IAEA SAFETY STANDARDS

for protecting people and the environment

Step 12: Endorsement of draft by CSS

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:

> "**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 regulatory bodies on establishing, implementing, assessing and continuously improving an operating experience programme for nuclear installations.

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

OBJECTIVE

1.6. This Safety Guide provides recommendations for regulatory bodies[1], on how to meet Requirement 15 of GSR Part 1 (Rev. 1) [2] on establishing, implementing, assessing and continuously improving arrangements for regulatory experience feedback. This includes disseminating 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 continuous improvement and enhance regulatory effectiveness for ensuring the safety of facilities and activities.

1.7. This Safety Guide is intended to be used by regulatory bodies as well as by their technical support organizations. This Safety Guide might also be useful for operating organizations,

[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]

vendors, designers and supply chain organizations particularly regarding their internal supervision and/or audit functions for ensuring safety.

SCOPE

1.8. The scope of this Safety Guide covers the arrangements for managing regulatory experience feedback for all functions and processes of a regulatory body with regard to all types of facility and activity that give rise to radiation risks.

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. Section 2 provides recommendations on developing and implementing arrangements for managing regulatory experience feedback, which includes information on collecting and analysing the findings, implementing action plan for improving the regulatory framework, functions and processes, and disseminating the lessons learned. It also provides recommendations on integrating 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. Section 4 provides recommendations on performing the analysis of the effectiveness of these arrangements and Section 5 provides recommendations on the training aspects.

1.11. Appendix I provides recommendations on the sources of regulatory experience. Appendix II provides recommendations on the identification of regulatory experience findings. Annex I describes the link between regulatory experience and operating experience and Annex II provides the example checklist for identifying lessons learned and good practices.

2. THE 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:

> "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."

Implementing effective arrangements for regulatory experience feedback is influenced by, and dependent on, a well-functioning management system.

2.3. 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.

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

2.5. In implementing Requirement 15 of GSR Part 1 (Rev. 1) [2], the regulatory body should differentiate between regulatory experience and operating experience. For the purpose of this publication, regulatory experience refers to insights and lessons to be learned from the analysis of information collected from all activities related to the implementation of regulatory functions and processes. This includes lessons learned from sources as outlined in Appendix I and incorporate:

(a) National;
(b) International; and
(c) Non-nuclear sources of regulatory experience.

Operating experience 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]):

(a) Events, including low level events and near misses;
(b) Potential problems relating to equipment and human performance;
(c) Safety related concerns;
(d) Situations that are likely to give rise to errors and need to be addressed to prevent undesired effects;
(e) Procedural deficiencies;
(f) Inconsistencies 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 regulatory experience and operating experience should be used to contribute to enhancing the safety of facilities and activities and to provide insights related to regulating the facilities and activities, with the aim of improving the regulatory framework. The link between regulatory experience and operating experience is explained in Annex I.

2.7. The regulatory body should strive to continually gather regulatory experience from both internal and external sources to identify possible improvements in delivering regulatory functions. The regulatory process 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). New 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.

2.8. The regulatory body should integrate regulatory experience feedback management into their practices and procedures. The regulatory body should use the feedback to ensure that the national regulatory framework and the associated regulatory functions and processes remain effective and up to date.

2.9. Paragraph 5.60 of GSG-12 [6] states:

> "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."

Some opportunities for improvements can result from learning from good practices in other national authorities with regulatory functions, as well as from international organizations and regulatory bodies in other States.

ARRANGEMENTS FOR MANAGING 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:

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

A schematic diagram illustrating the typical arrangements 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, developing and implementing the action plan, and disseminating lessons learned from regulatory experience. Alternatively, such arrangements could be integrated into the existing processes.

2.12. The regulatory body should collaborate with other national organizations in cases where the responsibility 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 paras 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.

