

**Form for Comments**  
**DS547 Regulatory Experience Feedback Management**

	<b>COMMENTS BY REVIEWER</b>				<b>RESOLUTION</b>			
	<b>Reviewer:</b> <b>Country/Organization: Canada, Finland, Germany, Iran, Japan, Pakistan, Russia</b>							
<b>Comment No.</b>	<b>Comment ID</b>	<b>Para/Line No.</b>	<b>Proposed new text</b>	<b>Reason</b>	<b>Accepted</b>	<b>Accepted, but modified as follows</b>	<b>Rejected</b>	<b>Reason for modification/rejection</b>
1.	GER/1	General 1	<i>As this Safety Guide provides recommendations for regulatory bodies on how to meet Requirement 15 of GSR Part 1 (Rev. 1), all aspects of Requirement 15 should be considered, this includes associated Requirements, namely paras 3.3, 3.4, 3.5 and 3.5A of GSR Part 1 (Rev. 1). Currently recommendations related to paras 3.3("reporting") and 3.5("feedback") are missing. We would propose to have these included.</i>				X	Already covered in 3.26 of DS547
2.	GER/2	General 2	<i>This draft does not take into account the existing guidance from GSG-12 in a systematic manner. Matching with and adjustments to GSG-12 should be carried out more carefully, especially with respect to already established integrated management system and terms established. In</i>		X			GSG-12 and GSG-13 do not talk about regulatory experience feedback management. The long-term objective is to integrate this subject in GSG-12 and GSG-13 during their next revisions. However, the relevant link to GSG-12 is established in this

			<p><i>addition, the consideration of regulatory experience should be treated as an activity within the integrated management system from the very beginning of this document.</i></p>					<p>safety guide as proposed at appropriate places.</p>
3.	GER/3	General 3	<p><i>An appendix, if included, is considered to form an integral part of the safety standard. Hence, material in an appendix has the same status as the body text.</i></p> <p><i>Furthermore, “Material for which there is no appropriate place in the body text (e.g. material that is subsidiary to or separate from the body text, is included in support of statements in the body text, or describes methods of calculation, procedures or limits and conditions) may be presented in appendices or annexes” (see GSR Part 1 (Rev. 1), Section INTERPRETATION OF THE TEXT).</i></p> <p><i>Therefore, Recommendations, being primary – not subsidiary issues - should be provided in the main part of the Guideline Document, not in Appendix, as it is done in current version.</i></p>		X			<p>Appendix are considered as part of the main text. The information provided in Appendices is assessed and appropriate adjustments/responses were made.</p>

4.	GER/4	General 4	<i>Some statements are repeated several times throughout the text. We made few suggestions to reduce this, however there are still more occurrences within the text. Could you please have a closer look at this issue.</i>		X			The document is checked for repetition and adjustments were made in the text to avoid repetitions.
5.	GER/5	General 5	<i>We are missing a connection to Section 3 of GSR-1 (Rev.1) „The Global Safety Regime”, namely to Requirement 14 “International obligations and arrangements for international cooperation and assistance” and to its associated Requirements, formulated in paras. 3.2 (b) - adoption of good practices, (d) - mutual learning by participating States - and (e) - sharing of knowledge and feedback of experience. Can you please include the recommendations to these Requirements into the current Safety Guide?</i>				X	The aspects mentioned in requirement 14 from GSR Part 1 is already covered in sources for identifying findings. The information can be found in Appendix-I.
6.	GER/6	General 6	<i>Out of seven paras in Section 4 are two that solely repeat requirements or suggestions of other IAEA Safety documents without giving any advice / recommendation on its implementation in relation to experience feedback. This expands the document</i>				X	The referenced paragraphs (4.1 and 4.2) were included to cite foundational requirements from IAEA GSR Part 2, thereby establishing the basis for integrating experience feedback into the management system. These references were

			<p><i>unnecessarily and diverts the attention from the novel messages addressed in this document. We suggest as an alternative to collect the substantial citations of other IAEA Safety Documents in the Section 1 and Section 2.</i></p> <p><i>Similarly, Section 5 – Three out of the six paras solely repeat the requirements or suggestions of other IAEA Safety documents without giving advice on their implementation.</i></p>					<p>intended to provide context and demonstrate alignment with established safety standards. Paragraphs 4.3 to 4.7 then elaborate on how the regulatory body should implement these requirements specifically in relation to the management of regulatory experience feedback. A similar structure has been applied in Section 5. The same approach is also highlighted in the comment above by Germany regarding connection between Section 3 and Requirement 14 of GSR Part 1.</p>
7.	GER/7	General 7	<p><i>In order to help with international exchange/harmonization a recommendation for categories should be provided within this guide, for instance as an additional annex. We would therefore like to suggest the creation of a further Annex (Annex III), which gives advices on how the categories are applied.</i></p> <p><i>Does IAEA plan to implement a portal for regulatory experience</i></p>				X	<p>The responsibility for categorizing the findings rests with the Member States as per their national circumstances. Typically, such information is documented in the IAEA informational publications. Therefore, general guidance on categorization practices, reflecting the diverse approaches of different Members States, is provided in the IAEA TECDOC-1899 (Section 4.2.1.4).</p>

