

# IAEA SAFETY STANDARDS

for protecting people and the environment

Step **711**: ~~First~~Second review of the  
draft by the Review Committees

**Regulatory Experience Feedback Management**

**DS547**

**DRAFT GENERAL SAFETY GUIDE**

New Safety Guide

## CONTENTS

1. INTRODUCTION .....	1
BACKGROUND (1.1-1.65).....	1
OBJECTIVE (1.6-1.7).....	1
SCOPE (1.8-1.10).....	2
STRUCTURE (1.10-1.11).....	2
<del>2. THE CONCEPT OF REGULATORY EXPERIENCE (2.1-2.6).....</del>	<del>32</del>
<del>23. THE MANAGEMENT OF REGULATORY EXPERIENCE FEEDBACK (3.1-3.5).....</del>	<del>54</del>
<del>THE CONCEPT OF REGULATORY EXPERIENCE (2.1-2.9)COLLECTING FINDINGS</del>	
<del>FROM VARIOUS SOURCES (3.6-3.15) .....</del>	<del>96</del>
<del>ARRANGEMENTS FOR MANAGING REGULATORY EXPERIENCE</del>	
<del>FEEDBACKANALYSING FINDINGS AND DEVELOPING THE ACTION PLAN (3.16-</del>	
<del>3.192.10-2.34) .....</del>	<del>117</del>
<del>INTEGRATING THE ARRANGEMENTS FOR REGULATORY EXPERIENCE</del>	
<del>FEEDBACK INTO THE MANAGEMENT SYSTEM IMPLEMENTING THE ACTION</del>	
<del>PLAN (3.202.35-2.41-3.24) .....</del>	<del>128</del>
<del>DISSEMINATING THE LESSONS LEARNED (3.25-3.28).....</del>	<del>129</del>
<del>4. INTEGRATION OF THE ARRANGEMENTS FOR MANAGING REGULATORY</del>	
<del>EXPERIENCE FEEDBACK INTO THE MANAGEMENT SYSTEM (4.1-4.7).....</del>	<del>1410</del>
<del>35. APPLICATION OF A GRADED APPROACH TO REGULATORY EXPERIENCE</del>	
<del>FEEDBACK MANAGEMENT (53.1-5.63.4).....</del>	<del>1544</del>
<del>46. ANALYSINGS-OF THE EFFECTIVENESS OF THE-ARRANGEMENTS FOR</del>	
<del>MANAGING THE-REGULATORY EXPERIENCE FEEDBACK (64.1-64.7).....</del>	<del>1742</del>
7. TRAINING OF PERSONNEL ON REGULATORY EXPERIENCE FFEDBACK	
MANAGEMENT (57.1-75.3).....	1944
APPENDIX I: SOURCES OF REGULATORY EXPERIENCE FINDINGSFEEDBACK	
.....	2045
APPENDIX II: IDENTIFICATION OF REGULATORY EXPERIENCE FINDINGS.....	2449
REFERENCES .....	25
ANNEX I: THE REALTIONSHIP LINKAGE BETWEEN OPERATING EXPERIENCE	
FEEDBACK AND REGULATORY EXPERIENCE FEEDBACKAS PART OF	
MANAGING THE REGULATORY EXPERIENCE .....	27
ANNEX II: CHECKLIST FOR IDENTIFYING LESSONS LEARNED AND GOOD	
PRACTICES FROM REGULATORY EXPERINCE FEEDBACK .....	29

DRAFT



# 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”.<sup>22</sup>

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 operating organizations 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.

~~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.~~

## OBJECTIVE

1.6. This Safety Guide provides recommendations for regulatory bodies<sup>1</sup>, on how to meet Requirement 15 of GSR Part 1 (Rev. 1) [2] on establishing, implementing, assessing and continuously improving arrangements for regulatory experience arrangements feedback. 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 other sources of national and international experience regarding the implementation of regulatory functions and processes to facilitate

<sup>1</sup> 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].

continuous improvement and enhanced regulatory effectiveness for ensuring the safety of facilities and activities.

1.7. This Safety Guide is applicable<sup>2</sup> intended to be used by regulatory bodies<sup>2</sup>, as well as to by 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.

## SCOPE

1.6.1.8. The scope of this Safety Guide covers the arrangements for managing the regulatory experience feedback for all functions and processes of a regulatory body and for with regard to all types of facility<sup>ies</sup> and activity<sup>ies</sup> that give rise to radiation risks taking into account the application of a graded approach.

1.7.1.1. This Safety Guide is applicable to regulatory bodies<sup>3</sup>, 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.

1.8.1.9. 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. The safety-security interface is addressed in this Safety Guide.

## STRUCTURE

1.10. The concept of regulatory experience, including the linkage between regulatory experience and operating experience, is provided in Section 2. Section 3 provides recommendations for on developing and implementing the arrangements for managing the regulatory experience feedback, which includes information on collecting and analyzing the findings, and implementing action plan for improving the regulatory framework, functions and processes, and. The recommendations on disseminating the lessons learned are also covered in Section 3. It also provides recommendations. Section 4 provides guidance on integrating regulatory experience feedback these arrangements into the management system. Recommendations on Applying a graded approach to the arrangements for managing regulatory experience feedback are provided in Section 3 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 these arrangements and Section 7 provides recommendations on covers the training aspects.

1.9.1.11. Appendix-I provides recommendations additional guidance on the sources of regulatory findings experience, while Appendix-II provides recommendations detailed guidance

<sup>2</sup>

<sup>3</sup> 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].

on the identification of regulatory experience findings. Annex I describe the linkage between regulatory experience and operating experience and Annex II provides the example checklist for identifying lessons learned and good practices.

## **2. THE CONCEPT OF REGULATORY EXPERIENCE MANAGEMENT OF REGULATORY EXPERIENCE FEEDBACK**

### **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 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 will take into account the knowledge and information resulting from both positive and negative experiences (e.g. good practices and bad practices). Examples of information and knowledge relevant for regulatory bodies include the following:

- The 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;
- Operating experience in authorized facilities and activities in the State and in other States. 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.

2.2.2.3. ~~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.

2.2.2.4. ~~The regulatory body should adopt a~~ proactive approach ~~of the regulatory body to managing regulatory experience. This involves systematically collecting and analysing findings, and applying lessons learned from their own experience as well as from other sources of national and international experience. This should then be used as a basis for implementing changes in regulatory requirements and modifications to regulatory practices thereby strengthening the regulatory framework 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.~~

~~2.5. In order to implementing~~ Requirement 15 of GSR Part 1 (Rev. 1) [2], the regulatory body should ~~distinguish the differences~~ between regulatory experience and operating experience. For the purpose of this ~~document publication~~, 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. This includes lessons learned from both national and international sources as outlined in Appendix I. Operating experience ~~pertains refers~~ to insights and lessons to be learned from the operation of regulated facilities and activities. These include (see para 2.23 of SSG-50 [3]); including

~~(a) eEvents, including low level events and near misses; and other observations, such as~~

~~(b) pPotential problems relating to equipment and human performance; and~~

~~(c) sSafety related concerns; and~~

~~(d) , sSituations that are likely to give rise to errors and need to be addressed to prevent undesired effects; and~~

~~(e) pProcedural deficiencies; and~~

~~(f) iInconsistencies in documentation.~~

Opportunities for improvement and good practices that are relevant to safety should also be identified and fed into the operating experience programme.

