# IAEA SAFETY STANDARDS

**for protecting people and the environment**

**Step 7: First review of the draft by the Review Committees**

# Regulatory Experience Feedback Management

# DS547

# DRAFT GENERAL SAFETY GUIDE

New Safety Guide

CONTENTS

# 1. INTRODUCTION

## BACKGROUND

1.1. Paragraph 1.2 of IAEA Safety Standards Series No. SF-1, Fundamental Safety Principles [1] states that: "Regulating safety is a national responsibility. However, radiation risks may transcend national borders, and international cooperation serves to promote and enhance safety globally by exchanging experience."

1.2. Principle 3 of SF-1 [1] states that **"Effective leadership and management for safety must be established and sustained in organizations concerned with, and facilities and activities that give rise to, radiation risks."** Further, para. 3.12 of SF-1 [1] states that "The management system also has to ensure the promotion of a safety culture, the regular assessment of safety performance and the application of lessons learned from experience."

1.3. Requirement 15 of IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety [2] 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."**

1.4. IAEA Safety Standards Series No. SSG-50, Operating Experience Feedback for Nuclear Installations [3] provides recommendations to operators and to regulatory bodies on establishing, implementing, assessing and continuously improving an operating experience programme for nuclear installations.

1.5. Reference [4] provides practical guidance to regulatory bodies for proactively collecting regulatory experience, analysing this experience, implementing any improvements and disseminating the lessons learned.

1.6. This Safety Guide provides recommendations for regulatory bodies on how to meet Requirement 15 of GSR Part 1 (Rev. 1) [2] on establishing, implementing, assessing and continuously improving regulatory experience arrangements.~~to effectively manage the regulatory experience feedback~~. ~~A proactive approach of the regulatory body to managing regulatory experience should contribute to enhancing their regulatory requirements and practices through the application of the lessons learned from their own experience and from the experience of regulatory bodies of other countries.~~

## OBJECTIVE

1.7. The objective of this Safety Guide is to provide recommendations for the regulatory bodies on how to systematically collect, analyse, implement and disseminate lessons learned from their own experience, as well as from national and international experience regarding the implementation of regulatory functions and processes to facilitate continuous improvement and ~~so that they can~~ enhanced ~~their~~ regulatory effectiveness for ensuring safety of facilities and activities.

~~1.7.~~

SCOPE

1.8. The scope of this Safety Guide covers regulatory experience feedback management for all functions and processes of a regulatory body and for all types of facilities and activities that give rise to radiation risks taking into account the application of a graded approach.

1.9. This Safety Guide is applicable to regulatory bodies[1], as well as to their technical support organizations. This Safety Guide might also be useful for operating organizations, vendors, designers and supply chain organizations particularly regarding their internal supervision and/or audit functions for ensuring safety.

1.10. This Safety Guide does not address regulatory experience relating to nuclear security, although some of the recommendations contained in this Safety Guide are general and can be applied to nuclear security.

STRUCTURE

1.11. The concept of regulatory experience, including the linkage between regulatory experience and operating experience, is provided in Section 2. Section 3 provides recommendations for developing and implementing a regulatory experience feedback management process which includes information on collecting and analyzing the findings and implementation of action plan for improving the regulatory framework, functions and processes. The recommendations on disseminating the lessons learned are also covered in Section 3. Section 4 provides guidance on integrating regulatory experience feedback into the management system. Application of a graded approach in establishing and implementing this process is presented in Section 5. Section 6 provides recommendations on performing the analysis of regulatory experience feedback management process and Section 7 covers the training aspects. ~~The~~ Appendix-I provides additional guidance on the sources of regulatory findings while Appendix-II provides ~~additional~~ detailed guidance on the identification of regulatory experience findings. Annex I describes the linkage between regulatory experience and operating experience and Annex II provides the example checklist for identifying lessons learned and good practices~~information on the sources of regulatory findings~~.

## 2. THE CONCEPT OF REGULATORY EXPERIENCE

2.1. Paragraph 3.4 of GSR Part 1 (Rev. 1) [2] states:

> “The regulatory body shall establish and maintain a means for receiving information from other States, regulatory bodies of other States, international organizations and authorized parties, as well as a means for making available to others lessons learned

[1] A regulatory body is “An authority or a system of authorities designated by the government of a State as having legal authority for conducting the regulatory process, including issuing authorizations, and thereby regulating the nuclear, radiation, radioactive waste and transport safety” [5].

from operating experience and regulatory experience. The regulatory body shall require appropriate corrective actions to be carried out to prevent the recurrence of safety significant events. This process involves acquisition of the necessary information and its analysis to facilitate the effective utilization of international networks for learning from operating experience and regulatory experience."

2.2. Paragraph 3.20 of IAEA Safety Standards Series No. GSG-12, Organization, Management and Staffing of the Regulatory Body for Safety [6] states that "effective management for safety ~~recommends regulatory body to~~will take into account the knowledge and information resulting from both positive and negative experiences (e.g. good practices and bad practices)~~operating and regulatory experiences for the effective management for safety~~. It includes a non-exhaustive list of examples of information and knowledge relevant for regulatory bodies, such as collective experience of the staff of the regulatory body, lessons learned from regulatory practices, feedback of experience from other authorities and national and international bodies, and operating experience in authorized facilities and activities in the State and in other States. Furthermore, IAEA Safety Standards Series No. GSG-13, Functions and Processes of the Regulatory Body for Safety [7] provides recommendations on utilizing operating and regulatory experience in order to enhance the regulatory functions and core processes.

~~2.2.~~2.3. A proactive approach of the regulatory body to managing regulatory experience should contribute to enhancing their regulatory requirements and practices through the application of the lessons learned from their own experience and from the experience of regulatory bodies of other Member States.

2.4. In order to implement Requirement 15 of GSR Part 1 (Rev. 1) [2], the regulatory body should distinguish the differences between regulatory ~~operating~~ experience and operating ~~regulatory~~ experience. For the purpose of this document, ~~The~~ regulatory experience refers to insights and lessons to be learned from the analysis of information gathered from all activities related to the implementation of regulatory functions and processes. ~~The o~~Operating experience pertains to insights and lessons to be learned from the operation of regulated facilities and activities, including events and other observations, such as potential problems relating to equipment and human performance, safety related concerns, situations that are likely to give rise to errors and need to be addressed to prevent undesired effects, procedural deficiencies and inconsistencies in documentation. The feedback from both the regulatory experience and operating experience contributes to enhancing the overall safety of facilities and activities. ~~The o~~Operating experience can also provide insights related to regulating the facilities and activities which may lead to improving the regulatory process. The link between regulatory experience and operating experience is explained in Annex I.

~~2.3. Regulatory bodies should make appropriate arrangements to identify lessons to be learned from regulatory experience, including regulatory experience in other States, as well as to disseminate these lessons to interested parties for their use.~~

~~2.4.~~2.5. The regulatory process reflects the ~~accumulated~~ knowledge and information resulting from operating and regulatory experiences for the effective management for safety at a given time, and new experiences and context developments can lead to further changes. Regulatory bodies should strive to continuously gain and manage regulatory experience from both internal and external sources to ~~have access to a wider range of information about situations they have experienced, as the analysis of these situations could lead to~~ identify improvement opportunities in delivering their mandate. Proactively seeking these opportunities by

integrating regulatory experience feedback management into the daily work of regulatory bodies helps the regulatory body fulfil its mission and ensures that the national regulatory framework, functions and processes remain effective and up to date.

~~2.5.~~2.6. The regulatory body should promote the concept of a learning organization ~~as a strategic objective~~ for continuously improving its performance. These improvements can be achieved at various levels in the regulatory body such as:

- At the organizational level, through organizational improvement projects under the supervision of senior management;
- At the level of management system processes, under the supervision of the process owners;
- At the working level within a process, by those directly involved in daily activities;~~.~~
- At the external level, by leveraging learning opportunities and best regulatory practices from national and international organizations and relevant activities.