			<i>feedback similar to others (INES, FINAS etc.)?</i>					Further, the development of a dedicated portal to regulatory experience feedback could be considered by the Agency, subject to further feedback from the MSs. In the meantime, the topic remains a standing item on the agenda for all regulatory conferences, forums, seminars and related events as a key channel for gathering insights and feedback on regulatory experience.
8.	PAK/1	General comment	It is recommended to <b><u>include examples of successful operating experience feedback programs from different countries, by highlighting challenges faced and lessons learned.</u></b> This would help regulators understand the practical aspects of implementation and this would demonstrate the tangible benefits of such feedback mechanisms.	To improve the relevance and usefulness			X	This is beyond the objective and scope of this safety guide. Such examples can be provided in informational publications (TECDOC, technical reports etc.) but not in the safety standards. Some examples can be found in TECDOC-1899 (Annex V is one example).
9.	PAK/18	General	Qualitative and/or Quantitative Performance Indicators may be included in the document	Regarding the Performance, no defined Success Targets or Performance Indicators are mentioned in the document	X	Following is added in para 6.5: The regulatory bodies may define some qualitative or quantitative performance indicators, as		

						appropriate, to assess how well the arrangements for managing REGEX has achieved the intended purpose.		
10.	PAK/2	1.2~1.5, Page #. 02	----	Ref" [2]. [3], [4] lacks specific paragraph or clause No.			X	Regarding paras 1.2 and 1.3, the requirement number and para numbers are referred adequately. However, for paras 1.4 and 1.5, the documents [3] and [4] are referenced in their entirety to provide general information on what these documents cover.
11.	GER/8	1.4A New issue	<u>Regulatory experience in this sense 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. Operating experience pertains to insights and lessons to be learned from the operation of regulated facilities and activities.</u>	Definition / explanation of regulatory experience and operation should be given at the very beginning of this Safety Guide; at the moment is it "hidden" in para 2.4.			X	The concept of regulatory experience is introduced in Section 2 along with the link between regulatory experience and operating experience. Accordingly, the definitions are given in Section 2.
12.	GER/9	1.4B New issue	<u>As stated in para 3.3 of GSR Part 1 (Rev. 1) [2]. "The reporting of operating experience and regulatory experience has led to significant corrective actions in relation to equipment, human performance and the management system</u>	Requirement 15 of GSR Part 1 (Rev. 1) has four associated requirements: paras 3.3, 3.4, 3.5 and 3.5A. We propose that Requirement 15 should be treated in this document with all of its associated requirements of GSR Part 1 (Rev. 1) (refer also to our comment <i>General 1</i> ).			X	The information is already covered in para 2.4 and 3.26 of DS547.

			<u>for safety, as well as changes to regulatory requirements and modifications to regulatory practices”.</u>					
13.	GER/10	1.4C New issue	<u>Additionally, para 3.5 of GSR Part 1 (Rev. 1) [2] states, that “To enhance the safety of facilities and activities globally, feedback shall be provided on measures that have been taken in response to information received via national and international knowledge and reporting networks”.</u>	Requirement 15 of GSR Part 1 (Rev. 1) has four associated requirements: paras 3.3, 3.4, 3.5 and 3.5A. We propose that Requirement 15 should be treated in this document with all of its associated requirements of GSR Part 1 (Rev. 1) (refer also to our comment <i>General 1</i> ).			X	The information is already covered in 3.26 of DS547 The databases are included in TECDOC.
14.	GER/11	1.5	<u>Reference The IAEA TECDOC Series No. 1899, Effective Management of Regulatory Experience for Safety [4] provides</u> practical guidance to regulatory bodies for proactively collecting regulatory experience, analysing this experience, implementing any improvements and disseminating the lessons learned.	Editorial			X	The way of referencing IAEA safety standards (SFs, SSRs, GSRs, GSGs and SSGs) is different to that of IAEA informational publications (TECDOCs, Safety report Series etc.). It is as per IAEA Style Manual for publication and documents.
15.	GER/12	1.6	<del>1.4</del> 1.6. This Safety Guide provides recommendations for regulatory bodies on how to meet Requirement 15 of GSR Part 1 (Rev. 1) [2] on establishing, implementing, assessing and continuously improving regulatory experience arrangements.	Please move this para before para currently numbered as 1.4 – to will allow to focus on the main issue, which is “regulatory experience” and makes the text more reader-friendly. The statements currently referred to as paras 1.4 and 1.5 are additional and contain complementary information.	X			

16.	JPN/1	1.6.	This Safety Guide provides recommendations for regulatory bodies on how to meet Requirement 15 of GSR Part 1 (Rev. 1) [2] on establishing, implementing, assessing and continuously improving <u>arrangements for regulatory experience arrangements feedback</u> .	Clarification.	X			
17.	GER/13	1.7	The objective of this Safety Guide is to provide recommendations for the regulatory bodies on how to systematically collect, analyse, implement and disseminate lessons learned from their own <u>and further national</u> experience, as well as from <del>national and</del> international experience regarding the ...	We suggest to distinguish between national and international experience, if grouping. Alternative: "...lessons learned from their own, <u>further national experience</u> , as well as from <del>national and</del> international experience regarding the..."	X	"...lessons learned from their own experience, as well as from <u>other sources of</u> national and international experience regarding the..."		
18.	GER/14	1.8	The scope of this Safety Guide covers the <u>recommendations how to make</u> arrangements for managing the regulatory experience feedback for all functions and processes of a regulatory body <u>with regard to</u> <del>and for</del> all types of facilities and activities that give rise to radiation risks taking into account the application of a graded approach.	We believe using "recommendations" is more suitable.	X (2nd part)		X (first part)	As the safety guide covers typical arrangements for managing regulatory experience feedback, we propose to stick with the initial text as it is outcome-focused and avoids sounding procedural or instructional.
19.	CAN/1	1.8, line 3	"The scope of this Safety Guide covers the arrangements for managing the regulatory experience feedback for	Clarify "taking into account the application of graded approach", i.e., does the graded approach apply to the implementation of the safety guide or the risks?	X			