~~2.6. The feedback from both the regulatory experience and operating experience should be used to contribute~~ to enhancing the ~~overall~~ safety of facilities and activities and ~~can to~~ provide insights related to regulating the facilities and activities, with the aim which may lead to of improving the regulatory process. The link between regulatory experience and operating experience is explained in Annex I.

~~2.7. The regulatory body should strive to continuously gather regulatory experience from both internal and external sources to identify possible improvements in delivering regulatory functions. The regulatory process reflects involves the knowledge and information resulting from operating and regulatory experience and from other elements associated to the effective management for safety at a given time (i.e. the level of scientific and technological development), and nNew experiences, the evolution of technology and changing contexts such as the introduction of a nuclear power programme in the State or adherence to new international conventions can all provide a basis for further improvements. Regulatory bodies should strive to continuously gain and manage regulatory experience from both internal and external sources to identify improvement opportunities in delivering their mandate.~~

~~2.4.2.8. The regulatory body should Proactively seeking these opportunities by integrating regulatory experience feedback management into their practices and procedures. daily work of regulatory bodies helps t~~The regulatory body should use the feedback to fulfil its mission and ensures that the national regulatory framework and the associated, regulatory functions and processes remain effective and up to date.



~~2.9. The regulatory body should promote the concept of a learning organization for continuously improving its performance. These improvements can be achieved at various levels in the regulatory body such as Paragraph 5.60 of GSG-12 [6] states:~~

~~2.5. “In accordance with the concept of a learning organization, a strategic objective of the regulatory body should be the continuous improvement of its performance... Improvements can be achieved:~~

~~— At the working level within a process, by those directly involved in daily activities;~~

~~—~~

~~— At the level of management processes, under the supervision of the process owners;~~

~~— 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;~~

~~Some opportunities for improvements can be achieved At the working level within a process, by those directly involved in daily activities;~~

~~At the externally level, by leveraging learning from opportunities and best regulatory practices in other national authorities with regulatory functions, as well as from national and international organizations and relevant activities regulatory bodies in other States.~~

~~—~~

## ARRANGEMENTS FOR MANAGING REGULATORY EXPERIENCE FEEDBACK

### 3. MANAGEMENT OF REGULATORY EXPERIENCE FEEDBACK

~~2.10. The effective management of regulatory experience feedback should adopt a graded approach (See Section 3) and should include appropriate arrangements for:~~

- ~~– Collecting findings from various sources (see paras 2.14–2.22);~~
- ~~– Analysing findings and developing an action plan to address the gaps and identify opportunities for improvement (see paras 2.23–2.26);~~
- ~~– Implementing the action plan with clearly assigned responsibilities (see paras 2.27 and 2.28);~~
- ~~– Disseminating the lessons learned (see paras 2.29–2.34).~~

~~A schematic diagram illustrating the typical arrangement for managing regulatory experience feedback, along with the key elements, is presented in Fig.1.~~

2.11. The regulatory body should determine how to establish arrangements for managing regulatory experience within its management system. This may involve creating specific arrangements dedicated to collecting and analysing findings, implementing the action plan, and disseminating lessons learned from regulatory experience. Alternatively, these arrangements could be integrated into the existing or new processes.

2.12. The regulatory body should collaborate with other organizations in cases where the responsibilities for regulating safety (including technical safety matters) and security is shared among multiple organizations. This collaboration should aim to establish effective regulatory practices while considering the specific roles and responsibilities of each organization. As part of this, the safety–security interface should be specifically considered to confirm 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.

2.13. The regulatory body should establish and maintain a comprehensive and retrievable dossier to document regulatory experience feedback management (see also para 5.64-5.70 of GSG-12 [6]). The dossier should retain information about any analyses performed, any trends identified and the decisions taken on the basis of the results.

### **Collecting findings from various sources**

~~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 decide how, in its management system, 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 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 to establish effective regulation considering the responsibilities assigned to 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. A complete retrievable dossier documenting the entire arrangements for regulatory experience feedback management 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.~~