~~2.6.1.1. In order to implement Requirement 15 of GSR Part 1 (Rev. 1) [2], the regulatory body should distinguish the differences between operating experience and regulatory experience. The regulatory experience refers to insights and lessons to be learned from the analysis of information gathered from all activities related to the implementation of regulatory functions and processes. The operating experience pertains to insights and lessons to be learned from the operation of regulated facilities and activities, including events and other observations, such as potential problems relating to equipment and human performance, safety related concerns, situations that are likely to give rise to errors and need to be addressed to prevent undesired effects, procedural deficiencies and inconsistencies in documentation. The feedback from both the regulatory experience and operating experience contributes to enhancing the overall safety of facilities and activities.~~

~~2.7. Requirement 24 of IAEA Safety Standards Series No. SSR-2/2 (Rev. 1), Safety of Nuclear Power Plants: Commissioning and Operation [8] states that **"The operating organization shall establish an operating experience programme to learn from events at the plant."** Paragraph 5.27 of SSR-2/2 (Rev. 1) [8] states that "[the operating organization] shall obtain and evaluate available information on relevant operating experience at other nuclear installations to draw and incorporate lessons for its own operations, including its emergency arrangements". SSG-50 [3] provides recommendations for establishing, implementing, assessing and continuously improving an operating experience programme for nuclear installations.~~

~~2.8. The operating experience can also provide insights related to regulating the facilities and activities which may lead to improving the regulatory process. The link between regulatory experience and operating experience is explained in Annex I.~~

## 3. MANAGEMENT OF REGULATORY EXPERIENCE FEEDBACK

3.1. Effective management of regulatory experience feedback involves appropriate arrangements for the collection and analysis of information and knowledge resulting from regulatory experience and for the implementation of lessons learned from that experience.

3.2. The regulatory body should ~~assess its existing integrated management system to~~ decide how, in its management system, ~~whether~~ the arrangements for managing regulatory experience should be established. This could be as a specific process to identify lessons to be learned from all the regulatory processes leading to regulatory experience or ~~whether the arrangements should~~it could be embedded within the existing regulatory functions and processes.

3.3. When the regulatory responsibility for ensuring safety is shared among more than one organization, the regulatory body should collaborate with these organizations ~~while developing and implementing the regulatory experience feedback management process~~to establish effective regulation considering the responsibilities assigned to different organizations. ~~This collaboration should aim at ensuring that regulatory processes are harmonized across different organizations.~~ The safety–security interface should also be addressed to ensure that regulatory requirements are applied consistently and effectively and in an integrated manner so that security measures do not compromise safety and safety measures do not compromise security.

3.4. The effective management of regulatory experience feedback should include appropriate arrangements for, taking into account a graded approach:

- Collecting findings from various sources (see paras 3.7–3.16);
- Analysing findings and developing the action plan to address the gaps and identify opportunities for improvement (see paras 3.17–3.20);
- Implementing the action plan (see paras 3.21–3.22);
- Disseminating the lessons learned (see paras 3.23-3.29).

– A typical arrangement for managing the regulatory experience feedback, containing the recommended elements, is depicted in the schematic diagram shown in Fig.1.

~~3.5. The process for managing regulatory experience feedback for safety should emphasize the importance of collecting and analysing findings and implementing improvement actions to enhance regulatory framework, functions and processes.~~

3.5. A complete retrievable dossier documenting the entire regulatory experience feedback management process should be maintained. The regulatory body may complement the information recorded in management system by creating a separate retrievable dossier documenting the entire regulatory experience feedback management process. The dossier will help retain information about the analysis performed and decisions taken for trending analysis and future consultation.

~~3.6.~~

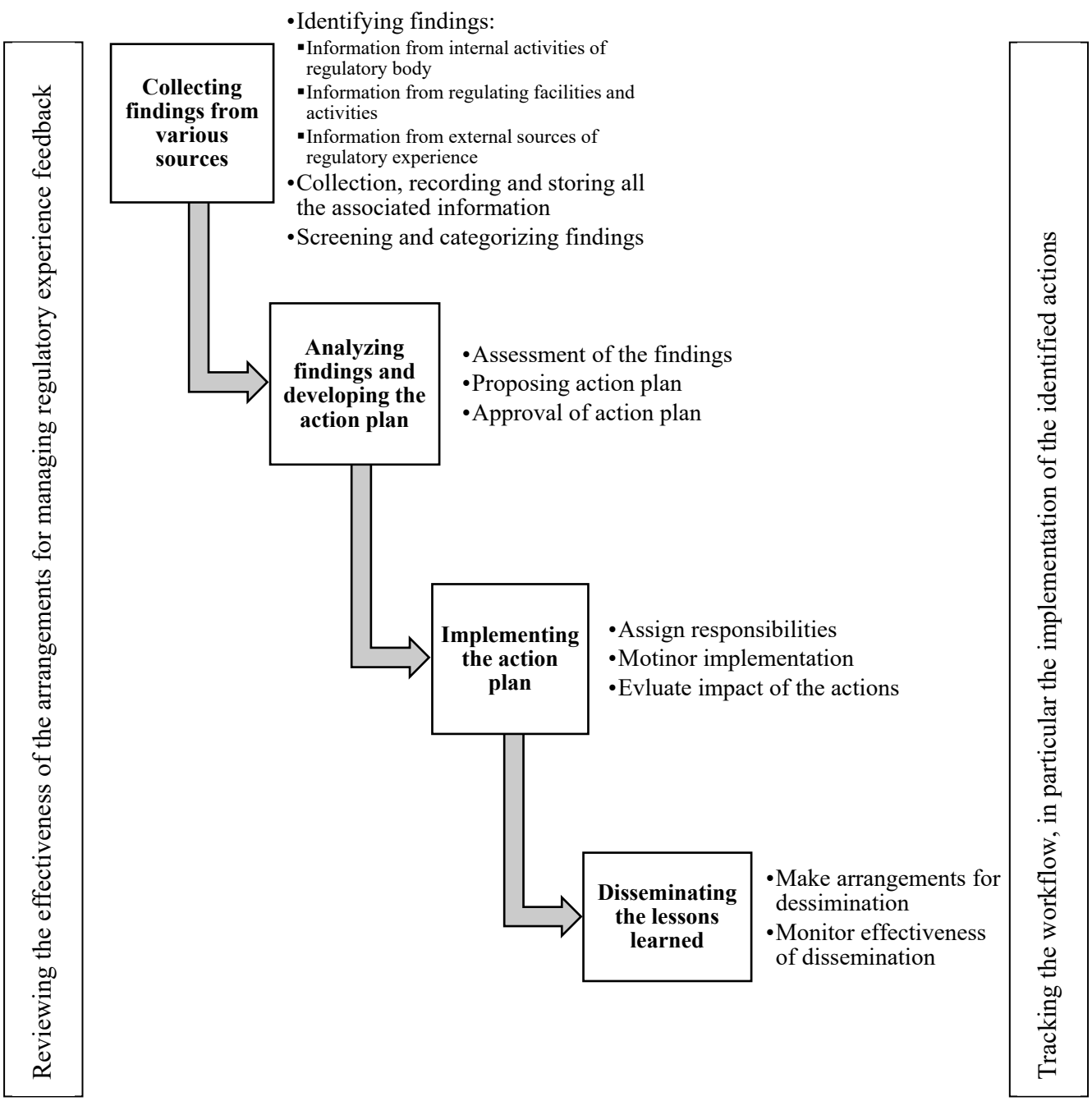


*FIG. 1~~1~~. Typical arrangement for managing regulatory experience feedback.*

COLLECTING FINDINGS FROM VARIOUS SOURCES

~~3.7.~~3.6. The first element of managing regulatory experience feedback is the collection of regulatory experience findings[2] from various sources utilizing appropriate tools and techniques for knowledge management ~~in order to improve the regulatory process~~. The collection of ~~regulatory experience~~ findings should clarify how the relevant information is identified; collected, recorded and stored; and screened and categorized.