			all functions and processes of a regulatory body and for all types of facilities and activities that give rise to radiation risks <del>taking into account the application of a graded approach.</del> ”	Suggest either removing the statement or clarify what is meant by ‘application of a graded approach’.				
20.	PAK/3	Page 2, Section 1.8 para-1, Line-3	“Facilities” may be replaced by <b>“Nuclear Facilities”</b>	To make it specific			X	‘Facilities and activities’ is used in the same context as defined in the IAEA safety and security glossary.
21.	GER/15	1.9	This Safety Guide <u>is intended to be used by</u> <del>is applicable to</del> regulatory bodies <sup>1</sup> , as well as <del>to</del> <u>by</u> their technical support organizations.	Clarification. Safety Guide rather “to be used” as “is applicable”, please check.	X			
22.	GER/16	1.10	This Safety Guide, <u>addressing safety–security interface</u> , does not address regulatory experience relating to nuclear security <u>itself</u> , although some of the recommendations contained in this Safety Guide are general and can be applied to nuclear security.	Please harmonize with para 3.3 of this Safety Guide, dealing with safety–security interface.  We made a suggestion.	X	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.  <u>The aspect of safety and security interface is addressed in this Safety Guide.</u>		
23.	CAN/2	1.11	Remove paragraph	Paragraph 1.11 does not provide more context than what is already provided in the table of contents; therefore, 1.11 is redundant. Recommend removing the paragraph or			X	It is general layout of the safety standards.

				revising the text to improve readability.				
24.	FIN/1	Para 1.11 (Structure), line 10	regulatory experience feedback management <b>arrangements</b>	Please consider using the same terminology throughout the text.	X			
25.	FIN/2	Para 1.11	Appendix-I provides additional guidance on the sources of regulatory findings while Appendix-II provides <del>detailed</del> <b>additional</b> guidance on the identification of regulatory experience findings.	More coherent description of appendices. Are appendices and annexes binding to member states; this shall be defined in the safety guide/ or in the paragraph.	X			Regarding appendices/annexes, it is explained in the section titled ‘interpretation of the text’ under the heading “ <b>IAEA Safety Standards</b> ”, which is an integral part of all the IAEA safety standards. Usually, all this information is added at the later stage once the main content is finalized.
26.	CAN/3	2.2	<del>“The Regulatory Body should effectively manage safety by taking 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</del> into account the knowledge and information resulting from both positive and negative experiences (e.g. good practices and bad practices). <u>As stated in paragraph 3.20 of IAEA Safety Standards Series No. GSG-12, Organization,</u>	There is no “should” statement in this requirement. The revised text adds an introductory sentence with a “should” statement to explicitly outlining the expectations placed on the regulatory body, aligning it with the structure and tone of other paragraphs in the standard. Starting with the “should” statement clearly delineates the responsibilities of the regulatory body. There is no change to the remainder of the text that follows the added first sentence.			X	The ‘should’ statement could not be produced without the basis from IAEA safety requirements.

			<u>Management and Staffing of the Regulatory Body for Safety [6]: “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).”</u>  <b># This</b> includes a non-exhaustive list of examples of information and knowledge relevant for regulatory bodies...”					
27.	GER/17	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 “ <u>E</u> ffective 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).” It includes a non-exhaustive list of examples of ...	Both quotation signs are needed for quotation from GSG-12, otherwise misleading.	X			
28.	GER/18	2.3	A proactive approach of the regulatory body to managing regulatory experience should contribute to enhancing their regulatory	Please align with para 1.7, which identifies the three types of experiences.  Additionally, the evolution of science and technology is	First part		Second part	Evolution of science and technology as a source of lessons is identified along with other sources in Appendix-I

			requirements and practices through the application of the lessons learned from their own experience, <u>from national experience</u> , from the experience of regulatory bodies of other Member States <u>as well as from relevant evolution of science and technology</u> .	important in regulatory requirements and is addressed nowhere within this document				(see comment 35)
29.	RUS/1	2.3/2 and appropriate provisions	<ol style="list-style-type: none"> <li>1. In 2.3/2 after "enhancing their regulatory requirements" to add: " , including cancellation or moderation of excessive (unduly) requirements,"</li> <li>2. As appropriate to develop and to add in DS547 recommendations in relation of feedback management for arrangement changes to regulatory requirements (regulations) including cancellation or moderation of excessive (unduly) requirements.</li> </ol>	<ol style="list-style-type: none"> <li>1. It seems that word "enhancing" primary perceived as strengthening or increasing but not as improving (but in any case enhancing-improving has also too general meaning).</li> <li>2. In the text of DS547 practically there are not provisions concerning problem of excessive regulatory requirements and recommendations for arranging this problem. This problem evidently takes place (more or less) in all states.</li> <li>3. As a whole DS547 does not contain recommendations for changes to regulatory requirements (regulations) (Table I in Appendix I mentions of the regulation only as sources of regulatory experience), <b>although</b> para. 1.6 of DS547 states that "This Safety Guide provides recommendations for regulatory bodies on how to meet <b>Requirement 15</b> of GSR Part I (Rev. 1) [2] on establishing, implementing, assessing and continuously improving</li> </ol>		<p>X</p> <p><u>The regulatory body should adopt a proactive approach to managing regulatory experience.</u></p> <p><u>This involves systematically collecting and analyzing findings, and applying</u> the lessons learned from their own experience as well as from <b>other sources of national and international experience. These lessons lead to changes in regulatory requirements and modifications to regulatory practices thereby strengthening the regulatory framework.</b></p>		<p>It corresponds to each regulatory body to assess and to evaluate the appropriateness of changes in regulatory requirements arising from regulatory experience, and always in accordance with its legal system. This could lead to either further strengthening the regulatory requirements or relaxing/deleting the regulatory requirements.</p> <p>We updated para 2.3 to make it in line with Requirement 15 of GSR Part 1.</p> <p>It also takes into account comments 30 and 31.</p>