DRAFT

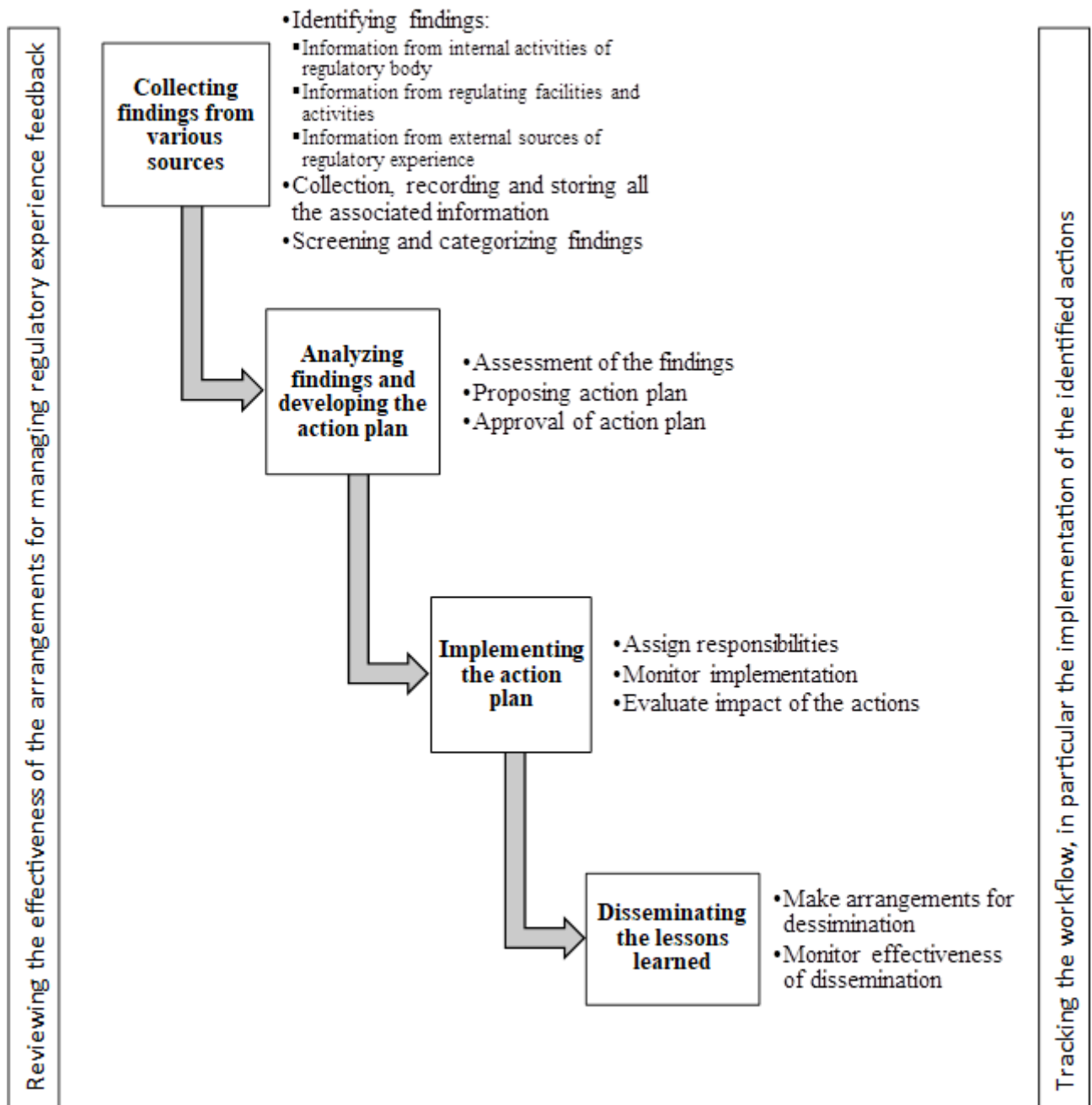


FIG. 1. Typical arrangement for managing regulatory experience feedback.

## COLLECTING FINDINGS FROM VARIOUS SOURCES

3.6.2.14. The first element of managing regulatory body should experience feedback is the collection of regulatory experience findings<sup>4</sup> from various sources utilizing appropriate procedures, tools and techniques for knowledge management (see table A-19 of GSG-12 [6]). Collecting findings is typically the first element of managing regulatory experience The feedback. The regulatory body should ensure that the collection process clearly identifies how to recognize and document collection of findings should clarify how the relevant information including clarity on how to is identified; collected, recorded and stored; and screened and categorized this information.

### *Identifying findings*

3.7. The management of the regulatory body should promote positive attitude in the personnel of the regulatory body through training activities, coaching and mentoring, and providing appropriate tools for documenting and communicating potential findings. 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.

3.8.2.15. The regulatory body should identify sources that can be used for identification of findings include information from its internal activities, of the regulatory body, information from its oversight of regulated facilities and activities, and information from external sources of regulatory experience. The regulatory body should define the most-relevant external sources whose from which lessons learned are to be followed. Further information recommendations are on the sources of findings is provided in Annex II. The Appendices I and IIx provides additional guidance for the regulatory bodies to assist the personnel in identifying potential findings.

3.9.2.16. Paragraph 5.43 of GSG-12 [6] states that “The regulatory body should also provide convenient means for staff to suggest improvements”. The regulatory body should address establish arrangements that actively encourage personnel at all levels to identify and report findings. Key elements of this approach include the following key areas to create an environment promoting the identification of findings by personnel at all levels:

- (a) Guidance: The management should provide guidance clear direction to the personnel on sources of regulatory experience, criteria for identifying potential findings, and means of for collection and reporting of these potential findings.
- (b) Questioning attitude: A culture of critical thinking should be promoted. The management should encourage personnel at all levels to maintain a questioning attitude and to proactively seek and recognize identify potential findings.
- (c) Ownership and commitment: The management should foster the value of accountability emphasize the importance of ownership, commitment, motivation,

<sup>4</sup> Regulatory experience findings, referred to as ‘findings’ throughout this publication Safety Guide, include information relating to issues, difficulties, inefficiencies, as well as good practices of the regulatory process, at the a national and international level.

~~continuous learning and sharing of knowledge and experience to ensure sustained effectiveness in and willingness to learn for sustaining an effective arrangement for managing the regulatory experience feedback among all personnel.~~

- (d) ~~Regulatory functions inquiry~~Being proactive and avoiding complacency: The management should ~~establish mechanisms to ensure that prompt~~ personnel at all levels are consistently prompted and encouraged to regularly evaluate and enhance~~to consider if~~ regulatory functions and processes ~~can be enhanced for more effective and efficient regulation of facilities and activities.~~

~~3.10.2.17. The regulatory body should take immediate measures to ensure that any safety significant issues identified through the arrangements for collecting findings are addressed. The identified finding together with the measures taken should be recorded for further analysis, implementation and dissemination, as appropriate. In case a new safety significant issue is identified from the process for identifying regulatory findings, immediate action should be taken to restore safe circumstances as soon as possible and report the action to management.~~

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

~~3.11.2.18. 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 collecting findings, including defining the assigning responsibilities of the personnel of the regulatory body for monitoring various different information sources and documenting substantive information related to findings to facilitate subsequent screening and categorization.~~

~~3.12.2.19. 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), in a structured manner.~~

~~3.13.2.20. The regulatory body should either consider integrating store findings into the an existing records keeping system or establish a new system for this purpose. within the management system or establishing a new This system should take into account the consideration factors such as type and reliability of the information, reliability, factors such as access, security and, retrievability, as well as the necessary and storage duration for storing of the collected findings.~~

#### *Screening and categorizing findings*

~~3.14.2.21. The regulatory body should develop make the necessary arrangements for screening and categorization of findings. This should, include ing clearly defined roles and responsibilities of personnel and identification of the 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.~~

~~3.15.2.22. In order to ensure effective screening and categorization of the findings, the regulatory body:~~

- (a) Should ~~establish and apply identify findings which require more detailed analysis by defining and utilizing clear~~ criteria to ensure ~~verifiable and~~ consistent implementation of arrangements to identify findings needing further analysis. Clear criteria to conduct the

screening (including the threshold for screening-in) should be established. The criteria may be quantitative (e.g. risk-informed) or qualitative, or a combination of the two. 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 the relevant information relating to the process such as the personnel as the name of the person conducting the screening and categorization, the date(s) of screening and investigation, and an identifier that a file title (following a file clear and consistent naming convention that allows for ease of reference), and a briefA concise description of the each finding should be included, along with the relevant justificationan explainexplanationing of why the finding was screened-in or screened-out for future reference and record. In addition, fFor screened-in findings, the categorization of the finding should be included to allow forenable further analysis.
- (c) Should establish a structured method for categorizing findings based on predefined criteria that ensure effective classification by type, significance, and relevance to regulatory objectives. The categorization should facilitate prioritization, trend analysis, and identification of appropriate actions to enhance the arrangements for managing regulatory experience.
- (b)-
- (e)(d) Should establish arrangements to identify instances where similar findings have been raised previously. It should then be, and if so determined whether there are existing action plans to address these findings or if additional a need for further analysis and actions are needed.

## **Analysing findings and developing the action plan**

3.16.2.23. The regulatory body should conduct a comprehensive analysis of the screened-in findings, using a graded approach. Based on this analysis, an action plan should be developed to address the gaps and list the actions to be taken to improve regulatory functions and processespurpose 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 improving the regulatory framework.