**Identifying findings**

~~3.8.~~3.7. The management of the regulatory body should promote positive ~~traits~~ attitude in the personnel of the regulatory body through training activities, coaching and mentoring, and providing appropriate tools for documenting and communicating potential findings. ~~Regulatory experience findings should be identified as part of the management of regulatory experience feedback.~~ Without findings there are no lessons to be learned. Therefore, guidance and training should be provided to personnel on how to recognize and document potential findings, internal and external, that can be used to improve the regulatory functions and processes, and to ensure that relevant regulatory experience is captured in a timely manner and can be used for improving regulatory effectiveness. This training and guidance can also help to optimize the resources of the organization for management of regulatory experience.

~~3.9.~~3.8. The sources that can be used for identification of findings include information from internal activities of the regulatory body, information from regulating facilities and activities, and information from external sources of regulatory experience. The regulatory body should define the most relevant external sources whose lesson learnt are to be followed. Further information on the sources of findings is provided in Annex II. The Appendix provides additional guidance for the regulatory bodies to assist the personnel in identifying potential findings.

~~3.10.~~3.9. The regulatory body should address the following key areas to create an environment promoting the identification of ~~regulatory experience~~ findings by personnel at all levels:

(a) Guidance: The management should provide guidance to the personnel on sources of regulatory experience, criteria for identifying potential findings, and means of collection and reporting of these potential findings.
(b) Questioning attitude: The management should encourage personnel at all levels to maintain a questioning attitude and proactively identify potential findings.
(c) Ownership and commitment: The management should emphasize the importance of ownership, commitment, motivation, and willingness to learn for sustaining an effective regulatory experience feedback management process among all personnel.
(d) Regulatory functions inquiry: The management should prompt personnel at all levels to consider if regulatory functions and processes can be enhanced for more effective and efficient regulation of facilities and activities.

~~3.11.~~3.10. In case a new safety significant issue is identified from the process for identifying regulatory findings, ~~appropriate~~ immediate action should be taken to restore safe circumstances

[2] Regulatory experience findings, referred to as 'findings' throughout this publication, include information relating to issues, difficulties, inefficiencies, as well as good practices of the regulatory process at the national and international level.

as soon as possible and report the action to management. ~~actions should be taken for further investigation and this should be considered as a potential topic for further regulatory research and development.~~

**Collecting, recording and storing information relating to findings**

~~3.12.~~3.11. Once 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. The regulatory body should make arrangements for gathering findings, including defining the responsibilities of the personnel of the regulatory body for monitoring various information sources and documenting substantive information related to findings.

~~3.13.~~3.12. The regulatory body should make arrangements for recording and storing the collected findings, including those findings which are communicated informally (e.g. orally or through other informal communication means).

~~3.14.~~3.13. The regulatory body should consider integrating ~~regulatory experience~~ findings into the existing records system within the management system or establishing a new system taking into consideration factors such as type of information, reliability, access, security, retrievability and storage duration of the collected findings.

**Screening and categorizing findings**

~~3.15.~~3.14. The regulatory body should make the necessary arrangements for screening and categorization of findings, including clearly defined roles and responsibilities of personnel and necessary resources, such as availability of suitably qualified personnel, financial resources, tools and equipment, thresholds for screening the findings and criteria for categorization of the findings.

~~3.16.~~3.15. In order to ensure effective screening and categorization of the findings, the regulatory body:

(a) Should identify findings which ~~involve~~ require more detailed analysis by defining and utilizing clear criteria to ensure verifiable and consistent implementation of the process for effectively managing the regulatory experience feedback. The criteria will determine the workload associated with further steps during the detailed assessment, identification of lessons, and development and implementation of the action plan.

(b) Should document information relating to the process such as the name of the person conducting the screening and categorization, dates of screening and investigation, a file title (following a file naming convention that allows ease of reference) and a brief description of the finding along with the relevant justification explaining why the finding was screened-in or screened-out for future reference and record. In addition, for screened-in findings, the categorization of the finding should be included to allow for further analysis.

~~(b)~~(c) Should identify where similar findings have been raised previously, and if so determine whether there are existing action plans to address the findings or a need for further analysis.

## ANALYSING FINDINGS AND DEVELOPING THE ACTION PLAN

~~3.17.~~3.16. The purpose of analysing the regulatory experience feedback findings is to undertake a comprehensive analysis of the screened-in findings, and to develop an action plan to address the gaps and identify opportunities for ~~improvement~~improving the regulatory framework.

~~3.18.~~3.17. The regulatory body should include the following arrangements for the analyses of findings and for developing the associated action plan:

(a) Involvement of suitably qualified personnel for conducting a multifaceted analysis. This analysis should comprise a comprehensive and thorough examination of the findings from multiple perspectives such as technical, operational and organizational, should involve experts from various disciplines and should take into consideration the impact of ~~regulatory experience~~ findings on regulatory functions and processes.

(b) Assessment of each finding covering the relevant elements potentially affected by the finding, including human, technical, legal, financial and managerial elements. Consultations may be held with internal (e.g. process owners, senior management, technical experts within the organization) and external interested parties (e.g. authorized parties, vendors, other regulatory bodies) to gather diverse perspectives and feedback on the findings.

(c) Development of an action plan, which may result in actions ranging from minimal to substantive changes in the regulatory framework, functions or processes. The action plan should ~~define the roles and responsibilities of~~identify the personnel responsible for its implementation.

(d) Review and approval of the action plan by the senior management of the regulatory body taking into account factors such as the safety implications of the identified actions; the outcomes of consultations; a cost-benefit analysis; the impact on interested parties; and follow-up actions.

~~3.19.~~3.18. The decision making process and the rationale for the finalization of the action plan should be documented for transparency and future reference.

~~3.20.~~3.19. The approved action plan should ~~include~~ consider specific instructions for disseminating the lessons learned, when necessary.

## IMPLEMENTING THE ACTION PLAN

~~3.21.~~3.20. After approval of the action plan, the actions should be assigned to the personnel responsible for its implementation.

~~3.22.~~3.21. The regulatory body should make the following arrangements for implementing the action plan derived from the regulatory experience feedback management process:

(a) Coordinating the execution of the action plan ensuring availability of the necessary resources, as well as ensuring the involvement of third parties or external interested parties, if necessary. For example, when there are more than one authority with responsibility for

safety, when cooperation with regulatory bodies of other countries or external technical support organizations is envisaged.

(b) Monitoring the implementation of the action plan which includes tracking the implementation progress. ~~and.~~

(c) Evaluating the impact of actions on the regulatory functions and processes, assessing their effectiveness by analyzing performance metrics, gathering feedback from the target audience, and comparing results to baseline data, and providing updates to senior management.

## DISSEMINATING THE LESSONS LEARNED

~~3.23.~~3.22. Paragraph 3.4 of GSR Part 1 (Rev. 1) [2] states:

> "The regulatory body shall establish and maintain a means for receiving information from other States, regulatory bodies of other States, international organizations and authorized parties, as well as a means for making available to others lessons learned from operating experience and regulatory experience."

~~3.24.~~3.23. Paragraph 3.5A of GSR Part 1 (Rev. 1) [2] states that "Relevant information and lessons learned from regulatory experience shall be reported in a timely manner to international knowledge and reporting networks."

~~3.25.~~3.24. Furthermore, para. 2.8 of GSR Part 1 (Rev. 1) [2] states:

> "To be effectively independent from undue influences on its decision making, the regulatory body:
>
> …….
>
> (f) Shall be able to liaise directly with regulatory bodies of other States and with international organizations to promote cooperation and the exchange of regulatory related information and experience."

~~3.26.~~3.25. Paragraph 2.33 of IAEA Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [9] states:

> "The regulatory body shall ensure that mechanisms are in place for the timely dissemination of information to relevant parties, such as suppliers of and users of sources, on lessons learned for protection and safety from regulatory experience and operating experience, and from incidents and accidents and the related findings. The mechanisms established shall, as appropriate, be used to provide relevant information to other relevant organizations at the national and international level."

~~3.27.~~3.26. The regulatory body should make arrangements for dissemination of the lessons learned from the regulatory experience feedback management process for their use by other

regulatory bodies with the responsibility for safety and other relevant organizations, nationally or internationally. The lessons learned might be useful for authorized parties, vendors, designers and supply chain organizations.