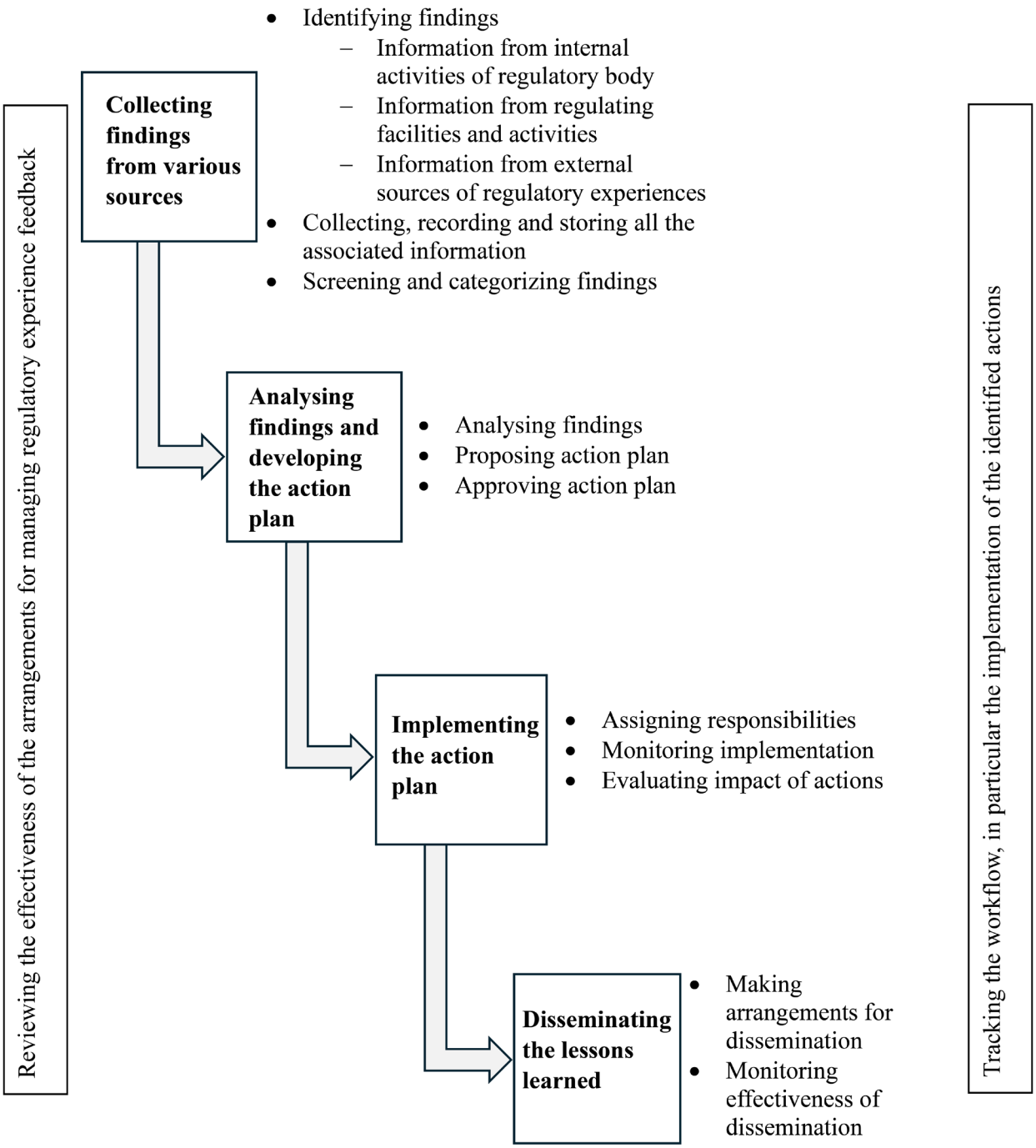

FIG. 1. Typical arrangements for managing regulatory experience feedback.

Collecting findings from various sources

2.14. The regulatory body should collect regulatory experience findings from various sources utilizing appropriate procedures, tools and techniques for knowledge management (see table A–19 of GSG-12 [6]). Regulatory experience findings, referred to as 'findings' throughout this Safety Guide, include information relating to issues, difficulties, inefficiencies, as well as good practices, at a national and international level. Collecting findings is typically the first element of managing regulatory experience feedback. The regulatory body should ensure that the collection process clearly identifies how to recognize the relevant information and how to collect, record, store, screen and categorize this information.