				regulatory experience arrangements" <b>and</b> <b>Requirement 15</b> of GSR Part 1 (Rev. 1) includes also para 3.3. "3.3. The reporting of operating experience and regulatory experience has led to significant corrective actions in relation to equipment, human performance and the management system for safety, as well as <b>changes to regulatory requirements</b> and modifications to regulatory practices"				
30.	CAN/4	2.3	<p><del>“The regulatory body should adopt a A proactive approach of the regulatory body to managing regulatory experience, should contribute to enhancing their regulatory requirements and practices through the application of This involves applying</del> the lessons learned from their own experience and from the experience of regulatory bodies of other Member States <u>to enhance regulatory requirements and practices.</u>”</p>	<p>The current sentence is quite long and combines several ideas. Breaking it into shorter sentences would improve readability.</p> <p>The current text is in the passive voice, the recommended text used the active voice for clarity.</p>		<u>X</u>		See comment 29 above.
31.	CAN/5	2.3	<p>Add to end of paragraph: <u>“A proactive approach includes systematically identifying, analyzing, and applying lessons learned to improve regulatory processes and ensure safety.”</u></p>	<p>There is no guidance on what a proactive approach looks like. This new proposed text (or similar) is recommended to be added to paragraph 2.3 to emphasize specific actions (systematic identification) and the benefits of a proactive</p>		X		See comment 29 above.

				approach (to improve regulatory processes and ultimately ensure safety).				
32.	CAN/6	2.4, line 5	<p>“...Operating experience <del>pertains-refers</del> to insights and lessons <del>to be</del> learned from the operation of regulated facilities and activities. <u>These include</u> <del>including</del> events and other observations, <del>such as potential problems relating to on</del> equipment, and human performance, safety <del>related</del> concerns, <u>and procedural issues that may lead situations that are likely to give rise to errors or require attention to avoid and need to be addressed to prevent</u> undesired effects, <del>procedural deficiencies and inconsistencies in documentation...</del>”</p>	<p>Current phrasing combines multiple ideas into one sentence. Break these into shorter, direct sentences for clarity and readability. Edits also suggested to streamline wording.</p>		<p>Operating experience refers to insights and lessons to be learned from the operation of regulated facilities and activities. These include:</p> <ul style="list-style-type: none"> <li>– events, including low level events and near misses;</li> <li>– potential problems relating to equipment and human performance;</li> <li>– safety related concerns;</li> <li>– situations that are likely to give rise to errors and need to be addressed to prevent undesired effects;</li> <li>– procedural deficiencies; and</li> <li>– inconsistencies in documentation</li> </ul> <p>Opportunities for improvement and</p>		Made in line with para 2.23 of IAEA SSG-50

						good practices that are relevant to safety should also be identified and fed into the operating experience programme as per para 2.23 of SSG-50.		
33.	GER/19	2.4	<p>In order to implement Requirement 15 of GSR Part 1 (Rev. 1) [2], the regulatory body should <del>differentiate</del> <del>distinguish the differences</del> between regulatory experience and operating experience. <u>As stated in para 1.4A,</u> <del>For the purpose of this document publication,</del> 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. <u>These include among others non-conformities observed in domestic or international facilities.</u> Operating experience pertains to insights and lessons to be learned from the operation of regulated facilities and activities, including <del>events and other observations, such as potential problems relating to equipment</del></p>	<p>1) The definition of regulatory experience and operating one should be placed more prominently and considered to be added to “Objective”. We made a suggestion for this in our comment to para 14A.  2) please expand the operational experience part  3) The explanation of operational experience is much more elaborated in this document including examples. As the principle of regulatory feedback is the focus of this Safety Guide, the explanation to this topic should be more detailed to better explain the difference.</p> <p>Maybe the difference could further be explained using simple examples of findings that could be added to the Annex or Appendix</p>		<p>In order to implement Requirement 15 of GSR Part 1 (Rev. 1) [2], the regulatory body should <del>distinguish the differences</del> <u>differentiate</u> between regulatory experience and operating experience. For the purpose of this <del>document</del> <u>publication,</u> 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. <u>This includes lessons learned from both national and international</u></p>		<p>The sources of regulatory findings are provided in Appendix-I and it is linked here. This para contains more information on operating experience as it's the only place where operating experience is explained whereas whole of this document provides guidance on managing regulatory experience feedback. This comment also takes into consideration of comment 32.</p>

			failures and human performance, safety related concerns, and situations that are likely to give rise to errors and need to be addressed to prevent undesired effects, procedural deficiencies and inconsistencies in documentation. The feedback from both the regulatory experience and operating experience contributes to enhancing the overall safety of facilities and activities and can provide insights related to regulating the facilities and activities which may lead to improving the regulatory process. The link between regulatory experience and operating experience is explained in Annex I.			sources as outlined in Appendix-I.		
34.	GER/20	2.5	The regulatory process reflects 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, and new experiences and context developments can lead to further changes. <del>Regulatory bodies should strive to continuously gain and manage regulatory experience from both</del>	This idea has been expressed several times already in the paragraphs above, therefore we suggest to delete the sentence at this instance.			X	Merged with comment 35. The deleted sentence has been rewritten in a should statement, essential to the understanding and the idea of the paragraph