~~3.28.~~3.27. The regulatory body should foster openness and transparency when deciding about sharing and disseminating lessons learned. Both areas for improvement as well as good practices could be shared and disseminated.

~~3.29.~~3.28. The regulatory body's plan for disseminating lessons learned from regulatory experience should include, at a minimum, the following four elements:

- Target recipients: Identifying and defining the recipients of the shared information, which may include the personnel of the regulatory body, licence holders, other national authorities and relevant international organizations.
- Means and channels for dissemination: Deciding on the best approach to reach the target recipients, considering factors like purpose for sharing the lessons learned, needs of the target recipients, and means of sharing.
- Implementing the action plan: Establishing clear instructions for implementing the action plan to effectively disseminate the lessons learned from regulatory experience.
- Monitoring mechanisms: Implementing mechanisms to monitor the execution and effectiveness of the sharing and dissemination activities, with provisions for necessary follow-up actions. To review the effectiveness of sharing and dissemination, the regulatory bodies should assess how well the sharing and dissemination has achieved the intended purpose. This can be achieved, by analyzing performance metrics, gathering feedback from the target audience, and comparing results to baseline data.

## 4. INTEGRATION OF THE REGULATORY EXPERIENCE FEEDBACK MANAGEMENT PROCESS INTO THE MANAGEMENT SYSTEM

4.1. Paragraph 4.11 of IAEA Safety Standards Series No. GSR Part 2, Leadership and Management for Safety [10] states that "The organizational structures, processes, responsibilities, accountabilities, levels of authority and interfaces within the organization and with external organizations shall be clearly specified in the management system."

4.2. Paragraph 1.5(b) of GSR Part 2 [10] states that "The management system also has to ensure the fostering of a strong safety culture, the regular assessment of safety performance and the application of lessons from experience". Moreover, para. 4.9 of GSR Part 2 [10] states that:

> "The management system shall be applied to achieve goals safely, to enhance safety and to foster a strong safety culture by:
>
> (a) Bringing together in a coherent manner all the necessary elements for safely managing the organization and its activities;"

4.3. The regulatory body should integrate the regulatory experience feedback management process within its ~~integrated~~ management system to foster a systematic approach to capturing, analysing and applying lessons learned from regulatory experience. These arrangements should be effectively interconnected with all processes contributing to regulatory experience and

should be consistent and well-aligned with quality management, knowledge management, and the promotion of safety culture. Recommendations on establishing an integrated management system of the regulatory body are provided in GSG-12 [6]

4.4. The regulatory body should provide in its policy a basis for formally documenting its intent and the senior management's commitment to maintaining effective regulatory oversight through continuous review and improvement, and through the use of regulatory experience feedback. Further, senior management should use these high level policy and leadership statements to underline the role of regulatory experience management within the organization's culture for safety.

4.5. The senior management of the regulatory body should allocate the necessary resources to develop, implement and sustain a regulatory experience feedback management process fostering an enabling environment by motivating the personnel and demonstrating commitment by its actions.

4.6. The regulatory body should ensure that knowledge management captures, ~~and~~ retains and keeps visible ~~the~~ outcomes of the regulatory experience feedback management process and vice-versa.

4.7. The regulatory body should promote the collection of information and knowledge resulting from experience at all levels in the organization to ensure that all learning opportunities are successfully managed. Therefore, a proactive attitude of individual process owners is an important contributing factor to successfully manage the regulatory experience. The owner of a specific regulatory process should proactively take regulatory experience feedback into account in reviewing the process to keep it up to date and effective. The process owners can play an important role by proactively raising ~~regulatory experience~~ findings to the attention of senior management. 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 and processes. This approach also encourages dialogue on the benefits to be gained from effective management of regulatory experience throughout the organization and promotes its daily utilization.

## 5. APPLICATION OF A GRADED APPROACH TO REGULATORY EXPERIENCE FEEDBACK MANAGEMENT

5.1. The application of a graded approach underpins the effective and efficient performance of the regulatory framework of a country. Paragraph 4.3 of GSR Part 1 (Rev. 1) [2] states that "The performance of regulatory functions shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."

5.2. Paragraph 4.5 of GSR Part 1 (Rev. 1) [2] states that "The regulatory body shall allocate resources commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."

~~5.3. Furthermore, para. 4.39A of GSR Part 1 (Rev. 1) [2] states that "The regulatory body shall ensure, adopting a graded approach, that authorized parties routinely evaluate operating experience and periodically perform comprehensive safety reviews of facilities."~~

~~5.4.~~5.3. The regulatory body should ~~apply a graded approach while~~ develop~~ing~~ and implement~~ing~~ the management of regulatory experience feedback in line with Requirement 16 of GSR Part 1 [2] and Requirement 7 of GSR Part 2 [10]. The regulatory body should take into account the criteria mentioned in para. 4.15 of GSR Part 2 [10] to identify and analyse the findings, define the actions and assign priority level or urgency to implement the actions originating from the management of regulatory experience feedback.

~~5.5.~~5.4. The management of regulatory experience feedback should be developed commensurate with the context, objectives, needs and priorities of the regulatory body. Other factors, such as the size of the regulatory body, its organizational structure, the overall design and structure of the management system should also be considered in the design. The regulatory body should consider additional factors when designing the management of regulatory experience feedback which may include the following:

- The existence of other processes of the management system that can contribute to the establishment and application of the regulatory experience feedback management process;
- Integration with other information management systems[3]~~;~~.
- Provision of adequate human and financial resources.

~~5.6. There are two key stages in the regulatory experience feedback management process where a graded approach should be applied: the identification of regulatory experience findings and the screening of the feedback from regulatory experience. The regulatory body should develop criteria in accordance with a graded approach to determine what regulatory experience feedback should be considered potentially relevant for screening. These criteria will determine the workload associated with further steps during the detailed assessment, development and implementation of the action plan and the identification of lessons.~~

~~5.7.~~5.5. The regulatory body should apply a graded approach in assessing the ~~regulatory experience~~ findings, defining actions and the implementation of the actions taking into account factors such as safety implications, external consultations, cost-benefit analysis, impact on stakeholders, as well as when and how to do it.

~~5.8.~~5.6. The regulatory body should ~~apply a graded approach in the~~ disseminat~~cion of~~ the lessons learned from the regulatory experience feedback management process. The significance of the ~~regulatory experience~~ findings may have a different degree of relevance, both inside and outside the organization of the regulatory body, nationally or internationally, depending on how the lessons learned will contribute to enhance the regulatory framework, functions and processes and, ultimately, to improve safety of the regulated facilities and activities.

[3] The information management system refers to a structured framework used to collect, store, manage and disseminate information within an organization which may include different types of databases.

## 6. ANALYSIS OF THE EFFECTIVENESS OF THE REGULATORY EXPERIENCE FEEDBACK MANAGEMENT PROCESS

6.1. Requirement 19 of GSR Part 1 (Rev.1) [2] states that **"The regulatory body shall establish, implement, assess and improve a management system that is aligned with its safety goals and contributes to their achievement."** Requirement 13 of GSR Part 2 [10] states that **"The effectiveness of the management system shall be measured, assessed and improved to enhance safety performance, including minimizing the occurrence of problems relating to safety."** To implement these requirements, the regulatory body should continuously evaluate the management of regulatory experience feedback for its effectiveness into its assessments of authorized party's safety performance.

6.2. Paragraph 6.7 of GSR Part 2 [10] states:

> "The management system should include evaluation and timely use of the following:
>
> (a) Lessons from experience gained and from events that have occurred, both within the organization and outside the organization, and lessons from identifying the causes of events;
>
> (b) Technical advances and results of research and development;
>
> (c) Lessons from identifying good practices."

6.3. Paragraph 6.8 of GSR Part 2 [10] states that "Organizations shall make arrangements to learn from successes and from strengths for their organizational development and continuous improvement."