3.17.2.24. The regulatory body should include implement the following arrangements for the analyses of findings and for developing the associated action plan:

- (a) Involvement of suitably qualified personnel for to conducting a multifaceted an analysis of findings. This analysis should comprise include a comprehensive and thorough examination of the findings from multiple perspectives such as technical, operational and organizational. It, should also involve experts from various diverse disciplines and should take into consideration the impact of the findings on regulatory functions and processes.
- (b) Assessment of each finding covering to identify the relevant elements potentially affected by the finding, includingaspects such as human, technical, legal, financial and managerial elementsaspects. Consultations may be held with iInternal partis should be consulted, including (e.g. process owners, senior management and, technical experts, within the organization) and eExternal interested parties should also be consulted, such as operating



~~organizations (e.g. authorized parties, vendors, and~~ other regulatory bodies) to gather diverse perspectives and feedback on the findings.

- (c) Development of an action plan to address the findings. This plan may include, which may result in actions ranging from minimal-minor adjustments to substantive-significant changes in the regulatory ~~framework~~, functions or processes. The regulatory body should ensure that the action plan ~~should identify~~ the personnel responsible for its timely implementation and monitoring.
- (d) Review and approval of the action plan by the senior management of the regulatory body. This should takeing 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 giving safety the highest priority.

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

3.19.2.26. The approved action plan should ~~include~~consider specific instructions for disseminating the lessons learned to ensure that the relevant findings and associated actions are effectively communicated to internal and external interested parties, when-as necessary.

### **Implementing the action plan**

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

3.21.2.28. The regulatory body should make the following arrangements for implementing the approved action plan:

- (a) Coordinating the ~~execution-implementation~~ of the action plan ~~ensuring-confirming the~~ availability of ~~the~~ necessary resources ~~and, as well as ensuring the~~ involvement of third parties or external interested parties, ~~if-as~~ necessary. This coordination might include collaboration with multiple ~~For example, when there is more than one~~ ~~authorities~~ with responsibility for safety, ~~when~~ cooperation with regulatory bodies of other ~~countries~~ States or engagement with external technical support organizations ~~is envisaged~~.
- (b) Monitoring the implementation of the action plan ~~by systematically~~which includes tracking the status of each action, resolving any delays or obstacles, and ensuring timelines and responsibilities are adhered to effectively. This monitoring process should involve regular updates, documentation of progress, and communication to an appropriate management level of any significant deviations~~implementation progress~~.
- (c) Evaluating the impact of actions on the regulatory functions and processes, assessing their effectiveness by using methodologies such as 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**

~~3.22. 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.”~~

2.29. Paragraph 2.33 of IAEA Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [89] 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.”

3.23.2.30. 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.”

3.24.2.31. Furthermore, pParagraph- 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.”

~~3.25.1.1. 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.”~~

3.26.2.32. The regulatory body should ~~make-establish mechanisms arrangements~~ for dissemination of the lessons learned from ~~the~~ regulatory experience feedback management ~~arrangements~~ for ~~their~~ use by other regulatory bodies (e.g. in other States) with the responsibility for safety and other relevant ~~organizationsparties~~ (e.g. operating organizations, vendors, designers, technical support organizations and supply chain organizations), nationally and/or internationally. The lessons learned might be useful for authorized parties, vendors, designers and supply chain organizations.

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

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

- ~~– Identifying the lessons to be disseminated. This involves establishing criteria to determine when a regulatory experience finding and associated actions qualify for dissemination.~~
- ~~– Target recipients: Identifying and defining the recipients of the shared-disseminated information, which may include the personnel of the regulatory body, licensee holders operating organizations, other national authorities and relevant international organizations.~~
- ~~– Means and channels for dissemination: Deciding on the best approach to reach the target intended recipients, considering factors like such as the purpose for sharing-disseminating the lessons learned, the needs of the target-recipients, and the means of sharing-dissemination.~~
- ~~– 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. INTEGRATING~~ON OF THE ARRANGMENTS FOR ~~MANAGING~~ REGULATORY EXPERIENCE FEEDBACK INTO THE MANAGEMENT SYSTEM

4.1.2.35. Paragraph 4.11 of IAEA Safety Standards Series No. GSR Part 2, Leadership and Management for Safety [409] 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.”

4.2.2.36. Paragraph 1.5(b) of GSR Part 2 [409] 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;”

4.3.2.37. The regulatory body should integrate the arrangements for regulatory experience feedback management ~~arrangements~~ within its 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 ~~management 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]

4.4.2.38. 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, s~~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.

4.5.2.39. ~~The s~~Senior management of the regulatory body should demonstrate commitment by allocating the necessary resources to develop, implement and sustain the arrangements for managing regulatory experience feedback. ~~This includes management arrangements~~ fostering an enabling environment ~~that by~~ motivating ~~the~~ personnel and reinforces the importance of effective management arrangements through leadership demonstrating commitment by its actions.

4.6.2.40. The regulatory body should ~~ensure that have~~ knowledge management processes that effectively capture, retains and make accessible the results and benefits of the arrangements for regulatory experience feedback management. ~~This may include documented lessons learned, identified improvements in regulatory functions and processes, and tangible actions that enhance safety and regulatory effectiveness keeps visible outcomes of the regulatory experience feedback management arrangements and vice versa.~~

4.7.2.41. The regulatory body should actively promote the collection of information and knowledge resulting from experience ~~at across~~ all levels ~~in of~~ the organization to ensure effective management of that all learning opportunities ~~are successfully managed.~~ This should involve fostering a proactive approach among individual process owners who should take regulatory experience feedback into account when reviewing processes and bring it to the attention of senior management, including facilitating continuous improvement. ~~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 findings to the attention of senior management. The s~~Senior management should regard ~~would be expected to use~~ regulatory experience feedback as one of the valuable inputs when completing a review and updating ~~the regulatory framework functions~~ and processes. This approach ~~also encourages~~ organization-wide dialogue on the benefits ~~to be gained from of~~ effectively managing ~~ingement of~~ regulatory experience ~~throughout the organization~~ and promotes its integration into daily ~~utilization~~ operations.

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

5.1.3.1. The application of a graded approach underpins the effective and efficient performance of ~~the a national~~ 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.”~~

~~3.2. The regulatory body should develop and implement the management of regulatory experience feedback in line with Requirement 16 of GSR Part 1 [2] and Requirement 7 of GSR Part 2 [109] states that “The management system shall be developed and applied using a graded approach.” The regulatory body should take into account the criteria mentioned in pPara. 4.15 of GSR Part 2 [109] states: 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.~~

“The criteria used to grade the development and application of the management system shall be documented in the management system. The following shall be taken into account:

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

5.3. The regulatory body should take into account these criteria when identifying and analysing the findings from the management of regulatory experience feedback, and when defining and prioritizing the actions arising.

