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Document Preparation Profile (DPP)
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1. IDENTIFICATION

Document Category **Safety Guide**

Working ID: **DS547**

Proposed Title: **Development and Implementation of an Effective and Efficient Regulatory Experience Feedback Program for Regulatory Bodies for Safety**

Proposed Action: **New publication: Safety Guide on Development and Implementation of Regulatory Experience Feedback Program for Regulatory Bodies in support of GSR Part 1(Rev.1)**

To be integrated in the long-term plan into the revisions of GSG-12 and GSG-13

Review Committee(s) or Group: **NUSSC (lead), RASSC, WASSC, TRANSSC and NSGC**

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2. BACKGROUND

IAEA Safety Fundamental SF-1 stipulates that regulating safety is a national responsibility and international cooperation serves to promote and enhance safety globally by exchanging experience. Principle 3 of SF-1 calls that the management system has to ensure the promotion of a safety culture, the regular assessment of safety performance and the application of lessons learned from experience.

Requirement 15 of GSR Part 1 (Rev. 1) states that “The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities.” Paragraph 3.4 further states that “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 first topic (for nuclear installations) is addressed in SSG-50. However, there is no equivalent safety guide for the management of regulatory experience. Also, the IAEA, in cooperation with other international organizations, has established mechanisms to foster the analysis and sharing of operating experience (IRS, FINAS, IRSRR etc.). Similar mechanisms to facilitate the analysis and sharing of regulatory experience at regional or global level do not exist. 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.” Para 4.39A of GSR Part 1 (Rev. 1) requires that the regulatory body shall ensure, adopting a graded approach, that authorized parties routinely evaluate operating experience and periodically perform comprehensive safety reviews of facilities. Further, requirement 4 para 2.8 (f) of GSR Part 1 (Rev. 1) necessitates the regulatory body be able to exchange regulatory related information and experience with regulatory bodies of other States and with international organizations as one means of effective independent on its decision making. To maintain and improve the regulatory oversight performance is one of the main purposes of the management system of the regulatory body. Requirement 19 of GSR Part 1 (Rev.1) necessitates the regulatory body to establish, implement, assess and improve a management system that is aligned with its safety goals and contributes to their achievement.

Requirement 5 para 2.48 (d) of GSR Part 3 requires that the principal parties shall ensure that the management system is designed and applied to enhance protection and safety by providing the regular assessment of performance for protection and safety, and the application of lessons learned from experience. Further, requirement 15 para 3.39 (d) requires registrants or licensees to take account of relevant developments concerning technical criteria, as well as the results of any relevant research on protection and safety and feedback of information on lessons learned from experience during all stages of facilities. Requirement 16 of GSR Part 3 states that “Registrants and licensees shall conduct formal investigations of abnormal conditions arising in the operation of facilities or the conduct of activities and shall disseminate information that is significant for protection and safety”. It is important for a regulatory body to use experience feedback during the development and implementation phases of its regulatory documents. Para 3.21 of GSG-13 states that “In developing guides, recent operating experience and developments should be taken into account, including technological advances that have been shown by experience or by research results to be capable of providing effective and reliable means of satisfying regulatory requirements.” Para 3.66 GSG-13 further states that “Experience from implementing the regulations should be examined and any problems or difficulties should be duly considered. The status of relevant requirements should also be examined in the light of new safety related developments. The possible effects of frequent changes in regulations and guides on the stability of the regulatory system should be taken into account. The reasons for revising regulations may include: changes in legislation; changes in the organization, responsibilities, policies or procedures of the regulatory body; experience gained by the regulatory body in the authorization process; feedback of information and experience from events, as well as from relevant national and international good practices; technological advances; and the need to improve or eliminate any impractical, misleading, unenforceable or otherwise inadequate regulations.”

In view of the importance of the subject, IAEA developed a TECDOC-1899, “Effective Management of Regulatory Experience for Safety-2020” but there is no specific IAEA Safety Standard on the subject except SSG-50 “Operating Experience Feedback for Nuclear Installations”.

3. JUSTIFICATION FOR THE PRODUCTION OF THE PUBLICATION

During the third International Conference on Effective Nuclear Regulatory Systems, Transforming Experience into Regulatory Improvement, held in Ottawa, Canada, from 8 to 12 April 2013, under Action item number 2 of the president report calls for assessing the need for a regulatory experience programme that is directed towards improving regulations as well as

regulatory systems and processes. Further, International Conference on Effective Nuclear and Radiation Regulatory Systems: Working Together to Enhance Cooperation (The Hague – 4th to 7th November 2019), many IAEA Member States pointed out that the management of regulatory experience, within the overall topic of Regulatory Effectiveness, is one of the major challenges being faced by the regulatory bodies and expressed the need for availability of guidance and training material (including e-learning) on the subject.