			<p><del>internal and external sources to identify improvement opportunities in delivering their mandate.</del> Proactively seeking these opportunities by integrating regulatory experience feedback management into the daily work of regulatory bodies helps the regulatory body fulfil its mission and ensures that the national regulatory framework, functions and processes remain effective and up to date</p>				
35.	CAN/7	2.5	<p>“The <u>Regulatory Body should strive to continuously gain and manage regulatory experience from both internal and external sources to identify improvement opportunities in delivering their mandate.</u> <del>The regulatory process reflects incorporates the</del> knowledge and information <del>resulting</del> from operating and regulatory experience, <u>as well as and from</u> other elements <del>associated to the of</del> effective management for safety, <del>at a given time, and</del> <del>a</del> New experiences and <u>changing contexts</u> <del>developments</del> can <u>lead to drive</u> further <del>changes</del>”</p>	<p>Improve Logical Flow: Reorganize the ideas for clearer progression:</p> <p>Start with the importance of regulatory experience. Follow with the role of continuous improvement. Conclude with how these efforts support the regulatory body’s mission.</p> <p>Suggest moving the second sentence up front as provided for better logical flow. In other words, start with the “should” statement as per other paragraphs.</p>		<p>X</p> <p>The regulatory body should strive to continuously gain and manage regulatory experience from both internal and external sources to identify improvement opportunities in delivering their mandate. The regulatory process <b>involves</b> the knowledge and information resulting from operating and regulatory experience, and from other elements associated to the</p>	<p>To take in consideration Comments 28 and 36</p>

			<p><del>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. Regulatory bodies should</del></p> <p><del>Proactively seeking these opportunities by integrating regulatory</del></p> <p><u>integrate</u> experience feedback management into <del>the</del> daily work of <del>regulatory bodies helps the regulatory body to</del> fulfil its mission and ensures that the national regulatory framework, functions and processes remain effective and up to date.”</p>			<p>effective management for the safety at a given time (i.e. The level of scientific and technological development). New experiences, the evolution of technology and changing contexts can drive further improvements. Regulatory bodies should proactively integrate experience feedback management into their <b>practices and procedures</b> to fulfil its mission and ensure that the national regulatory framework, functions and processes remain effective and up to date.</p>		
36.	PAK/6	<p>Page 3 Section2.5 Line- 7</p>	<p>Proactively seeking these opportunities by integrating regulatory experience feedback management into the <del>daily work</del> <b><u>practices and procedures</u></b> of regulatory bodies helps the regulatory body fulfil its mission and ensures that the national regulatory framework, functions and processes remain effective and up to date.</p>	<p>Daily work may be replaced with practices and procedures to integrate &amp; institutionalize the experience feedback as regular feature in the regulatory framework</p>	X			Merged with comment 35

37.	GER/21	2.6	<p>The regulatory body should <del>foster and promote the concept of</del> <u>itself as</u> a learning organization for continuously improving its performance. <u>As stated in para 5.60 of GSG-12</u>, these “improvements can be achieved <del>at various levels in the regulatory body</del> such as:</p> <ul style="list-style-type: none"> <li>— <u>At the working level within a process, by those directly involved in daily activities;</u></li> <li>— <u>At the level of management processes, under the supervision of the process owners;</u></li> <li>— <u>At the organizational level, through organizational improvement projects under the supervision of senior management” and</u></li> <li>– At the external level, by leveraging learning opportunities and best regulatory practices from national and international organizations and relevant activities.</li> </ul>	<p>This para is to similar to para 5.60 of GSG-12, the actual wording is the same. We therefore suggest to quote it directly (see our comment <i>General 2</i>).</p>	X			
38.	IRN/1	2.6.	<p>The regulatory body should promote the concept of a learning organization and <b>Knowledge management</b> for continuously improving its performance. These improvements</p>	<p>Because the subject of knowledge management (with its dimensions such as knowledge creation, coddng, documentation, sharing and retention), like the subject of the learning organization, has a very close relationship with the subject of</p>			X	<p>Not included in paragraph 5.60 of GSG-12</p> <p>Furthermore, the same is reflected in para 4.3, 4.6 and 7.2 which is sufficient in the context of this guide.</p>

			can be achieved at various levels in the regulatory body such as:	regulatory experience feedback and is very similar in concept to it, it seems necessary to mention this at the beginning of the document and in this section or in an independent paragraph.				
39.	JPN/2	2.6.	<p>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:</p> <ul style="list-style-type: none"> <li>– At the organizational level, through organizational improvement projects under the supervision of senior management;</li> <li>– At the level of management system processes, under the supervision of the process owners<sup>(*)</sup>;</li> <li>– At the working level within a process, by those directly involved in daily activities;</li> <li>– At the external level, by leveraging learning opportunities and</li> </ul>	<p>For clarification, suggested to add definition of “process owner” in a footnote.</p> <p>The footnote proposed comes from para. 5.14. of GSG-12 “Organization, Management and Staffing of the Regulatory Body for Safety”.</p>			X	<p>It is a very detailed information, not necessary here, in REGEX context. It is more appropriate in GSG-12 when describing the Integrated Management System. In case of doubt, GSG-12 can be consulted.</p> <p>We also referred the relevant para of GSG-12 (para 5.60).</p>