6.4. Paragraph 5.34 of GSG-12 [6] states that:

> "To achieve sustained success, managers at all levels should monitor, measure and review performance with the aim of:
>
> — Learning from experience, and improving performance and the integrated management system;"

6.5. An appropriate governance should be established within the management system of the organization to monitor performance and effectiveness of the regulatory experience feedback management process and to embrace a culture of continuous improvement.

6.6. The regulatory body should periodically evaluate the degree of utilization and proper functioning of the arrangements to manage the regulatory experience feedback to explore possible improvements. Tools such as management reviews, self-reflections, self-assessments or ~~independent~~ external assessments, including peer reviews and advisory missions, can be used to carry out these evaluations.

6.7. The regulatory body should address the following elements in the context of its organization that might impact the effectiveness of regulatory experience feedback management:

(a) Resources: The regulatory body should establish a balance between the resources needed to manage regulatory experience feedback and the added value of this feedback towards improving the regulatory framework, as well as the regulatory functions and processes.

~~(a)~~(b) Complacency: The regulatory body should take measures to avoid complacency and ensure that the management of regulatory experience feedback adds value by enhancing the effectiveness and efficiency of regulatory processes.

~~(b)~~(c) Misuse: The regulatory body should ensure that the management of regulatory experience feedback is not being misused to express organizational or personal issues. This might occur, in particular if there are no other channels available for raising such issues.

~~(c)~~(d) Silo mentality[4]: The regulatory body should avoid the development of a silo mentality by fostering an environment of sharing experience, including information, knowledge and know-how that is valuable for enhancing the regulatory functions and processes.

~~(d)~~(e) Fear of personal consequences: The regulatory body should foster a 'no-blame'[5] working environment by establishing individual and institutional expectations towards managing regulatory experience. Management should ensure that personnel do not face any negative consequences when conducting assessments and reporting regulatory experience feedback findings.

~~(e)~~(f) Demotivation: The regulatory body should ensure that the additional workload entailed by the personnel in managing regulatory experience feedback does not demotivate personnel, which might result in less active contribution. Management should consider options for encouraging effective utilization of the management of regulatory experience feedback ~~by the personnel~~such as providing feedback on findings, involving individuals in the feedback process, emphasizing their contributions to safety, organizing regular meetings to discuss improvements, and acknowledging these efforts in reports and newsletters.

(g) Overly bureaucratic or unsuitable design: The regulatory body should design the management of regulatory experience feedback in such a way as to ensure that the workload associated with processing the findings is the minimum necessary to ensure transparency and traceability, commensurate with the radiation risks associated with facilities and activities, ~~while maintaining a reasonable balance between cost and benefit~~ in accordance with a graded approach.

(h) Safety Culture: The regulatory body should promote a positive safety culture by integrating safety considerations into all aspects of regulatory experience feedback management. This includes encouraging open communication about safety issues and ensuring that safety is a core value within the organization.

~~(f)~~(i) Risk Management: The regulatory body should make take into account the risk management in managing the regulatory experience feedback.

## 7. TRAINING OF PERSONNEL ON REGULATORY EXPERIENCE FFEDBACK MANAGEMENT

[4] For the purpose of this Safety Guide, silo mentality is used to describe 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 functions and processes.

[5] In general, a 'no-blame' environment refers to a workplace culture where staffs are encouraged to speak up about mistakes, problems, or failures without fear of blame, retaliation or negative consequences.

7.1. For effective management of regulatory experience feedback, the regulatory body should develop and implement appropriate training for the ~~relevant~~ involved personnel taking into account a graded approach. ~~This training should be tailored to the organization's specific characteristics and management system.~~ Recommendations on developing and maintaining adequate competences for the staff of the regulatory body are provided in GSG-12 [6].

7.2. The regulatory body should train the personnel so that they can develop knowledge, skills and attitude to identify, analyse and use regulatory experience feedback. Necessary tools such as non-conformance reporting mechanisms, sharing of good practices and opportunities to raise concerns, empower employees to contribute towards the continuous improvement of the process. The Appendix provides guidance on essential topics to be covered for training on regulatory experience.

7.3. The regulatory body should make arrangements to train the relevant personnel 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.

## APPENDIX I

## SOURCES OF REGULATORY EXPERIENCE FINDINGS

I.1. This appendix presents possible sources for collecting regulatory experience from which the regulatory bodies can learn lessons that could assist them in improving the regulatory framework, functions and processes. The sources listed in Tables 1 to Table 3 could be consulted, as appropriate, for the identification of potential findings.

TABLE 1. NATIONAL SOURCES OF REGULATORY EXPERIENCE

| Regulatory Function or Process | Examples of activities that can serve as a source of 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 licence conditions |
| | Licensing appeals |
| | Public consultations |
| | Policy statements |
| | Feedback from licence holders |
| Review and assessment | Safety evaluations |
| | Benchmarking with other regulatory bodies |
| | Lessons identified from operating experience feedback |
| | Lessons identified from any relevant research and development activities |
| | Technical meetings |
| Inspection of facilities and activities | Inspection reports |
| | Inspection findings |

| Regulatory Function or Process | Examples of activities that can serve as a source of regulatory experience |
|---|---|
| | Operating experience feedback from activities and facilities |
| | Relevant operating experience feedback from non-nuclear industries |
| Enforcement of regulatory requirements | Enforcement appeals |
| | Corrective actions |
| | Enforcement procedures of other national regulatory bodies |
| Emergency preparedness and response | Emergency drills and exercises, including interaction with participants and the public |
| | Coordination committees involving local, regional and State authorities |
| | Learnings identified from responses to incidents and emergencies |
| | Interaction with other national authorities directly linked with the preparation and response to emergencies |
| 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 allocating resources for government bodies, including the regulatory body |
| | Interaction with regional authorities with transferred or entrusted regulatory competences |
| | Interaction with educational and research centres |
| Communication with interested parties | Public hearings |
| | Consultation with interested parties |

TABLE 2. INTERNATIONAL SOURCES OF REGULATORY EXPERIENCE

| Topic | Examples of activities that can serve as a source of 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<br>Committees, working groups and task forces of international organizations<br>Exercises promoted by international organizations<br>Technical documents and policy guidance published by international organizations and participation in their drafting<br>Activities of the technical cooperation programmes operated by international organizations such as training courses, fellowships and scientific visits, workshops and expert missions.<br>Peer reviews and advisory missions |
| Development and use of international safety standards | Drafting groups to develop international safety standards |
| International codes of conduct on safety | Technical meetings<br>Guidance and technical reports |
| International cooperation settings among nuclear regulatory bodies | Bilateral and multilateral cooperation agreements among nuclear regulatory bodies<br>Technical exchanges under the umbrella of bilateral and multilateral agreements (e.g. benchmarking, combined exercises, shared intelligence) |
| Standards, codes of practices and publicly available technical reports of the industry | National and international standards<br>Codes of practice Technical reports from international associations for the nuclear and radiation industry |
| International reporting systems and databases | IAEA databases (e.g. INES, INIS, PRIS, IRS, FINAS, IRSRR)<br>Other databases (e.g. NEA nuclear databases, ICSBEP database on criticality safety benchmarks) |
| International research | International research programmes or projects Cooperative research projects |
| Associations, forums and networks of nuclear regulatory bodies | Associations, forums and networks of nuclear regulatory bodies and of safety related activities |

TABLE 3. NON-NUCLEAR SOURCES OF REGULATORY EXPERIENCE

| Topic | Examples of activities that can serve as a source of 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)<br><br>Lessons learned from national non-safety research and technology programmes by other non-nuclear regulatory bodies |
| International convention, treaties and agreements | Governing bodies and diplomatic conferences<br><br>Review meetings of contracting parties to conventions and national reports submitted by the Member States<br><br>Multilateral implementing regulations and agreements |
| Other international non-nuclear sources | Events from non-nuclear industries<br><br>Activities and documents of other non-nuclear international organizations (WHO, OECD/IEA, IATA…) |

I.2. The regulatory body should also decide on developing and implementing measures to facilitate access to potential sources of experience (e.g. hosting peer review missions, encouraging personnel to participate in international training and to enroll in fellowship programmes or scientific visits) or to remove access barriers to such sources (e.g. engaging in international research, concluding bilateral agreements with other countries). The regulatory body can enable reaching the external sources and the personnel of the regulatory body needs to maintain an open mind and exercise judgement on what information might or might not be useful.