Identifying findings

2.15. The regulatory body should identify findings from its internal activities, from its oversight of regulated facilities and activities, and from external sources of regulatory experience. The regulatory body should define the relevant external sources from which lessons learned are to be followed. Further recommendations are provided in Appendices I and II.

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 establish arrangements that actively encourage staff at all levels to identify and report findings. Key elements of this approach include:

(a) Guidance: The management should provide clear direction on sources of regulatory experience, criteria for identifying potential findings, and means for collection and reporting.
(b) Questioning attitude: A culture of critical thinking should be promoted, encouraging staff to proactively seek and recognize potential findings.
(c) Ownership and commitment: The management should foster the value of accountability, motivation, continuous learning and sharing of knowledge and experience to ensure sustained effectiveness in regulatory experience feedback.
(d) Being proactive and avoiding complacency: The management should establish mechanisms such as regular review meetings, feedback sessions and internal audits to ensure that staff at all levels are consistently prompted and encouraged to regularly evaluate and enhance regulatory functions and processes.

2.17. The regulatory body should take measures to ensure that any safety significant issues identified through the arrangements for collecting and screening findings are addressed in a timely manner. The identified finding together with the measures taken should be recorded for further analysis, implementation and dissemination, as appropriate.

Collecting, recording and storing information relating to findings

2.18. The regulatory body should make arrangements for collecting findings, including assigning responsibilities for monitoring different information sources and documenting information related to findings to facilitate subsequent screening and categorization.

2.19. The regulatory body should make arrangements for recording and storing the collected findings, including findings communicated informally (e.g. orally or through other informal communication means), in a structured manner.

2.20. The regulatory body should either store findings into an existing record keeping system or establish a new system for this purpose. This system should take into account the type and reliability of the information, factors such as access, security and retrievability, as well as the necessary duration for storing the collected findings.

Screening and categorizing findings

2.21. The regulatory body should develop arrangements for screening and categorizing findings. This should include clearly defined roles and responsibilities and identification of the necessary resources, such as suitably qualified staff, financial resources, tools and equipment, thresholds for screening the findings and criteria for categorization of the findings.

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

(a) Should establish and apply criteria to ensure 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 both.

(b) Should document relevant information on the screening and categorization performed, including an identifier that follows a clear and consistent naming convention for easy reference. A concise description of each finding should be included, along with an explanation of why the finding was screened-in or screened-out for future reference. For screened-in findings, the categorization of the finding should be included to enable 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. General guidance is given in Section 4.2.1.4 of [4].

(d) Should establish arrangements to identify instances where similar findings have been raised previously. It should then be determined if additional analysis and actions are needed.

Analysing findings and developing an action plan

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 processes.

2.24. The regulatory body should implement the following arrangements to ensure thorough analysis of findings and, where necessary, effective development of an action plan:

(a) Involvement of suitably qualified staff to conduct an analysis of screened-in findings. This analysis should include a thorough examination from multiple perspectives, such as technical, operational and organizational. It should consider the impact of the findings on regulatory functions and processes.

(b) Analysis of each screened-in finding to identify the relevant aspects such as human, technical, legal, financial and managerial. Internal parties should be consulted, including process owners, senior managers and technical experts. Whenever appropriate, external interested parties should also be consulted, such as operating organizations, 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 actions ranging from minor adjustments to significant changes in the regulatory functions or processes. The regulatory body should ensure that the action plan identifies the staff 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 take 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. These factors should be considered with safety given the highest priority.

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

2.26. The approved action plan should include 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, as necessary.

Implementing the action plan

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

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

(a) Coordinating the implementation of the action plan by confirming the availability of necessary resources and involving third party or external interested parties, as necessary. This coordination might include collaboration with multiple authorities responsible for safety, cooperation with regulatory bodies of other States, or engagement with external technical support organizations.

(b) Monitoring the implementation of the action plan by systematically 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.

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

Disseminating the lessons learned

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 [8] 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."

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."