			<p>best regulatory practices from national and international organizations and relevant activities.</p> <p><u>(footnote *) The process owner is responsible for the management of the assigned process and should be made accountable for ensuring that the process is clearly identified, documented, reviewed, maintained and improved. Usually, this is a manager with a direct interest in the outcome of the process or who has the most resources involved.</u></p>					
40.	JPN/3	2.6	<p>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:</p> <ul style="list-style-type: none"><li>– At the organizational level, through organizational improvement projects under the supervision of senior management;</li><li>– At the level of management system</li></ul>	<p>While three of four elements indicate clear responsibility for implementation, the fourth element differs from the other three in terms of who will carry it out.</p> <p>It is suggested to rewrite the fourth factor separately with adding reference to good or best practices implemented by regulatory bodies in other States 、 as interactions and cooperation among regulatory bodies will be proactively sought in evolutionary design and operation of new type of nuclear installations.</p>	X			

			<p>processes, under the supervision of the process owners;</p> <ul style="list-style-type: none"> <li>At the working level within a process, by those directly involved in daily activities;</li> </ul> <p>Also, some opportunity of improvements can be gained externally <del>—At the external level,</del> by leveraging learning opportunities and best regulatory practices from other national authorities with regulatory function, as well as from <del>and</del> international organizations and <del>relevant activities</del> regulatory bodies in other States.</p>					
41.	GER/22	3.1	<p><del>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.</del></p> <p><u>The effective management of regulatory experience feedback should include, taking into account a graded approach,</u></p>	<p>The given statement is not entirely correct, as regulatory experience is not independent - there is influence of operating experience and a number of other factors.</p> <p>We suggest to change the current formulation of para 3.1 and instead use the text from para 3.4 (here slightly modified), due to a significant overlap in content</p>	X	<p>The effective management of regulatory experience feedback should include, taking into account a graded approach, appropriate arrangements for:</p> <ul style="list-style-type: none"> <li>Collecting findings from various sources (see paras 3.7–3.16);</li> <li>Analyzing findings and</li> </ul>		<p>Para 3.1 and 3.4 are merged. Last part is incorporated in para 6.6 of DS547</p>

			<p><u>appropriate arrangements for:</u></p> <ul style="list-style-type: none"> <li>– <u>Collecting findings from various sources (see paras 3.6–3.15);</u></li> <li>– <u>Analysing findings and developing the action / improvement plans to address the gaps and identify opportunities for improvement (see paras 3.16–3.19);</u></li> <li>– <u>Implementing the improvement plans (see paras 3.20–3.21);</u></li> <li>– <u>Communication: use, dissemination and exchange of information (see paras 3.22–3.28).</u></li> </ul> <p><u>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).</u></p>			<p>developing the action plan to address the gaps and identify opportunities for improvement (see paras 3.17–3.20);</p> <ul style="list-style-type: none"> <li>– Implementing the action plan with clearly assigned responsibilities (see paras 3.21–3.22);</li> <li>– Disseminating the lessons learned (see paras 3.23-3.29).</li> </ul> <p>A schematic diagram illustrating a typical arrangement for managing regulatory experience feedback, along with the recommended key elements, is presented in Fig.1</p>		
42.	GER/23	3.2.	The regulatory body should decide how, in its management system, the arrangements for managing regulatory experience should be established. This could	1) As regulatory experience and operating experience are correlated, it follows that regulatory processes alone do not lead to regulatory experience. We therefore		X		Comment 43 covers this comment. The comment is accepted and addressed with the wording proposed in comment 43 below.

			<p>be as a specific process to identify lessons to be learned from all the <del>regulatory</del> processes leading to regulatory experience or it could be embedded within the existing <u>or new</u> regulatory functions and processes. <u>Regulatory experience should be used to improve the integrated management system in line with requirements of GSG-12.</u></p>	<p>suggest leaving this statement open.</p> <p>2) The possibility to embed the management of regulatory experience in other regulatory functions and processes that are being developed at the same time should not be excluded.</p> <p>3) A clear link to GSG-12, where improvement to the Integrated Management System (IMS) based on experience is already covered, is missing. Please add this here.</p>			<p>As regulatory experience could be used to improve regulatory functions and processes including the management system, therefore the last part is not added here as it limits the final outcomes of the arrangements for managing regulatory experience feedback.</p> <p>Moreover, regulatory functions are well defined but there might be new processes, so the last line is modified a bit keeping in view your proposal.</p>
43.	CAN/8	3.2	<p>“The regulatory body should <del>determine decide</del> how <del>to establish, in its management system, the</del> arrangements for managing regulatory experience <del>should be established within its management system.</del> This <u>may involve creating could be as a</u> specific <del>arrangements dedicated to collecting and analyzing findings, implementing the action plan, and disseminating lessons learned from regulatory experience.</del> <u>Alternatively, these arrangements could be</u></p>	<p>This is a key paragraph as it will determine the amount of effort needed to introduce REGEX into RBs existing functions and processes.</p> <p>The recommended text attempts to improve clarity. This proposed version emphasizes clearly the 2 options, improving readability without losing any details.</p> <p>This proposed version also adds the other 3 missing elements of REGEX arrangements as the previous version only mentioned “identifying”, whereas there are clearly 4 elements as listed in section 3.4 and figure 1.</p> <p>The revised text also suggests linking the second option to</p>		<p>X</p> <p>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 analyzing findings, implementing the action plan, and disseminating</p>	<p>Accepted, but removed the final words “to ensure seamless implementation” as this is subjective.</p> <p>Moreover, this comment also takes above comment into consideration.</p> <p>Comment on discrepancy between section 3.2 and 4.3 is addressed in comment 133 below.</p>