I.3. Research and development is an important source of regulatory experience and, as such, a regulatory body has to explore how to effectively utilize lessons identified from research and development in keeping their framework and regulatory functions and processes up to date and effective. Regulatory bodies, though, may need to establish arrangements to address the specific characteristics of this source of regulatory experience.

## APPENDIX II

## IDENTIFICATION OF REGULATORY EXPERIENCE FINDINGS

II.1. The identification of potential ~~regulatory experience~~ findings is the primary driver of the regulatory experience management process.

II.2. Managers at all levels of the regulatory body should instill positive ~~traits~~ attitude in personnel through training and coaching, and by providing personnel with the appropriate guidance and tools to identify, document and submit potential findings.

II.3. The regulatory body should provide appropriate guidance and training to personnel to ensure that only relevant regulatory experiences are captured. This approach helps to streamline resources and avoid unnecessary expenditure on assessing findings unsuitable for the regulatory experience management process.

II.4. This appendix provides recommendations to regulatory bodies for developing and providing appropriate guidance and training to personnel to recognize and document potential findings that can improve the regulatory process.

TEMPLATES TO GUIDE THE IDENTIFICATION OF REGULATORY EXPERIENCE FINDINGS

II.5. The regulatory bodies should consider developing and using management tools such as templates, checklists and other means to guide personnel in conducting a preliminary assessment of the relevance and significance of potential findings before initiating an assessment using the regulatory experience management process. Annex-II shows a checklist that could be used for building tools to support personnel in deciding whether there are lessons to be learned to improve the regulatory process, including the identification of good practices.

II.6. When designing management tools for identifying ~~regulatory experience~~ findings, the regulatory body should also develop guidelines to help personnel identify weaknesses that should be addressed as well as strengths that could be shared related to the regulatory framework, functions and processes. At a minimum, guidance should be provided taking into consideration the following three basic dimensions associated with a finding under consideration:

- The regulatory function or process: Aspects relating to the framework, structure and constituents of the regulatory process subject to assessment, including the basic principles and methodology; regulatory objectives and criteria; technical soundness, accuracy and relevance of the information;
- The personnel: Aspects relating to the individuals in charge of the implementation of the function or process, including their qualifications, the available resources, and the availability of guidance and support by the management;
- The organizational aspects: Aspects relating to the conditions under which the regulatory process is conducted, including working environment, leadership and involvement of management, interfaces and safety culture of the organization.

II.7. Table 1 shows a checklist that should be used for building tools to support personnel in deciding whether there are lessons to be learned to improve the regulatory process, including the identification of good practices.

TABLE 1. EXAMPLE OF A CHECKLIST TO SUPPORT THE IDENTIFICATION OF REGULATORY EXPERIENCE FINDINGS

| Opportunities for improvement | Strengths |
|---|---|
| **Aspects relating to regulatory functions and processes** | |
| The regulatory process (as implemented) does not fully meet the policy, strategy and goals of the organization | The regulatory process sets an example of how to foster the principles and goals of the organization |
| The methodology of the process is not well-informed and/or technically sound and has not been sufficiently tested | The implementation methodology of the regulatory process could be replicated as a good practice for other processes |
| Interfaces between the regulatory process and other regulatory processes are not considered or properly covered | The regulatory process creates strong synergies with connected processes |
| There are not enough regulatory criteria or a consistent framework to implement the regulatory process | The regulatory process is a good example of effective and efficient compliance with regulatory criteria |
| The frequency and depth of the regulatory process do not fit the purpose and regulatory criteria | The regulatory process represents a good practice to achieve the objective and meet the requirements while optimizing the time and resources needed |
| The process (as implemented) has not been updated to cover all known regulatory experience | The process has been developed or improved based on existing 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 introduces improvements that minimize interferences and the use of resources. These improvements could be worth sharing with other interested parties |
| **Aspects relating to the personnel** | |
| There are no available appropriate procedures for personnel to implement the process | The regulatory body has put in place and revised procedures and arrangements to keep them up-to-date with new knowledge and experience |
| Personnel have not received appropriate training and guidance to understand the principles and goals of the process | The regulatory body has in place exemplary capacity building programmes, including coaching of newly recruited personnel by experienced personnel |
| There are not enough resources and means (human and technical) to implement the process | Appropriate mechanisms are in place to ensure that there are enough personnel available to implement the regulatory process in an effective and efficient way |
| Personnel do not have access to specialized support and advice to implement the regulatory process and reach the regulatory objectives | |

| ~~Opportunities for improvement~~ | ~~Strengths~~ |
|---|---|
| | ~~The regulatory body has set up appropriate arrangements to ensure availability of external expert support to ensure effective delivery of the regulatory process~~ |
| **~~Organizational aspects~~** | |
| ~~The management (at the corresponding level) is not appropriately informed of and involved in the process~~<br>~~There is not an appropriate 'no blame' culture to foster a questioning attitude and to raise concerns in the implementation of the regulatory process~~<br>~~The outcome of the process, as implemented, is not taken into consideration as part of the broader regulatory oversight process of the regulatory body~~ | ~~The outcome of the process is used to identify the lessons and to disseminate them as appropriate within and outside the organization~~<br>~~There are appropriate mechanisms to raise concerns and identify regulatory experience findings for effectively managing the regulatory experience feedback.~~<br>~~The process is well integrated within the management system and there is a multidisciplinary and complementary approach in assessing its outcomes.~~ |

MOTIVATION OF PERSONNEL

~~II.8.~~II.7. The personnel of the regulatory body at all levels play a fundamental role in achieving successful utilization of regulatory experience. Regardless of the source of regulatory experience, whether internal or external to the regulatory body, it is the individual or a group of personnel that will take the initiative to document and submit a finding for screening and analysis.

~~II.9.~~II.8. All personnel should be willing to do so based on their individual commitment to the objectives of the regulatory body and to continuous improvement. The management of the regulatory body should explore opportunities to motivate personnel, and at a minimum, should do the following:

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

— Involve personnel who raise findings along the process of regulatory experience feedback management;

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

— Organize meetings with the personnel periodically to collectively discuss examples of improvements in the regulatory process achieved through the implementation of lessons learned from ~~regulatory experience~~ findings;

— Identify personnel with the necessary skills to motivate and mentor other employes to raise regulatory findings;

— Manage the additional workload on the individuals to promote active contribution towards the process of regulatory experience feedback management;

— Reflect the improvements in the regulatory process in the annual report of the regulatory body or in internal newsletters or circulars to acknowledge involvement of personnel and further promote the utilization of the system.

TRAINING OF PERSONNEL

~~II.10.~~II.9. Suitable educational resources and training should be made available to familiarize the personnel of the regulatory body with the concept of regulatory experience management and to guide them in utilizing available tools, ensuring the effective management of regulatory experience.

~~II.11.~~II.10. The education and training of the personnel of the regulatory body on regulatory experience should be tailored to fit the regulatory experience management process. The content of an education and training programme aimed at the effective management of regulatory experience should cover the eight topics presented in Table 4. Regulatory bodies can use the guidance provided under these eight topics to develop their specific training programme as appropriate while meeting the purpose of each topic.

TABLE 4. TOPICS TO BE COVERED FOR TRAINING ON REGULATORY EXPERIENCE

| Topic | Purpose |
|---|---|
| **Topic 1: Basic Principles** | |
| Possible subjects to cover as appropriate:<br>• Concept and definition of regulatory experience<br>• Objective<br>• International standards<br>• National regulations<br>• Mission and policy statements<br>• International commitments and contribution to the global safety regime<br>• Structure of the regulatory body<br>• Interaction and coordination with other national regulatory bodies | 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 |

| Topic | Purpose |
|---|---|
| • Liaison with licence holders<br>• Liaison with advisory bodies, technical support organizationso, ther regulatory bodies and involvement in international programmes and activities<br>• Linkage and differences between operating and regulatory experience | |

**Topic 2: Benefits from effective management of the regulatory experience**

Possible subjects to cover as appropriate:

- Added value of the management of regulatory experience for enhancing the regulatory process
- Examples of situations in which regulatory experience resulted in further enhancing the management of regulatory experience feedback

This Section seeks to provide evidence of the added value of the effective management of regulatory experience by showing practical examples.