~~5.4.3.3. The regulatory body should ensure the arrangements for managing regulatory experience feedback are developed commensurate with the context, its objectives, needs and priorities, and of the regulatory body. Other factors, such as the size of the regulatory body, its and 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 such as when designing the management of regulatory experience feedback which may include the following:~~

- ~~–(a) The existence of other processes of the management system that can contribute to the establishment and application of the regulatory experience feedback management arrangements;~~
- ~~–(b) Integration with other information management systems<sup>5</sup>;~~
- ~~–(c) Provision of adequate human and financial resources.~~

---

<sup>5</sup> 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.

~~5.5. The regulatory body should apply a graded approach in assessing the 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 giving safety the highest priority.~~

~~5.6.3.4. The regulatory body should apply a graded approach when disseminating the lessons learned, ensuring that this is commensurate with ~~from the regulatory experience feedback management arrangements.~~ The safety significance of the findings and their ~~may have a different degree of~~ relevance, both within inside and outside the organization and externally, at of the regulatory body, nationally or and international levelsly, 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.~~

#### **6.4. ANALYSINGS OF THE EFFECTIVENESS OF THE ARRANGEMENTS FOR MANAGING THE REGULATORY EXPERIENCE FEEDBACK**

~~4.1. 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.”~~

~~6.1.4.2. Requirement 13 of GSR Part 2 [109] 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.~~

~~6.2.4.3. Paragraph 6.7 of GSR Part 2 [109] 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.”~~

~~6.3.4.4. Paragraph 6.8 of GSR Part 2 [109] 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;”~~

~~6.5.4.5. The regulatory body~~ An appropriate governance should be established ~~arrangements within the management system of the organization to monitor the performance and effectiveness of the arrangements for managing regulatory experience feedback management arrangements and to embrace. This should support the organizations’ commitment to embracing a culture of continuous improvement. The regulatory body may define qualitative or quantitative performance indicators, as appropriate, to assess how well the arrangements for managing regulatory experience feedback have achieved the intended purpose.~~

~~6.6.4.6. The regulatory body should periodically evaluate assess how effectively the degree of utilization and proper functioning of the arrangements to for manage the regulatory experience feedback are functioning and being utilized. Effective management of regulatory experience feedback should be part of the review of the integrated management system (see paras 5.47–5.62 of GSG-12 [6]). to explore possible improvements. ToolsMethods such as management reviews, self-reflections, self-assessments or external assessments, including peer reviews and advisory missions, can be employed as part of these reviews used to carry out these evaluations.~~

~~6.7.4.7. The regulatory body should address the following elements in the context terms of its the organization that might impact on 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.
- (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.
- (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.
- (d) Silo mentality<sup>6</sup>: The regulatory body should avoid the development of a silo mentality by fostering an environment of sharing information, knowledge and experience, ~~including information, knowledge and know-how~~ that is valuable for enhancing the regulatory functions and processes.
- (e) Fear of personal consequences: The regulatory body should foster a ‘no-blame’<sup>7</sup> 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.
- (f) Demotivation: The regulatory body should ensure that the additional workload ~~entailed associated with by the personnel in~~ managing regulatory experience feedback does not

---

<sup>6</sup> 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.

<sup>7</sup> 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.

demotivate personnel, ~~which might and~~ result in less active contribution. Management should consider options for encouraging ~~effective utilization of the management of regulatory experience feedback 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-rationalize the management of~~ regulatory experience feedback ~~management, in such a way as to ensure that the workload associated with processing the findings is the minimum necessary to ensure~~ transparency and traceability ~~while minimizing any administrative burden. The approach should be proportionate to, commensurate with~~ the radiation risks associated with facilities and activities, ~~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.
- (i) Risk Management: The regulatory body should take into account the risk management in managing the regulatory experience feedback.

## **7.5. TRAINING OF PERSONNEL ON REGULATORY EXPERIENCE FFEDBACK MANAGEMENT**

7.1.5.1. For effective management of regulatory experience feedback, the regulatory body should develop and implement appropriate training for the ~~involved~~ personnel ~~involved taking into account a graded approach.~~ Recommendations on developing and maintaining adequate competences for the staff of the regulatory body are provided in GSG-12 [6].

7.2.5.2. The regulatory body should ~~provide training to help the~~ personnel ~~so that they can~~ develop ~~the~~ knowledge, skills and attitude to ~~effectively~~ identify, analyse and use regulatory experience feedback. ~~Necessary t~~Tools, such as non-conformance reporting mechanisms, sharing of good practices and ~~offering~~ opportunities to raise concerns, ~~should be utilized to empower employees to contribute towards the and support~~ continuous improvement ~~Table 4 in Appendix II outlines key topics that should be included in of the process. The Appendix provides guidance on essential topics to be covered for~~ training on regulatory experience ~~feedback.~~

7.3.5.3. The regulatory body should ~~make arrangements provide appropriate to~~ training ~~to the~~ relevant personnel to ~~identify recognize those external~~ sources of regulatory experience that ~~could be more are~~ valuable ~~for to~~ the organization. ~~The regulatory body should also encourage personnel to routinely utilize and to motivate them to regularly use these external~~ sources to identify lessons ~~learned and integrate this approach to be learned as part of their routine~~ duties.

## APPENDIX I

### SOURCES OF REGULATORY EXPERIENCE ~~FINDINGS~~FEEDBACK

I.1. This appendix presents possible sources ~~for collecting of~~ regulatory experience from which the regulatory bodies can learn lessons that could assist ~~them-it~~ in improving the regulatory framework, functions and processes. The sources listed in Tables 1 ~~to Table 3~~ ~~could-should~~ 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	<p>Issuance of new laws and regulations <del>(National/Federal and Regional/States) on matters</del> relevant to safety</p> <p>Legislative proceedings<sup>8</sup></p> <p>Regulations from other <del>national regulatory</del> authorities <del>in matters</del> with safety implications</p> <p>Public consultations and hearings</p> <p>Congressional committees</p> <p><u>Codes and</u> Standards of professional organizations (including non-nuclear organizations)</p> <p>Reports and feedback from <del>TSOs</del> <u>technical support organizations</u> and advisory bodies</p> <p>Reports and feedback from research organizations</p>
Notification and Authorization	<p>Issuance of authorizations</p> <p>Regulatory review of modifications and process changes</p> <p>Oversight of compliance with <del>licensee</del> <u>authorization</u> conditions</p> <p>Licensing appeals</p> <p>Public consultations</p> <p>Policy statements</p> <p>Feedback from <del>licensee holders</del> <u>operating organizations</u></p>
Review and assessment	<p>Safety evaluations</p> <p>Benchmarking with other regulatory bodies</p> <p>Lessons identified from operating experience feedback</p> <p>Lessons identified from <del>any relevant</del> research and development activities</p> <p>Technical meetings</p>

<sup>8</sup> Legislative proceeding refers to the formal processes and activities through which laws are proposed, discussed and enacted by a legislative body.