During 66th General Conference, the Nuclear and Radiation Safety Resolution, GC(66)/RES/6 adopted on 30 September 2022, under item 26, requests the Secretariat to help Member States' regulatory bodies, upon request, to establish systematic regulatory experience feedback mechanisms;

The analysis of operating experience of regulated facilities and activities has traditionally been considered an important source of learning for improving the regulatory process. However, regulatory bodies are continuously exposed to learning possibilities from multiple sources of experience, such as the implementation of regulatory functions by peers, regulatory research and work carried out by international committees and working groups. Taking advantage of all these learning possibilities could be beneficial in further enhancing the effectiveness and efficiency of the regulatory process. Regulatory experience feedback is one of the prime factors that improve the regulatory process. However, regulatory bodies get these experiences from multiple sources, and it is necessary to effectively manage such multidirectional inputs.

While IAEA safety standards assist countries in developing programmes and processes within their regulatory frameworks, there is no specific direction or assistance on how to develop and implement a regulatory experience feedback programme. In this regard, a technical guidance document (TECDOC-1899) was developed in 2020, however, NUSSC in its 52nd meeting encouraged the IAEA to develop a Safety Guide on development and implementation of an effective and efficient regulatory experience feedback program for regulatory bodies (a new guide under GSR Part 1(Rev.1)). Further, NUSSC discussed the topic of effective management of regulatory experience in its meeting of June 2022 and recommended the IAEA secretariat to initiate the development of an IAEA publication following formal proceedings.

The safety guide will further strengthen actions of regulatory bodies to improve their processes and of international community to establish mechanisms to facilitate the sharing and dissemination of regulatory experience. This guide will also provide further information to assist Member States in addressing the requirement for management of regulatory experience stated in GSR Part 1 (Rev. 1); Requirement 15.

4. OBJECTIVE

This Safety Guide will provide practical guidance and recommendations for the regulatory bodies to systematically gather, analyse, disseminate, maintain and implement knowledge and experience of its regulatory functions and process for facilities and activities, while taking into account:

- Identifying internal and external sources on regulatory experience;
- Establishing and maintaining a means for receiving information from its own functions and processes;
- Establishing and maintaining means for receiving information from other regulatory bodies of other Member States and international organizations, and authorized parties;

- Establishing processes for screening, and analysing the information collected or received and evaluating the effectiveness of corresponding activities;
- Record keeping, maintaining and utilizing regulatory experience, including sharing lessons learned from regulatory experience

5. SCOPE

The proposed Safety Guide will cover management of regulatory experience in all functions and processes of a regulatory body for all facilities and activities that give rise to radiation risks. The primary audience is regulatory bodies and its technical support organizations. It might also be useful for operators and particularly their internal regulator/audit functions, vendors, design and supply chain organizations.

6. PLACE IN THE OVERALL STRUCTURE OF THE RELEVANT SERIES AND INTERFACES WITH EXISTING AND/OR PLANNED PUBLICATIONS

When drafting the Safety Guide, due account will be given in particular to the following documents:

- 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).
- 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.
- INTERNATIONAL ATOMIC ENERGY AGENCY, Governmental, Legal and Regulatory Framework for Safety, IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), IAEA, Vienna (2016).
- 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).
- INTERNATIONAL ATOMIC ENERGY AGENCY, Safety of Nuclear Power Plants: Design, IAEA Safety Standards Series No. SSR-2/1 (Rev. 1), IAEA, Vienna (2016).
- INTERNATIONAL ATOMIC ENERGY AGENCY, Safety of Research Reactors, IAEA Safety Standards Series No. SSR-3, IAEA, Vienna (2016).

