

cases, special sessions are conducted with a specialized group of participants. Attendees of the ordinary meetings are usually the heads of the competent authorities. For every ordinary meeting of the General Committee and of the Technical Committees one of the items on the agenda are reports from the Länder supervisory authorities, including experiences made and lessons learned in the period since the last meeting of the respective committee. This agenda item gives the opportunity to collect and analyse regulatory experience and disseminate it to all the supervisory authorities concerned.

The General Committee awards topics to the Technical Committees. The topics of the Technical Committees will be included in a work program with an indication of the goal and the deadline, which will be updated and decided at the respective meetings of the Technical Committees. The work programs of the Technical Committees are regularly submitted to the General Committee for approval.

At each meeting of the General Committee there is a decision protocol, which is drawn up by the BMU and agreed by the participants. The members of the LAA pass on the information from the meetings to their Länder authorities. Major decisions of the General Committee are even made public.

IX-4. LESSONS LEARNED

The LAA, with its Technical Committees and its associated Working Groups, is an institution for self-coordination of the federal structure of the Federal Republic of Germany and is not subject to any instructions. The committee is a well-established method to develop agreed new regulations and procedures based on the collected and analysed regulatory experience.

The discussions in the LAA are an important instrument of early and full involvement of the federal states which supplements the formal right of participation of the federal states in the legislative procedure.

The LAA can be seen as a good example for other states that rely on the successful cooperation of several different institutions or even regional offices that need to be coordinated in order to ensure the regulatory supervision of nuclear facilities and activities.

ABBREVIATIONS

ANSI	American Standards Institute
ANS	American Nuclear Society
ANSN	Asian Nuclear Safety Network
ASME	American Society of Mechanical Engineers
GNSSN	Global Nuclear Safety and Security Network
ENSREG	European Nuclear Safety Regulators Group
EPRI	Electric Power Research Institute
EPREV	Emergency Preparedness Review
FINAS	Joint IAEA/NEA Fuel Incident Notification and Analysis System
IATA	International Air Transport Association
IEA	International Energy Agency of the OECD
IEEE	Institute of Electrical and Electronics Engineers
INES	International Nuclear and Radiological Event Scale
INPO	Institute of Nuclear Power Operations
IRRS	Integrated Regulatory Review System
IRS	Joint IAEA/NEA International Reporting System for Operating Experience
IRSRR	IAEA Incident Reporting Systems for Research Reactor
ISO	International Organization for Standardization
NEA	Nuclear Energy Agency of the OECD
OECD	Organization for Economic Co-operation and Development
OSART	Operational Safety Review Team
PRIS	Power Reactor Information System
REGNET	International Regulatory Network
SMR	Small Modular Reactors

SALTO	Safety Aspects of Long Term Operation
WANO	World Association of Nuclear Operators
WENRA	Western European Nuclear Regulators Association
WHO	World Health Organization

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2nd Consultancy Meeting: Vienna, Austria: 27 November – 1 December 2017
3rd Consultancy Meeting: Vienna, Austria: 16 – 20 April 2018
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