2.31. Paragraph 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."

2.32. The regulatory body should establish mechanism for dissemination of the lessons learned from regulatory experience feedback management for use by other regulatory bodies (e.g. in other States) with the responsibility for safety and other relevant parties (e.g. operating organizations, vendors, designers, technical support organizations and supply chain organizations), nationally and/or internationally.

2.33. The regulatory body should apply an approach based on openness and transparency when deciding about disseminating lessons learned. Areas for improvement as well as good practices should both be disseminated.

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

(a) Identifying the lessons to be disseminated. This involves establishing criteria to determine when a finding and associated actions qualify for dissemination and which findings and actions are to be disseminated.
(b) Identifying the recipients of the disseminated information, which may include the staff of the regulatory body, operating organizations, other national authorities and relevant international organizations.
(c) Deciding on the best approach to reach the intended recipients, considering factors such as the purpose for disseminating the lessons learned, the needs of the recipients and the means of dissemination.

INTEGRATING THE ARRANGEMENTS FOR REGULATORY EXPERIENCE FEEDBACK INTO THE MANAGEMENT SYSTEM

2.35. Paragraph 4.11 of IAEA Safety Standards Series No. GSR Part 2, Leadership and Management for Safety [9] 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."

2.36. Paragraph 1.5(b) of GSR Part 2 [9] 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 [9] states:

> "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".

2.37. The regulatory body should integrate the arrangements for regulatory experience feedback management within its management system to foster a systematic approach to capturing, analysing and applying lessons learned from regulatory experience. These arrangements should be interconnected with all processes contributing to regulatory experience feedback. Recommendations on establishing an integrated management system of the regulatory body are provided in section 5 of GSG-12 [6].

2.38. The regulatory body should document 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. Senior managers should use these statements to underline the role of regulatory experience feedback within the organization's culture for safety.

2.39. 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 fostering an enabling environment that motivates staff and reinforces the importance of effective management arrangements through leadership actions.

2.40. The regulatory body should have knowledge management processes that effectively capture, retain 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.

2.41. The regulatory body should actively promote the collection of information and knowledge resulting from experience across all levels of the organization to ensure effective management of learning opportunities. 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 managers, including facilitating continuous improvement. Senior managers should regard regulatory experience feedback as a valuable input when reviewing and updating regulatory functions and processes. This approach

encourages organization-wide dialogue on the benefits of effectively managing regulatory experience and promotes its integration into daily operations.

3. APPLICATION OF A GRADED APPROACH TO REGULATORY EXPERIENCE FEEDBACK MANAGEMENT

3.1. The application of a graded approach underpins the effective and efficient performance of a national regulatory framework. 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."

3.2. Requirement 7 of GSR Part 2 [9] states that "**The management system shall be developed and applied using a graded approach.**" Para 4.15 of GSR Part 2 [9] states:

> "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."

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

3.3. The regulatory body should ensure that the arrangements for managing regulatory experience feedback are also commensurate with its objectives, needs and priorities, and its size and organizational structure. The regulatory body should also consider factors such as:

(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[2];
(c) Provision of adequate human and financial resources.

3.4. The regulatory body should apply a graded approach when disseminating lessons learned, ensuring that this is commensurate with the safety significance of the findings and their relevance both within the organization and externally, at national and international levels.

[2] 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 database.

4. ANALYSING THE EFFECTIVENESS OF ARRANGEMENTS FOR MANAGING 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.**"

4.2. Requirement 13 of GSR Part 2 [9] 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.**"

4.3. Paragraph 6.7 of GSR Part 2 [9] states:

> "The management system shall 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."

4.4. Paragraph 6.8 of GSR Part 2 [9] states that "Organizations shall make arrangements to learn from successes and from strengths for their organizational development and continuous improvement."

4.5. The regulatory body should establish arrangements within its management system to monitor the performance and effectiveness of the arrangements for managing regulatory experience feedback. 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.

4.6. The regulatory body should periodically assess how effectively the arrangements for managing 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]). Methods 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.

4.7. The regulatory body should address the following in terms of the 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 in terms of improving the regulatory framework, 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 if there are no other channels available for raising such issues.

(d) 'Silo mentality'[3]: The regulatory body should avoid the development of a silo mentality by fostering an environment of sharing information, knowledge and experience that is valuable for enhancing regulatory functions and processes.