**Topic 3: Sources of regulatory experience**

Possible subjects to cover as appropriate:

- Internal sources:
  - — Core regulatory processes and functions
  - — Other regulatory functions and processes
  - — Management system
  - — Operating experience
  - — Research and development in the field of nuclear and radiation safetyAdvisory bodies and technical support organizations
- 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

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 be prioritized under the regulatory experience management process

| Topic | Purpose |
|---|---|
| ○ Associations, forums and networks of regulatory bodies | |
| **Topic 4: Arrangements for managing regulatory experience** | |
| Possible subjects to cover as appropriate:<br>• Approach and modality<br>• Roles and responsibilities in managing regulatory experience<br>• Integration within the management system and interfaces with relevant processes<br>• Management of external sources of regulatory experience<br>• Arrangements for the following:<br>— Identification of regulatory experience (e.g. through the use of templates or other means, guidance and practical examples)<br>— Collection of regulatory experience, including channels for reporting and organizing the information<br>— Storage of information, including type of information stored, means of storage, provisions for accessing and retrieving information<br>• Arrangements for analysis of regulatory experience:<br>— Criteria and thresholds for screening of findings<br>— Assessment of ~~regulatory experience~~ findings and elaboration of action plans to address findings<br>— Decision making<br>• Arrangements for implementing action plans and sharing lessons learned:<br>— Monitoring the implementation of action plans<br>— Monitoring the impact of the actions in the regulatory process<br>— 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. |
| **Topic 5: Leadership and management** | |
| Possible subjects to cover as appropriate:<br>• Management commitment to the management of regulatory experience | This Section is intended to illustrate how the management of the organization commits to an effective and efficient management of regulatory experience |

| Topic | Purpose |
|---|---|
| • Management reviews of the regulatory experience management system | |
| **Topic 6: Engaging personnel** | |
| Possible subjects to cover as appropriate:<br>• Roles and responsibilities<br>• Expectations from personnel<br>• 'No blame' culture in the work environment<br>• Personnel involvement throughout the analysis of ~~regulatory experience~~ findings and feedback<br>• Recognition of personnel contributing to the management of regulatory experience<br>• Means available to personnel for handling and communicating ~~regulatory experience~~ findings | This Section is intended to foster and encourage the personnel of the regulatory body and associated organizations to actively use the regulatory experience management process and to acknowledge the contribution of individuals in enhancing the regulatory process |
| **Topic 7: Continuous improvement of the arrangements for managing regulatory experience** | |
| Possible subjects to cover as appropriate:<br>• Self-reflection/Self-assessment<br>• 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 |
| **Topic 8: International forums for reporting on lessons learned from regulatory experience** | |
| Possible subjects to cover as appropriate:<br>• Existing international forums for reporting operating experience and how they relate to reporting regulatory experience<br>• 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 |

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## ANNEX I

## LINKAGE BETWEEN OPERATING EXPERIENCE AND REGULATORY EXPERIENCE AS PART OF MANAGING THE REGULATORY EXPERIENCE FEEDBACK

I.1. Both regulatory experience and operating experience can contribute to the enhancement of regulatory processes as well as to the safety and security of facilities and activities. However, the two concepts are different yet correlated. ~~and this~~ This annex describes the connections and differences between them. The operating experience refers to insights and lessons learned from the review of information related to the operation of facilities and activities, including events[6], while the regulatory experience refers to insights and lessons learned from the analysis of information gathered from all activities relating to the regulatory process, including lessons learned from external sources of regulatory experience.

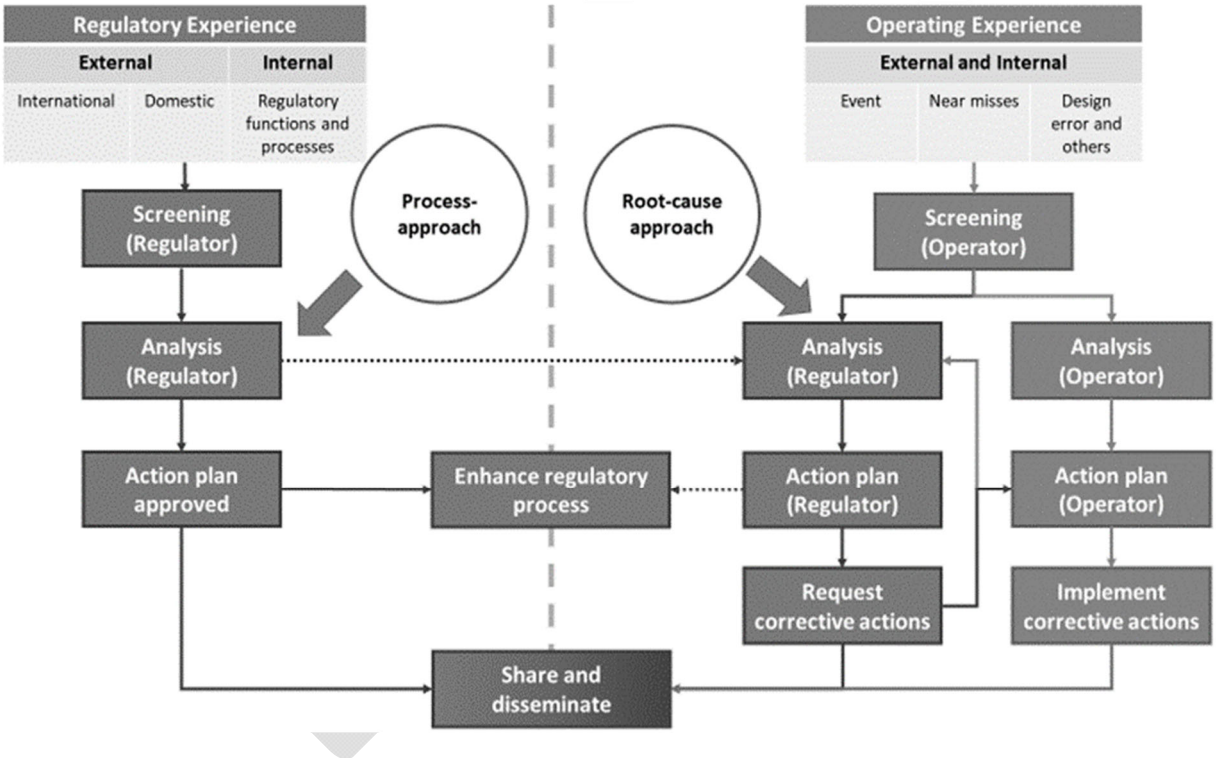


*FIG. I-1. Linkage between regulatory experience and operating experience*

I.2. Figure I-1 illustrates the linkage between regulatory experience and operating experience. As shown in the right-hand side of Fig. I-1, once an event has been identified, the operating organization informs the regulatory body as per national regulatory requirements and initiates action in a timely manner for its screening and further analysis on the basis of the actual or

[6] An event is "any occurrence unintended by the operator, including operating error, equipment failure or other mishap, and deliberate action on the part of others, the consequences or potential consequences of which are not negligible from the point of view of protection and safety" [8]. This also includes initiating events, accident precursors, near misses, accidents, as well as unauthorized acts. Operating experience includes experience from such events.

potential consequences of the event for safety. The analysis focuses on the identification of the root cause that led to the event in order to prevent or minimize the risk of similar future events.

I.3. In parallel, the regulatory body, through its own operating experience programme, assesses the operating experience reported by the operating organizations and, where relevant, made available from operating organizations in other States. The analysis of the regulatory body focuses on the identification of appropriate corrective actions to be carried out by the operating organization in order to prevent the recurrence of similar events. In addition, the regulatory body evaluates whether corrective actions are to be carried out to improve regulatory processes and practices based on the analysis of such operating experience.