Regulatory Function or Process	Examples of activities that can serve as a source of regulatory experience
	<u>Incident Investigations</u>
Inspection of facilities and activities	<p>Inspection reports</p> <p>Inspection findings</p> <p>Operating experience feedback from <u>facilities and activities</u> <del>and facilities</del></p> <p>Relevant operating experience feedback from non-nuclear <del>industries</del> <u>facilities and activities</u></p>
Enforcement of regulatory requirements	<p>Enforcement appeals</p> <p>Corrective actions</p> <p>Enforcement procedures of other <del>national</del> regulatory bodies</p>
Emergency preparedness and response	<p>Emergency drills and exercises, including interaction with participants and the public</p> <p>Coordination committees involving <del>local, regional and State</del> <u>national</u> authorities</p> <p>Learnings identified from responses to <del>incidents and</del> emergencies</p> <p>Interaction with other national authorities directly linked with <del>the emergency preparedness and response to emergencies</del></p>
Management system	<p>Quality management audits</p> <p>Independent assessments</p> <p>Self-assessments</p> <p>Government audits</p> <p>Peer review reports and findings</p> <p>Findings from management system reviews</p>
Staffing and competence <del>of staff</del>	<p>Interaction with national authorities responsible for allocating resources for government bodies, including the regulatory body</p> <p>Interaction with regional authorities with transferred or entrusted regulatory competences</p> <p>Interaction with educational and research centres</p>
Communication with interested parties	<p>Public hearings</p> <p>Consultation with interested parties</p>

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 <del>activities</del> <u>facilities and energy and associated matters</u>	<p>International conferences, meetings and seminars hosted by international organizations, in particular those focused on sharing experience from regulating facilities and activities</p> <p>Committees, working groups and task forces of international organizations</p> <p>Exercises promoted by international organizations</p> <p>Technical documents and policy guidance published by international organizations and participation in their drafting</p> <p>Activities of the technical cooperation programmes operated by international organizations such as training courses, fellowships and scientific visits, workshops and expert missions.</p> <p>Peer reviews and advisory missions</p>
Development and use of international safety standards	Drafting groups to develop international safety standards
International codes of conduct on safety	<p>Technical meetings</p> <p>Guidance and technical reports</p>
International cooperation settings among nuclear regulatory bodies	<p>Bilateral and multilateral cooperation agreements among nuclear regulatory bodies</p> <p>Technical exchanges under the umbrella of bilateral and multilateral agreements (e.g. benchmarking, combined exercises, shared intelligence)</p>
<u>Codes and Standards</u> , <del>codes of practices and</del> publicly available technical reports <del>of the industry</del>	<p>National and international <u>codes and</u> standards</p> <p>Codes of practice <u>and</u> Technical reports from international associations for the nuclear and radiation industry <del>iesy</del></p>
International reporting systems and databases	<p>IAEA databases (e.g. INES, INIS, PRIS, IRS, FINAS, IRSRR)</p> <p>Other databases (e.g. NEA nuclear databases, ICSBEP database on criticality safety benchmarks)</p>
International research	International research programmes or projects <del>Cooperative research projects</del>

Topic	Examples of activities that can serve as a source of regulatory experience
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 <del>national</del> authorities not linked to the regulatory process	Exchanges with other <del>national</del> -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 by other non-nuclear regulatory bodies
International convention, treaties and agreements	Governing bodies and diplomatic conferences Review meetings of contracting parties to conventions and national reports submitted by the <del>Member</del> States Multilateral implementing regulations and agreements
Other international non-nuclear sources <u>of regulatory experience</u>	Events from non-nuclear industries Activities and documents of other non-nuclear international organizations (WHO, OECD/IEA, IATA...)

I.2. The regulatory body should ~~take 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 enrol<sup>1</sup> in fellowship programmes or scientific visits) ~~or and to~~ remove access barriers to accessing 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~~ The regulatory body ~~has to~~ should explore how to effectively utilize lessons identified from research and development ~~in to~~ keeping their regulatory 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

~~H.1.—The regulatory body should consider the identification of potential findings is-as the primary driver of the -regulatory experience management-~~arrangements~~.~~

~~H.2.II.1. \_\_\_\_\_~~ Managers at all levels of the regulatory body should instill positive attitude in personnel through training and coaching, and by providing personnel with the appropriate guidance and tools to identify, document and submit potential findings.

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

~~H.4.II.2. \_\_\_\_\_~~ ~~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

~~H.5.II.3. \_\_\_\_\_~~ 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 arrangements for managing the regulatory experience feedback. Annex-II ~~shows-provides~~ 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.

~~H.6.II.4. \_\_\_\_\_~~ ~~When designing management tools for identifying findings, t~~The regulatory body should ~~also~~ develop guidelines to help personnel identify areas for improvement in weaknesses that should be addressed as well as strengths that could be shared related to the regulatory framework, functions and processes as well as strengths that should be disseminated. ~~At a minimum~~This, 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 function or process under consideration. This subject to assessment, including the basic principles and methodology for the function or process; regulatory objectives and criteria; as well as the 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 o~~Organizational aspects: ~~Aspects relating to of~~ the conditions under which the regulatory function or process is conducted, including the working environment, leadership and involvement of management, interfaces between functions and processes and safety culture of the organization.

## MOTIVATION OF PERSONNEL

~~II.7.—The personnel of the regulatory body should ensure that personnel at all levels within the organization understand their play a fundamental role in achieving successful utilization of regulatory experience feedback management. 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.8-II.5.~~ 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:

- (a) 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;
- (b) Involve personnel who raise findings in the subsequent stages along the process of the regulatory experience feedback management including analysis, development and implementation of action plan;
- (c) 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;
- (d) Periodically Organize meetings with the personnel periodically to collectively discuss examples of improvements in the regulatory process achieved through the implementation of lessons learned from findings;
- (e) Identify personnel with the necessary skills to motivate and mentor other employees to raise regulatory findings;
- (f) Manage the additional workload on the individuals to promote active contribution towards the process of regulatory experience feedback management;
- (g) 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.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.~~

~~H.10.II.6. The education and training of the personnel of the regulatory body on regulatory experience should be tailored to fit the arrangements for regulatory experience management arrangements. The content of the education and training programme aimed at the effective management of regulatory experience should cover the eight topics presented listed 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
<b>Topic 1: Basic Principles</b>	
<p>Possible subjects to cover as appropriate:</p> <ul style="list-style-type: none"> <li>• Concept and definition of regulatory experience</li> <li>• Objective <u>of regulatory experience management</u></li> <li>• International standards</li> <li>• National regulations</li> <li>• Mission and policy statements</li> <li>• International commitments and contribution to the global safety regime</li> <li>• Structure of the regulatory body</li> <li>• Interaction and coordination with other national regulatory bodies</li> <li>• Liaison with licence holders</li> <li>• Liaison with advisory bodies, technical support organizations, <u>other regulatory bodies authorities</u> and involvement in international programmes and activities</li> <li>• Linkage and differences between operating <u>experience feedback</u> and regulatory experience <u>feedback</u></li> </ul>	<p>This Section is intended to provide trainees with insights about the concept of regulatory experience <u>management</u> and how it relates to the organization of the regulatory body and to the regulatory process, including liaison with other <u>national authorities</u> and <u>interested parties stakeholders</u></p>
<b>Topic 2: Benefits <del>from effective</del> management of <del>the</del> regulatory experience</b>	
<p><del>Possible s</del>Subjects to cover, as appropriate:</p> <ul style="list-style-type: none"> <li>• Added value of the management of regulatory experience for enhancing the regulatory process</li> </ul>	<p>This Section seeks to provide evidence of the added value of the effective management of regulatory experience by showing practical examples.</p>