(e) Fear of personal consequences: The regulatory body should foster a 'no-blame'[4] working environment by establishing individual and institutional expectations towards managing regulatory experience. Management should ensure that staff 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 associated with managing regulatory experience feedback does not demotivate staff, and result in less active participation. Management should consider options for encouraging 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 rationalize regulatory experience feedback management to ensure effectiveness and minimize administrative burden, taking into account the application of a graded approach as described in Section 3 of this Safety Guide.

(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.

5. TRAINING OF STAFF ON REGULATORY EXPERIENCE FEEDBACK MANAGEMENT

5.1. For effective management of regulatory experience feedback, the regulatory body should develop and implement appropriate training for the staff involved. Recommendations on developing and maintaining adequate competences for the staff of the regulatory body are provided in section 6 of GSG-12 [6].

5.2. The regulatory body should provide training to help staff develop the knowledge, skills and attitude needed to effectively identify, screen, analyse and use regulatory experience feedback. Tools, such as non-conformance reporting mechanisms, sharing of good practices

[3] 'Silo mentality' refers to an attitude that can emerge when individuals or organizational units do not want or are not able to share experience, including information, knowledge and experience, which could be valuable for enhancing performance.

[4] 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. This approach does not preclude accountability in cases of deliberate violations or gross negligence.

and offering opportunities to raise concerns, should be utilized to empower employees and support continuous improvement. Table 4 in Appendix II outlines key topics that should be included in training on regulatory experience feedback.

5.3. The regulatory body should provide appropriate training to relevant staff to identify sources of regulatory experience that are valuable to the organization. The regulatory body should also encourage staff to routinely utilize these sources to identify lessons learned and integrate this approach into their routine duties.

APPENDIX I

SOURCES OF REGULATORY EXPERIENCE FEEDBACK

I–1. This appendix presents possible sources of regulatory experience from which the regulatory bodies can learn lessons that could assist it in improving the regulatory framework, functions and processes. The sources listed in Tables 1–3 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	New national laws and regulations relevant to safety
	Legislative proceedings[5]
	Regulations from other authorities with safety implications
	Public consultations and hearings
	High-level committees
	Codes and standards of professional organizations (including non-nuclear organizations)
	Reports and feedback from technical support organizations and advisory bodies
	Reports and feedback from research organizations
Notification and Authorization	Issue of authorizations
	Regulatory review of modifications and process changes
	Oversight of compliance with authorization conditions
	Licensing appeals
	Public consultations
	Policy statements
	Feedback from operating organizations
Review and assessment	Safety evaluations
	Benchmarking with other regulatory bodies
	Lessons identified from operating experience feedback
	Lessons identified from research and development activities
	Technical meetings
	Incident investigations

[5] 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
Inspection of facilities and activities	Inspection reports
	Inspection findings
	Operating experience feedback from facilities and activities
	Relevant operating experience feedback from non-nuclear facilities and activities
Enforcement of regulatory requirements	Enforcement appeals
	Corrective actions
	Enforcement procedures of other regulatory bodies
Emergency preparedness and response	Emergency drills and exercises, including interaction with participants and the public
	Coordination committees involving national authorities
	Learnings identified from responses to emergencies
	Interaction with other national authorities directly linked with emergency preparedness and response
Management system	Quality management audits
	Independent assessments
	Self-assessments
	Government audits
	Peer review reports and findings
	Findings from management system reviews
Staffing and competence	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 facilities and activities	International conferences, meetings and seminars hosted by international organizations, in particular those focused on sharing experience from regulating facilities and activities
	Committees, working groups and task forces of international organizations
	Exercises promoted by international organizations
	Technical documents and policy guidance published by international organizations and participation in their drafting
	Activities of the technical cooperation programmes operated by international organizations such as training courses, fellowships and scientific visits, workshops and expert missions
	Peer reviews and advisory missions
Development and use of international safety standards	Drafting groups to develop international safety standards
International codes of conduct on safety	Technical meetings
	Guidance and technical reports
International conventions, treaties and agreements	Governing bodies and diplomatic conferences
	Review meetings of contracting parties to conventions and national reports submitted by the States
	Multilateral implementing regulations and agreements
International cooperation settings among nuclear regulatory bodies	Bilateral and multilateral cooperation agreements among nuclear regulatory bodies
	Technical exchanges under the umbrella of bilateral and multilateral agreements (e.g. benchmarking, combined exercises, shared intelligence)
Codes and standards, publicly available technical reports	National and international codes and standards
	Codes of practice and technical reports from international associations for nuclear and radiation industries
International reporting systems and databases	IAEA databases (e.g. INES, INIS, PRIS, IRS, FINAS, IRSRR)
	Other databases (e.g. NEA nuclear databases, ICSBEP database on criticality safety benchmarks)
International research	International research programmes or 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 authorities not linked to the regulatory process	Exchanges with other 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
Other international non-nuclear sources of regulatory experience	Events from non-nuclear industries
	Activities and documents of other non-nuclear international organizations (e.g. WHO, OECD/IEA, IATA)