- INTERNATIONAL ATOMIC ENERGY AGENCY, Safety of Nuclear Fuel Cycle Facilities, IAEA Safety Standards Series No. SSR-4, IAEA, Vienna (2017).
- INTERNATIONAL ATOMIC ENERGY AGENCY, Establishing the Safety Infrastructure of a Nuclear Power Programme, IAEA Safety Guide Series No. SSG-16(Rev.1), IAEA, Vienna, (2020).
- INTERNATIONAL ATOMIC ENERGY AGENCY, Organization, Management and Staffing of the Regulatory Body for Safety, IAEA Safety Standards Series No. GSG-12, IAEA, Vienna (2018).
- INTERNATIONAL ATOMIC ENERGY AGENCY, Functional and Processes of the Regulatory Body, IAEA Safety Standards Series No. GSG-13, IAEA, Vienna (2018).
- INTERNATIONAL ATOMIC ENERGY AGENCY, Operating Experience Feedback for Nuclear Installations, IAEA Safety Standards Series No. SSG-50, IAEA, Vienna (2018).
- INTERNATIONAL ATOMIC ENERGY AGENCY, Use of a Graded Approach in the Application of the Safety Requirements for Research Reactors, IAEA Safety Standards Series No. SSG-22(Rev.-1), IAEA, Vienna (2023).
- INTERNATIONAL ATOMIC ENERGY AGENCY, Effective Management of Regulatory Experience for Safety, IAEA TECDOC 1899, Vienna (March 2020).
- INTERNATIONAL ATOMIC ENERGY AGENCY, IRS Guidelines Joint IAEA and OECD/NEA International Reporting System for Operating Experience(IRS) Services Series 19 (Rev.1), IAEA Vienna (2022)
- INTERNATIONAL ATOMIC ENERGY AGENCY, Best Practices in the Utilization and Dissemination of Operating Experience at Nuclear Power Plants, IAEA TECDOC 1580, Vienna (March 2008).
- INTERNATIONAL ATOMIC ENERGY AGENCY, Best Practices in the Management of an Operating Experience at Nuclear Power Plants, IAEA TECDOC 1653, Vienna (2010).
- INTERNATIONAL ATOMIC ENERGY AGENCY, Application of a Graded Approach in Regulating Nuclear Installations, IAEA-TECDOC-1980, IAEA, Vienna (2021).
- INTERNATIONAL ATOMIC ENERGY AGENCY, Application of a Graded Approach in Regulating the Safety of Radiation Sources, IAEA TECDOC 1974, Vienna (2021).
- INTERNATIONAL ATOMIC ENERGY AGENCY, Use of a Graded Approach in the Application of the Management System Requirements for Facilities and Activities, IAEA-TECDOC-1740, IAEA, Vienna (2014).
- INTERNATIONAL ATOMIC ENERGY AGENCY, Report on Strengthening Nuclear Regulatory Effectiveness in the Light of the Accident at the Fukushima Daiichi Nuclear Power Plant, IAEA, Vienna (2013).

- *INTERNATIONAL ATOMIC ENERGY AGENCY, Establishing the Nuclear Security Infrastructure for a Nuclear Power Programme, IAEA Nuclear Security Series No. 19, IAEA, Vienna (2013).*
- *INTERNATIONAL ATOMIC ENERGY AGENCY, Objective and Essential Elements of a State's Nuclear Security Regime, IAEA Nuclear Security Series No. 20, IAEA, Vienna (2013).*
- *INTERNATIONAL ATOMIC ENERGY AGENCY, Nuclear Security Recommendations on Physical Protection of Nuclear Material and Nuclear Facilities (INFCIRC/225/Revision 5), IAEA Nuclear Security Series No. 13, IAEA, Vienna (2011).*
- *INTERNATIONAL ATOMIC ENERGY AGENCY, Security during the Lifetime of a Nuclear Facility, IAEA Nuclear Security Series No. 35-G, IAEA, Vienna (2019).*
- *INTERNATIONAL ATOMIC ENERGY AGENCY, Nuclear Security Culture, IAEA Nuclear Security Series No. 7, IAEA, Vienna (2008).*
- *INTERNATIONAL ATOMIC ENERGY AGENCY Disposal of Radioactive Waste, SSR-5 (2011)*
- *INTERNATIONAL ATOMIC ENERGY AGENCY Predisposal Management of Radioactive Waste, GSR-5 (2009)*
- *INTERNATIONAL ATOMIC ENERGY AGENCY Predisposal Management of Radioactive Waste from the Use of Radioactive Material in Medicine, Industry, Agriculture, Research and Education, SSG-45 (2019)*
- *INTERNATIONAL ATOMIC ENERGY AGENCY Regulations for the Safe Transport of Radioactive Material, SSR-6(Rev.1) (2018)*
- *INTERNATIONAL ATOMIC ENERGY AGENCY Radiation Protection and Safety in Medical Uses of Ionizing Radiation, SSG-46 (2018)*
- *INTERNATIONAL ATOMIC ENERGY AGENCY Decommissioning of Nuclear Power Plants, Research Reactors and other Nuclear Fuel Cycle Facilities, SSG-47 (2018)*
- *INTERNATIONAL ATOMIC ENERGY AGENCY Radiation Safety of X-ray generator and other Radiation Sources used for Inspection Purposes and for Non-medical Human Imaging, SSG-55 (2020)*
- *INTERNATIONAL ATOMIC ENERGY AGENCY Radiation Safety of Accelerator Based Radioisotope Production Facilities, SSG-59 (2020)*
- *INTERNATIONAL ATOMIC ENERGY AGENCY Establishing the infrastructure for Radiation Safety, SSG-44 (2018)*

7. OVERVIEW

While developing the safety guide, the content of TECDOC- 1899 will be reviewed and incorporated, with necessary revisions where applicable or where revised documents are available. An outline is set out below, however, the final contents may vary during the drafting process.