			<p><u>integrated into the existing regulatory functions and processes or into a Regulatory Body's existing Management System (see section 4) to ensure seamless implementation 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."</u></p>	<p>section 4, Integration of REGEX into the Management System and adds the option of including the arrangements not only into existing functions and processes but specifically into the Management System, for clarity.</p> <p>Also note comment 36 related to paragraph 4.3 that may identify conflicting messages between paragraph 3.2 and 4.3.</p>		<p>lessons learned from regulatory experience. Alternatively, these arrangements could be integrated into the existing or new processes.</p>		
44.	CAN/9	3.3	<p><del>"When the regulatory responsibility for ensuring safety is shared among more than one organization, t</del>The regulatory body should collaborate with <del>these</del> <u>other</u> organizations <u>when the responsibility for ensuring safety is shared among multiple entities.</u> <u>This collaboration aims</u> to establish effective <del>regulation</del> <u>regulatory practices while</u> considering the <u>specific roles and responsibilities of each organization assigned to different organizations.</u> <u>Additionally, t</u>The safety–security interface should <del>also</del> be addressed to ensure <del>that</del> regulatory requirements are applied <u>in a consistent</u>ly and</p>	<p>Recommended revision to improve clarity and readability.</p>		<p>X</p> <p>The regulatory body should collaborate with other organizations when the responsibility for regulating safety (including technical safety matters) and security is shared among multiple entities. This collaboration aims to establish effective regulatory practices while considering the specific roles and responsibilities of each organization. Additionally, the safety–security interface should be addressed to ensure</p>		<p>Replaced first sentence with:          “.... when the responsibility for regulating safety (including technical safety matters) and security are shared among multiple entities...”          As explained in comment 45 below.</p>

			effectively and in an integrated manner. <u>This ensures</u> so that security measures do not compromise safety and safety measures do not compromise security.”			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.		
45.	RUS/2	3.3/1-2	After "When the regulatory responsibility for ensuring safety is shared among more than one organization" to add text "(not only for regulating radiation safety, but also other technical safety matters)'	In many cases the atomic (radiation) facilities includes activities with other dangerous materials and more else often includes common technical hazard equipment (crane, lifts, etc) that are sometimes (or often) under regulating of non-atomic (radiation) regulatory bodies. Appropriate coordination of such various regulatory bodies is necessary. It concerns also the transport of radioactive materials as just one class (class 7) of the 9 classes of dangerous goods. Appropriate coordination of various transport regulations (requirements) and regulating bodies do exist and have to be maintained.		X .... where the responsibilities for regulating safety (including technical safety matters) and security is shared among multiple organizations ....		Radiation safety is already embedded in the definition of ‘safety’ as per IAEA safety glossary.
46.	CAN/10	3.4	“The effective management of regulatory experience feedback should <u>adopt a graded approach and include systematic arrangements for the following key elements-</u>	Recommended edit to clearly indicate that the list is of elements of the systematic arrangements in question. The identification that these 4 elements is reflected in the last sentence of this paragraph.	X			Agree with comment 41 to merge para 3.4 and 3.1. Revised text is provided in comment 41.

			<p><del>appropriate arrangements for, taking into account a graded approach:</del></p> <ul style="list-style-type: none"> <li>– Collecting findings from various sources (see paras 3.7–3.16);</li> <li>– Analysing findings and developing the action plan to address the gaps and identify opportunities for improvement (see paras 3.17–3.20);</li> <li>– Implementing the action plan <u>with clearly assigned responsibilities</u> (see paras 3.21–3.22);</li> <li>– Disseminating the lessons learned (see paras 3.23–3.29).</li> </ul> <p>A <u>schematic diagram illustrating a typical arrangement for managing the regulatory experience feedback, along with its containing</u> <del>the</del> recommended <u>key</u> elements, is <del>depicted in the schematic diagram shown</del> <u>presented</u> in Fig.1.”</p>	<p>This proposed change attempts to further clarify and link the four “boxes” in the referenced figure 1, to “key elements” of a systematic arrangement for the effective management of regulatory experience feedback. It is also recommended to change recommended elements, to key elements. If we go with recommended element, which sounds prescriptive, that would eliminate the possibility of RBs exploring other elements that may be considered. Using “key elements” allows RBs the flexibility to explore additional elements that may improve their regulatory experience management.</p>				
47.	GER/24	3.4	<p>The effective management of regulatory experience feedback should include, <u>taking into account a graded approach,</u> <del>appropriate arrangements for, taking into account a graded approach:</del></p> <ul style="list-style-type: none"> <li>– Collecting findings from various sources</li> </ul>	<p>1) Please move the whole content to para. 3.1, as paras 3.1 and 3.4 significantly overlap in content.</p> <p>2) Please check references / para numbers</p> <p>3) Please harmonize with GSG-12. See para 5.62 of GSG-12. Please use consistently terminology of GSG-12 (et al.</p>		X		<p>Agree to move content to section 3.1 and delete this section. New merged text is proposed in comment 41.</p> <p>While evaluating the action plan implementation, there might be some actions with not having</p>