I–2. The regulatory body should take measures to facilitate access to potential sources of experience (e.g. hosting peer review missions, encouraging staff to participate in international training and to enrol in fellowship programmes or scientific visits) and remove barriers to accessing such sources (e.g. engaging in international research, concluding bilateral agreements with other countries).

I–3. The regulatory body should explore how to effectively utilize lessons identified from research and development to help keep the regulatory framework, functions and processes up to date and effective.

APPENDIX II

IDENTIFICATION OF FINDINGS

II.1. The regulatory body should consider the identification of potential findings as being the primary driver of regulatory experience feedback. Managers at all levels of the regulatory body should instil positive attitude in staff through training and coaching, and by providing staff with the appropriate guidance and tools to identify, document and submit potential findings.

II.2. The regulatory body should provide appropriate guidance and training to staff to ensure that only relevant findings are captured. This approach helps to streamline resources and avoid unnecessary expenditure.

TOOLS TO GUIDE THE IDENTIFICATION OF FINDINGS

II.3. The regulatory body should consider developing and using tools such as templates, checklists and other means to guide staff 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 provides a checklist that could be used to support staff in deciding whether there are lessons to be learned to improve the regulatory process, including the identification of good practices.

II.4. The regulatory body should develop guidelines to help staff identify areas for improvement in the regulatory framework, functions and processes as well as strengths that should be disseminated. This guidance should take into consideration:

(a) Aspects relating to the framework, structure and constituents of the regulatory function or process under consideration. This includes the basic principles and methodology for the function or process; regulatory objectives and criteria; as well as the accuracy and relevance of the information.
(b) 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.
(c) Organizational aspects 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 STAFF

II.5. The regulatory body should ensure that staff at all levels within the organization understand their role in achieving successful regulatory experience feedback management. The management of the regulatory body should explore opportunities to motivate staff, 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 staff who raise findings in the subsequent stages of the regulatory experience feedback management including analysis, development and implementation of action plan;

(c) Emphasize to staff the relevance of individual contributions to the safety objective of the organization in policy statements and in the training of staff;

(d) Periodically organize meetings with the staff to collectively discuss examples of improvements in the regulatory process achieved through the implementation of lessons learned from findings;

(e) Identify staff with the necessary skills to motivate and mentor other employees to raise regulatory findings;

(f) Manage the additional workload on 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 staff and further promote the utilization of regulatory experience feedback.

TRAINING OF STAFF

II.6. Suitable training should be made available to familiarize the staff of the regulatory body with the concept of regulatory experience feedback and to guide them in utilizing available tools. This training should be tailored to fit the arrangements for regulatory experience feedback. The content of the training programme should cover the topics listed in Table 4.

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

Topic	Purpose
Topic 1: Basic Principles Subjects to cover, as appropriate: • Concept and definition of regulatory experience • Objective of regulatory experience feedback • International standards • National regulations • Mission and policy statements • International commitments and contribution to the global safety regime • Structure of the regulatory body • Interaction and coordination with other national regulatory bodies • Liaison with licence holders	This topic is intended to provide trainees with insights about the concept of regulatory experience feedback and how it relates to the organization of the regulatory body and to the regulatory process, including liaison with other authorities and interested parties.