1. Introduction: Background – Objective – Scope – Structure

2. Process for Development and Implementation of Regulatory Experience

- i. Identification and Collection
- ii. National Operating and Regulatory Experience
- iii. International Operating and Regulatory Experience
- iv. Records and Storage
- v. Screening
- vi. Evaluation
- vii. Actions and Outcomes
- viii. Develop and Disseminate Lessons Learned

3. Analysis of Effectiveness of Regulatory Experience

4. Harmonization and Improvement of Existing Processes

5. Dissemination of the Lessons Learned

- i. i. Changes to Regulatory Requirements
- ii. ii. Regulatory processes
- iii. iii. Management System
- iv. vi. Human performance

Equipment

6. Application of a Graded Approach

- i. Use of a Graded Approach During the Development Process of a Regulatory Experience Feedback Program
- ii. Use of a Graded Approach for Implementation of a Regulatory Experience Feedback Program

7. Integration of Regulatory Experience Feedback System process to the Management system

8. Appendices

9. References

8. PRODUCTION SCHEDULE: Provisional schedule for preparation of the publication, outlining realistic expected dates for each step

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STEP 1: Preparing a DPP	DONE		
STEP 2: Internal review of the DPP (Approval by the Coordination Committee)	September 2022		
STEP 3: Review of the DPP by the review Committee(s) (Approval by review Committee(s))	Q2.2023		
STEP 4: Review of the DPP by the CSS (approval by CSS) or information of the CSS on the DPP	Q1 2024		
STEP 5: Preparing the draft publication	Q2 2024		

STEP 6: First internal review of the draft publication (Approval by the Coordination Committee)	Q3 2024		
STEP 7: First review of the draft publication by the review Committee(s) (Approval for submission to Member States for comments)	Q4 2024		
STEP 8: Soliciting comments by Member States	Q4 2024		
STEP 9: Addressing comments by Member States	Q1 2025		
STEP 10: Second internal review of the draft publication (Approval by the Coordination Committee)	Q2 2025		
STEP 11: Second review of the draft publication by the review Committee(s) (Approval of the draft)	Q3 2025		
STEP 12: (For Safety Standards) Editing of the draft publication in MTCD and endorsement of the draft publication by the CSS (For nuclear security guidance) DDG's decision on whether additional consultation is needed, establishment by the Publications Committee and editing	Q3 2025		
STEP 13: Approval by the Board of Governors (for SF and SR only)			
STEP 14: Target publication date	Q4 2025		

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10. RESOURCES

It is estimated that the development of the Safety Guide would involve approximately 60 weeks of effort by experts. This is based upon assuming 5 one-week consultant's meetings, involving no more than 6 experts and an average of one week of work per expert between meetings. An additional Technical Meeting will be considered.

Agency resources involved are estimated at 15 weeks of effort by the Technical Officers from NSNI/RAS and NSRW/RIT. Additionally, it is estimated that a total of 10 weeks of effort from TOs from other divisions/sections will be needed for consultation.

ANNEX: GAP ANALYSIS

- I. Sharing of regulatory experience is cited in many IAEA safety standards, but there is no generic guidance available for regulatory bodies for development and implementation of an effective and efficient regulatory experience feedback program. Further, other IAEA safety standards provide high level recommendations for different

areas of regulatory experience but do not provide methods of development and implementation. As a result, the documentation and guidance are not available in a coherent framework.

- II. Experience feedback from IRRS missions has identified the need to address and further explain the intent of GSR Part-1 (Rev.1) for a regulatory experience feedback program with emphasis on:
- arrangements for sharing of operating and regulatory experience to ensure systematic analysis, dissemination and feedback on measures taken in response to information received;
 - formalisation and improvement of existing processes by utilizing regulatory experience feedback;
 - increasing international participation and involvement of staff to improve the regulatory experience and feedback;
 - development of clear reporting criteria;
 - Effective, formal, documented and sustainable implementation of arrangements for analysing events and identifying lessons learned from operating experience and regulatory experience.
 - Application of graded approach based on important factors considered in implemented core and support regulatory processes

These areas will be considered and addressed in the proposed Safety Guide.