Topic	Purpose
<ul style="list-style-type: none"> <li>Examples of <u>how the application of regulatory experience has led to improvements in the design, implementation or effectiveness of the situations in which regulatory experience resulted in further enhancing the management of regulatory experience feedback arrangements itself</u></li> </ul>	

### Topic 3: Sources of regulatory experience

Possible subjects to cover as appropriate:

- Internal sources:
  - Core regulatory functions and processes and functions
  - Other regulatory functions and processes
  - Management system
  - Operating experience
  - Research and development in the field of nuclear and radiation safety
  - Advisory bodies and technical support organizations
- External sources:
  - National and International:
    - Research and development in the field of nuclear and radiation safety
  - National:
    - Non-nuclear legislation and policy
    - Non-nuclear regulatory bodies
    - Non-nuclear industries
    - Industry standards
  - International
    - International safety standards
    - International industry codes and standards
    - International nuclear research
    - International organizations
    - Associations, forums and networks of regulatory bodies

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 arrangements

### Topic 4: Arrangements for managing regulatory experience

Topic	Purpose
<p><del>Possible</del> <u>s</u>Subjects to cover, as appropriate:</p> <ul style="list-style-type: none"> <li>• Approach and <u>methods used for managing regulatory experience</u><del>modality</del></li> <li>• Roles and responsibilities in managing regulatory experience</li> <li>• Integration within the management system and interfaces with relevant processes</li> <li>• Management of <u>internal and</u> external sources of regulatory experience</li> <li>• Arrangements for the following: <ul style="list-style-type: none"> <li>— Identification of regulatory experience (e.g. through the use of templates or other means, guidance and practical examples)</li> <li>— Collection of regulatory experience, including channels for reporting and organizing the information</li> <li>— Storage of information, including type of information stored, means of storage, provisions for accessing and retrieving information</li> </ul> </li> <li>• Arrangements for analysis of regulatory experience: <ul style="list-style-type: none"> <li>— Criteria and thresholds for screening of findings</li> <li>— Assessment of findings and elaboration of action plans to address findings</li> <li>— Decision making</li> </ul> </li> <li>• Arrangements for implementing action plans and sharing lessons learned: <ul style="list-style-type: none"> <li>— Monitoring the implementation of action plans</li> <li>— Monitoring the impact of the actions in the regulatory process</li> <li>— Criteria for sharing and dissemination of regulatory experience</li> </ul> </li> </ul> <p><b>Topic 5: Leadership and management</b></p> <p><del>Possible</del> <u>s</u>Subjects to cover, as appropriate:</p> <ul style="list-style-type: none"> <li>• Management commitment to the management of regulatory experience</li> <li>• Management reviews of the <u>arrangements for</u> regulatory experience management<del>-system</del></li> </ul> <p><b>Topic 6: Engaging personnel</b></p>	<p>This <del>Section</del> <u>topic</u> is the bulk of the programme and its purpose is to provide step-by-step information on how to complete an <u>sound</u> analysis of <del>the</del> regulatory experience findings <del>identified by the staff of the regulatory body, including findings from external sources of experience.</del></p> <p>This <del>Section</del> <u>topic</u> is intended to illustrate how the management of the <del>organization</del> <u>regulatory body</u> commits to an effective and efficient management of regulatory experience</p>



Topic	Purpose
<p><del>Possible</del> <u>s</u>Subjects to cover, as appropriate:</p> <ul style="list-style-type: none"> <li>• Roles and responsibilities</li> <li>• Expectations from personnel</li> <li>• ‘No blame’ culture in the work environment</li> <li>• Personnel involvement throughout the analysis of findings and feedback</li> <li>• Recognition of personnel contributing to the management of regulatory experience</li> <li>• Means available to personnel for handling and communicating findings</li> </ul>	<p>This <del>Section</del> <u>topic</u> is intended to foster and encourage the personnel of the regulatory body <del>and associated organizations</del> to actively use the arrangements for managing the regulatory experience and to acknowledge the contribution of individuals in enhancing the regulatory process.</p>
<p><b>Topic 7: Continuous improvement of the arrangements for managing regulatory experience</b></p>	
<p><del>Possible</del> <u>s</u>Subjects to cover, as appropriate:</p> <ul style="list-style-type: none"> <li>• Self-reflection/Self-assessment</li> <li>• Benchmarking and peer reviews</li> </ul>	<p>This <del>Section</del> <u>topic</u> discusses the process for reviewing the effectiveness and efficiency of the existing arrangements and to enhance them as necessary</p>
<p><b>Topic 8: International forums for reporting on lessons learned from regulatory experience</b></p>	
<p><del>Possible</del> <u>s</u>Subjects to cover, as appropriate:</p> <ul style="list-style-type: none"> <li>• Existing international forums for reporting operating experience and how they relate to reporting regulatory experience</li> <li>• Advantages and disadvantages of existing international systems to share regulatory experience</li> </ul>	<p>This <del>Section</del> <u>topic</u> illustrates how to use existing incident reporting systems to share regulatory experience</p>



## REFERENCES

- [1] EUROPEAN ATOMIC ENERGY COMMUNITY, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, INTERNATIONAL MARITIME ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Fundamental Safety Principles, IAEA Safety Standards Series No. SF-1, IAEA, Vienna (2006), <https://doi.org/10.61092/iaea.hmxn-vw0a->
- [2] INTERNATIONAL ATOMIC ENERGY AGENCY, Governmental, Legal and Regulatory Framework for Safety, IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), IAEA, Vienna (2016).
- [3] INTERNATIONAL ATOMIC ENERGY AGENCY, Operating Experience Feedback for Nuclear Installations, IAEA Safety Standards Series No. SSG-50, IAEA, Vienna (2018).
- [4] INTERNATIONAL ATOMIC ENERGY AGENCY, Effective Management of Regulatory Experience for Safety, IAEA TECDOC Series No. IAEA-TECDOC-1899, IAEA, Vienna (2020).
- [5] IAEA Nuclear Safety and Security Glossary: Terminology Used in Nuclear Safety, Nuclear Security, Radiation Protection and Emergency Preparedness and Response, 2022 (Interim) Edition, IAEA, Vienna, <https://doi.org/10.61092/iaea.rrxi-t56z>
- [6] INTERNATIONAL ATOMIC ENERGY AGENCY, Organization, Management and Staffing of the Regulatory Body for Safety, IAEA Safety Standards Series No. GSG-12, IAEA, Vienna (2018).
- [7] INTERNATIONAL ATOMIC ENERGY AGENCY, Functions and Processes of the Regulatory Body for Safety, IAEA Safety Standards Series No. GSG-13, IAEA, Vienna (2018).
- ~~[8] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety of Nuclear Power Plants: Commissioning and Operation, IAEA Safety Standards Series No. SSR-2/2 (Rev. 1), IAEA, Vienna (2016).~~
- ~~[9]~~[8] EUROPEAN COMMISSION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014), <https://doi.org/10.61092/iaea.u2pu-60vm->
- ~~[10]~~[9] INTERNATIONAL ATOMIC ENERGY AGENCY, Leadership and Management for Safety, IAEA Safety Standards Series No. GSR Part 2, IAEA, Vienna (2016), <https://doi.org/10.61092/iaea.cq1k-j5z3->