I.4. The analyses of both regulatory experience and operating experience may lead to the identification of corrective actions to enhance the regulatory process but the aim and the focus of the analyses are different. In the case of the regulatory experience, the aim is at the regulatory body itself and the analysis focuses on the performance of the regulatory processes. In the case of the operating experience, the aim is at the operating organizations and the analysis focuses on the root cause of the events.

I.5. The relevant lessons learned both from regulatory experience and from operating experience are shared and disseminated to national and international organizations considering general and targeted mechanisms and approaches to ensure effective dissemination of lessons learned~~and on a need to know basis~~.

## ANNEX II

## ~~SOURCES OF REGULATORY FINDINGS~~CHECKLIST FOR IDENTIFYING LESSONS LEARNED AND GOOD PRACTICES

II.1. This annex presents 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 as shown in Table II-1.

TABLE II-1. EXAMPLE OF A CHECKLIST TO SUPPORT THE IDENTIFICATION OF REGULATORY EXPERIENCE FINDINGS

| Opportunities for improvement | Strengths |
|---|---|
| **Aspects relating to regulatory functions and processes** | |
| The regulatory process (as implemented) does not fully meet the policy, strategy and goals of the organization | The regulatory process sets an example of how to foster the principles and goals of the organization |
| The methodology of the process is not well-informed and/or technically sound and has not been sufficiently tested | The implementation methodology of the regulatory process could be replicated as a good practice for other processes |
| Interfaces between the regulatory process and other regulatory processes are not considered or properly covered | The regulatory process creates strong synergies with connected processes |
| There are not enough regulatory criteria or a consistent framework to implement the regulatory process | The regulatory process is a good example of effective and efficient compliance with regulatory criteria |
| The frequency and depth of the regulatory process do not fit the purpose and regulatory criteria | The regulatory process represents a good practice to achieve the objective and meet the requirements while optimizing the time and resources needed |
| The process (as implemented) has not been updated to cover all known regulatory experience | The process has been developed or improved based on existing 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 introduces improvements that minimize interferences and the use of resources. These improvements could be worth sharing with other interested parties |
| **Aspects relating to the personnel** | |

| Opportunities for improvement | Strengths |
|---|---|
| There are no available appropriate procedures for personnel to implement the process<br><br>Personnel have not received appropriate training and guidance to understand the principles and goals of the process<br><br>There are not enough resources and means (human and technical) to implement the process<br><br>Personnel do not have access to specialized support and advice to implement the regulatory process and reach the regulatory objectives | The regulatory body has put in place and revised procedures and arrangements to keep them up-to-date with new knowledge and experience<br><br>The regulatory body has in place exemplary capacity building programmes, including coaching of newly recruited personnel by experienced personnel<br><br>Appropriate mechanisms are in place to ensure that there are enough personnel available to implement the regulatory process in an effective and efficient way<br><br>The regulatory body has set up appropriate arrangements to ensure availability of external expert support to ensure effective delivery of the regulatory process |
| **Organizational aspects** | |
| The management (at the corresponding level) is not appropriately informed of and involved in the process<br><br>There is not an appropriate 'no blame' culture to foster a questioning attitude and to raise concerns in the implementation of the regulatory process<br><br>The outcome of the process, as implemented, is not taken into consideration as part of the broader regulatory oversight process of the regulatory body | The outcome of the process is used to identify the lessons and to disseminate them as appropriate within and outside the organization<br><br>There are appropriate mechanisms to raise concerns and identify findings for effectively managing the regulatory experience feedback.<br><br>The process is well integrated within the management system and there is a multidisciplinary and complementary approach in assessing its outcomes. |

~~II.2.~~

~~TABLE II-1. NATIONAL SOURCES OF REGULATORY EXPERIENCE~~

| ~~Regulatory Function or Process~~ | ~~Examples of activities that can serve as a source of regulatory experience~~ |
|---|---|
| ~~Regulations and guides~~ | |
| ~~Review and assessment~~ | ~~Safety evaluations~~<br><br>~~Benchmarking with other regulatory bodies~~<br><br>~~Lessons identified from operating experience feedback~~<br><br>~~Lessons identified from any relevant research and development activities~~ |

| Regulatory Function or Process | Examples of activities that can serve as a source of regulatory experience |
|---|---|
| | Technical meetings |
| Inspection of facilities and activities | Inspection reports<br>Inspection findings<br>Operating experience feedback from activities and facilities<br>Relevant operating experience feedback from non-nuclear industries |
| Enforcement of regulatory requirements | Enforcement appeals<br>Corrective actions<br>Enforcement procedures of other national regulatory bodies |
| Emergency preparedness and response | Emergency drills and exercises, including interaction with participants and the public<br>Coordination committees involving local, regional and State authorities<br>Interaction with other national authorities directly linked with the preparation and response to emergencies |
| Integrated management system | Quality management audits<br>Independent assessments<br>Self-assessments<br>Government audits<br>Peer review reports and findings<br>Findings from management system reviews |
| Staffing and competence of staff | Interaction with national authorities responsible for allocating resources for government bodies, including the regulatory body<br>Interaction with regional authorities with transferred or entrusted regulatory competences<br>Interaction with educational and research centres |

TABLE II-2. INTERNATIONAL SOURCES OF REGULATORY EXPERIENCE

| Topic | Examples of activities that can serve as a source of 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 |

| Topic | Examples of activities that can serve as a source of regulatory experience |
|---|---|
| | Committees, working groups and task forces of international organizations<br>Exercises promoted by international organizations<br>Technical documents and policy guidance published by international organizations and participation in their drafting<br>Activities of the technical cooperation programmes operated by international organizations such as training courses, fellowships and scientific visits, workshops and expert missions.<br>Peer reviews and advisory missions |
| Development and use of international safety standards | Drafting groups to develop international safety standards |
| International codes of conduct on safety | Technical meetings<br>Guidance and technical reports |
| International cooperation settings among nuclear regulatory bodies | Bilateral and multilateral cooperation agreements among nuclear regulatory bodies<br>Technical exchanges under the umbrella of bilateral and multilateral agreements (e.g. benchmarking, combined exercises, shared intelligence) |
| Standards, codes of practices and publicly available technical reports of the industry | National and international standards<br>Codes of practice Technical reports from international associations for the nuclear and radiation industry |
| International reporting systems and databases | IAEA databases (e.g. INES, INIS, PRIS, IRS, FINAS, IRSRR)<br>Other databases (e.g. NEA nuclear databases, ICSBEP database on criticality safety benchmarks) |
| International research | International research programmes or projects Cooperative research projects |
| Associations, forums and networks of nuclear regulatory bodies | Associations, forums and networks of nuclear regulatory bodies and of safety related activities |

TABLE II-3. NON-NUCLEAR SOURCES OF REGULATORY EXPERIENCE

| Topic | Examples of activities that can serve as a source of 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)<br><br>Lessons learned from national non-safety research and technology programmes by other non-nuclear regulatory bodies |
| International convention, treaties and agreements | Governing bodies and diplomatic conferences<br><br>Review meetings of contracting parties to conventions and national reports submitted by the Member States<br><br>Multilateral implementing regulations and agreements |
| Other international non-nuclear sources | Events from non-nuclear industries<br><br>Activities and documents of other non-nuclear international organizations (WHO, OECD/IEA, IATA…) |

II.3. The regulatory body can also decide on developing and implementing measures to facilitate access to potential sources of experience (e.g. hosting peer review missions, encouraging personnel to participate in international training and to enroll in fellowship programmes or scientific visits) or to remove access barriers to such sources (e.g. engaging in international research, concluding bilateral agreements with other countries). The regulatory body can enable reaching the external sources and the personnel of the regulatory body needs to maintain an open mind and exercise judgement on what information might or might not be useful.

II.4. Research and development is an important source of regulatory experience and, as such, a regulatory body has to explore how to effectively utilize lessons identified from research and development in keeping their framework and regulatory functions and processes up to date and effective. Regulatory bodies, though, may need to establish arrangements to address the specific characteristics of this source of regulatory experience.

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