Topic	Purpose
• Liaison with advisory bodies, technical support organizations, other regulatory authorities and involvement in international programmes and activities • Linkage and differences between operating experience feedback and regulatory experience feedback	

Topic 2: Benefits of management of regulatory experience

Subjects to cover, as appropriate:

- Added value of the management of regulatory experience for enhancing the regulatory process
- Examples of how the application of regulatory experience has led to improvements in the design, implementation or effectiveness of the regulatory experience feedback arrangements itself

This topic 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

Subjects to cover, as appropriate:

- Internal sources:
  - — Core regulatory functions and processes
  - — 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:
    - o Research and development in the field of nuclear and radiation safety
    - o Non-nuclear legislation and policy
    - o Non-nuclear regulatory bodies
    - o Non-nuclear industries
    - o Industry codes and standards
  - — International
    - o International safety standards
    - o International industry codes and standards
    - o International nuclear research
    - o International organizations

This topic 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.

Topic	Purpose
○ Associations, forums and networks of regulatory bodies ○ International conventions ○ Research and development in the field of nuclear and radiation safety	
Topic 4: Arrangements for managing regulatory experience	
Subjects to cover, as appropriate: • Approaches and methods used for managing regulatory experience • Roles and responsibilities in managing regulatory experience • Integration within the management system and interfaces with relevant processes • Management of internal and external sources of regulatory experience • Arrangements for the following: — Identification of regulatory experience (e.g. through the use of templates or other means, guidance and practical examples) — Collection of regulatory experience, including channels for reporting and organizing the information — Storage of information, including type of information stored, means of storage, provisions for accessing and retrieving information • Arrangements for analysis of regulatory experience: — Criteria and thresholds for screening of findings — Assessment of findings and elaboration of action plans to address findings — Decision making • Arrangements for implementing action plans and sharing lessons learned: — Monitoring the implementation of action plans — Monitoring the impact of the actions in the regulatory process — Criteria for sharing and dissemination of regulatory experience	This topic is the bulk of the programme and its purpose is to provide step-by-step information on how to complete an analysis of findings.
Topic 5: Leadership and management	
Subjects to cover, as appropriate: • Management commitment to the management of regulatory experience • Management reviews of the arrangements for regulatory experience feedback	This topic is intended to illustrate how the management of the regulatory body commits to an effective and efficient management of regulatory experience.

Topic	Purpose
Topic 6: Engaging staff Subjects to cover, as appropriate: • Roles and responsibilities • Expectations for staff • 'No blame' culture in the work environment • Staff involvement throughout the analysis of findings and feedback • Acknowledgement of staff contributing to the management of regulatory experience • Means available to staff for handling and communicating findings	This topic is intended to foster and encourage the staff of the regulatory to actively use the arrangements for managing regulatory experience and to acknowledge the contribution of individuals in enhancing the regulatory process.
Topic 7: Continuous improvement of the arrangements for managing regulatory experience Subjects to cover, as appropriate: • Self-reflection and self-assessment • Benchmarking and peer reviews	This topic 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 Subjects to cover, as appropriate: • Existing international forums for reporting operating experience and how they relate to reporting regulatory experience • Advantages and disadvantages of existing international systems to share regulatory experience	This topic illustrates how to use existing incident reporting systems to share regulatory experience.

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Annex I

THE RELATIONSHIP BETWEEN OPERATING EXPERIENCE FEEDBACK AND 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, while 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.