## ANNEX I

### **THE RELATIONSHIP LINKAGE BETWEEN OPERATING EXPERIENCE FEEDBACK AND REGULATORY EXPERIENCE FEEDBACK 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. 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<sup>9</sup>, 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.

---

<sup>9</sup> 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.

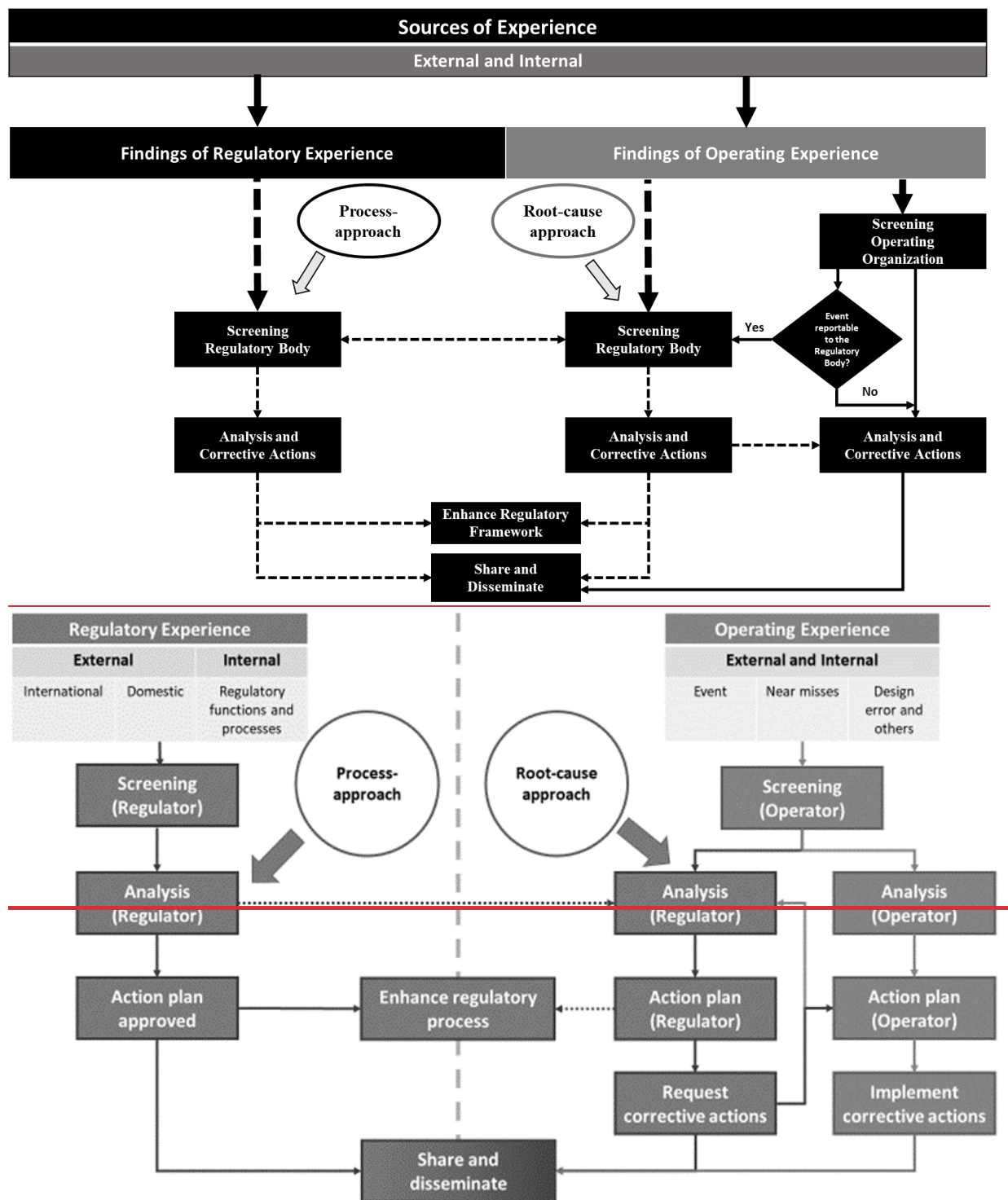


FIG. I-1. Linkage between regulatory experience and operating experience

I.2. Figure I-1 illustrates the linkage-relationship 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 in accordance with regulatory requirements, undertakes and initiates action in a timely manner for its screening and further analysis on the basis of the actual or potential consequences of the event and implements corrective actions 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~~implemneted 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.~~





## ANNEX II

### CHECKLIST FOR IDENTIFYING LESSONS LEARNED AND GOOD PRACTICES FROM REGULATORY EXPERIENCE FEEDBACK

II.1. This annex presents an example of a checklist that could be used ~~to help 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. When designing such tools, suitable questions or sample text to help staff identify both weaknesses and strengths need to be considered. This involves considering the interrelation of three factors: the regulatory function or process (including its structure, objectives, and accuracy); the staff (their qualifications, resources, and support); and the organization (its environment, leadership, and safety culture).

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

Opportunities for improvement	Strengths
<b>Aspects relating to <u>the</u> regulatory <del>functions and</del> processes</b>	
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 <del>foster</del> <u>achieve</u> 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 <del>the</del> <u>a</u> facility or activity	The regulatory process introduces improvements that minimize interferences <u>in the operation of a facility or activity</u> and the use of resources. These improvements <del>could be</del> <u>are</u> worth sharing with other interested parties
<b>Aspects relating to the personnel</b>	

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

## CONTRIBUTORS TO DRAFTING AND REVIEW

Alm-Lytz, K.	International Atomic Energy Agency
Bhatti, S.A.N.	Pakistan Nuclear Regulatory Authority, Pakistan
Glover, J.	Canadian Nuclear Safety Commission, Canada
Sanchez-Cervera, S.	Consejo De Seguridad Nuclear, Spain
Javaid, M.A.	International Atomic Energy Agency
Poirier, J.C.	Canada
Recio Santamaria, M.	International Atomic Energy Agency
Shah, Z.H.	International Atomic Energy Agency
Vastamaki, P.	Radiation and Nuclear Safety Authority, Finland