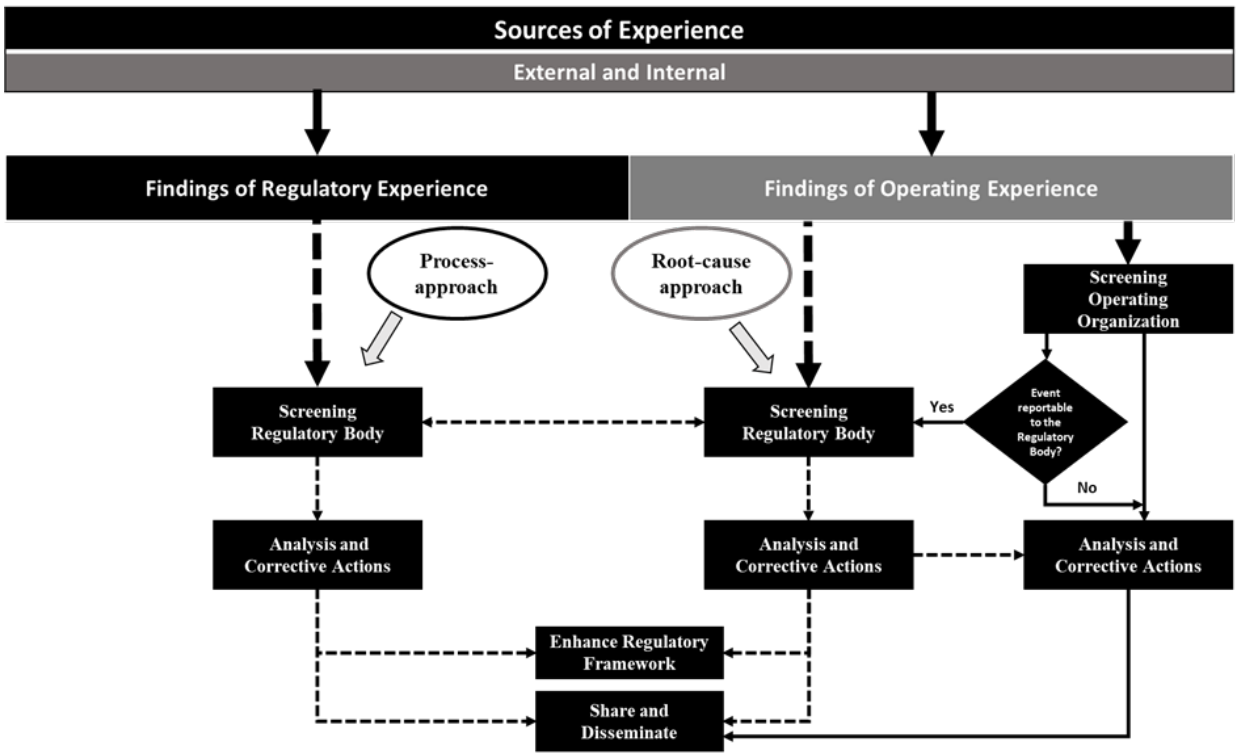

FIG. I–1. Relationship between regulatory experience and operating experience

I–2. Figure I–1 illustrates the 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 in accordance with regulatory requirements, undertakes screening and analysis on the basis of the actual or potential safety consequences of the event and implements corrective actions. 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 implemented 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 implemented 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.

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 decide 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 FINDINGS

Opportunities for improvement	Strengths
Aspects relating to the regulatory process	
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 achieve the policy, strategy 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 different 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 a facility or activity	The regulatory process introduces improvements that minimize interferences in the operation of a facility or activity and the use of resources. These improvements are worth sharing with other interested parties

Aspects relating to the staff

There are no available appropriate procedures for staff to implement the regulatory process	The regulatory body has established and revised procedures and arrangements to keep staff up-to-date with new knowledge and experience
Staff have not received appropriate training and guidance to understand the principles and goals of the regulatory process	The regulatory body has effective capacity building programmes, including coaching of newly recruited staff by experienced staff
There are not enough resources and means (human and technical) to implement the regulatory process	Appropriate mechanisms have been established to ensure that there are enough staff to implement the regulatory process in an effective and efficient way
Staff do not have access to specialized support and advice to implement the regulatory process and reach the regulatory objectives	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 regulatory process	The outcome of the regulatory process is used to identify the lessons and to disseminate them as appropriate within and outside the organization
There is not an appropriate 'no blame' culture to foster a questioning attitude and to raise concerns in the implementation of the regulatory process	There are appropriate mechanisms to raise concerns and identify findings for effectively managing regulatory experience feedback
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 regulatory process is well integrated within the management system and there is a multidisciplinary and complementary approach in assessing its outcomes.

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