			<p>(see paras <del>3.6–3.15–3.7–3.16</del>);</p> <ul style="list-style-type: none"> <li>– Analysing findings and developing the action / <u>improvement plan</u> to address the gaps and identify opportunities for improvement (see paras <del>3.16–3.19–3.17–3.20</del>);</li> <li>– Implementing the <u>improvement plans</u> <del>action plan</del> (see paras <del>3.20–3.21–3.21–3.22</del>);</li> <li>– <u>Communication: use, dissemination and exchange of information</u> <del>Disseminating the lessons learned</del> (see paras <del>3.22–3.28–3.23–3.29</del>).</li> </ul> <p><u>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)</u></p>	improvement plan instead of action plan, or at least both terms parallel).				<p>tangible improvements or achieving the desired objective to improve regulatory functions and processes, practice. In our opinion, action plan is better than improvement plan in this context.</p> <p><u>Last part of the text is covered in para 6.5.</u></p>
48.	IRAN/2	3.4.	<p>Since the analyzing of findings and developing the action plans for improvement are two separate steps, it is proposed to separate these steps. So, Fig.1 could be modified in a way that the second box be split in two boxes, which mentioned before.</p>	<p>If the Action plan would not be effective practically, it would be necessary to review the related findings and analysis. So, As shown in Fig I-I, there is a vector from the Request Corrective Action box to the Analysis box in right side, therefor there should be a similar approach for the regulator for regulatory experience feedback in left side.</p>			X	<p>Current steps provide more practical information regarding regulatory experience feedback process. This shows the typical arrangements for managing regulatory experience and the Member states may adopt as per their national circumstances.</p>

49.	PAK/7	Page 4, Section 3.4	<p>Following bullet may be added after;</p> <p>2<sup>nd</sup> bullet ---<b><u>Screening, categorization and coding of findings.</u></b></p> <p><b><u>Last bullet--- Review effectiveness of actions implemented as a result of action plan developed during analysis of findings.</u></b></p>	Mandatory for loop closing of system.			Rejected	In the document, screening is part of the “Collection” which is key element of regulatory feedback management arrangements. For this paragraph, only the high level key elements of the arrangements as listed in figure 1 are listed. The screening is captured in sections 3.14 and 3.15 of the draft.
50.	GER/25	3.5	<p>A complete <u>comprehensive</u> retrievable dossier <del>documenting the entire arrangements for regulatory experience feedback management</del> should be maintained <u>to document regulatory feedback management.</u></p> <p>The regulatory body may complement the information recorded in <u>its</u> 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.</p> <p><u>Requirements on the documentation of the</u></p>	<p>Clarification.</p> <p>The link to GSG-12, para 5.64 is missing. Please add.</p>		<p>X</p> <p>Para 3.5 is modified as: The regulatory body should establish and maintain a comprehensive and retrievable dossier to document regulatory experience feedback management arrangements, in accordance with the documentation guidelines provided in GSG-12. The dossier will help retain information about the analysis performed and decisions taken for trending analysis and future consultation.</p>		This comment also takes Comments 51, 52 and 53 into consideration.

			<u>integrated management system are given in para 5.64 – 5.70 of GSG-12.</u>					
51.	CAN/11	3.5	<p><del>“The regulatory body shall ensure the establishment and maintenance of a A-complete retrievable dossier to documenting the entire arrangements for regulatory experience feedback management should be maintained. This dossier shall:</del></p> <p><u>1. document arrangements comprehensively, covering all aspects of regulatory experience feedback management;</u></p> <p><u>2. be maintained as either:</u></p> <p><u>- a complete, standalone dossier that provides all necessary documentation, or</u></p> <p><u>- a complementary dossier integrated within the regulatory body’s existing management system, while ensuring the documentation of the entire regulatory experience feedback management arrangements.</u></p> <p><del>The regulatory body may complement the information recorded in management system by</del></p>	<p>This section is difficult to understand.</p> <p>Upon reviewing paragraph 3.5, the lack of clarity appears to stem from the redundancy in mentioning both maintaining a "retrievable dossier" and supplementing management system records with a separate dossier. The phrasing could lead to confusion about whether one or both steps are necessary and how they relate to each other.</p> <p>Additionally, the purpose of the dossier—specifically for future consultation and trending analysis—could be elaborated for better comprehension.</p> <p>This paragraph should be redrafted for clarity.</p> <p>Lastly, this paragraph requirement is stated with a “may” statement whereas the others are stated with a “should” statement. For consistency we included “should” statements in the proposed text.</p> <p>Sample proposed text provided.</p>		X		<p>The text is revised keeping in view the comments 50, 52 and 53.</p> <p>Please see the revised text in comment 50.</p> <p>Moreover, as para 3.5 is linked to documentation guidelines provided in GSG 12 (para 5.64 to para 5.70), therefore the proposed details in this comment are not included in the revised text.</p>

			<p><del>creating a separate retrievable dossier documenting the entire regulatory experience feedback management process.</del> The dossier <u>shall support the retention of</u> will help retain information <u>about on the analysis analyses</u> conducted and decisions <u>taken performed and</u> decisions taken for <u>trending analysis and future consultation.</u> <u>The Regulatory Body shall utilize the dossier for trending analysis and future consultations to enhance the regulatory body's effectiveness and ensure informed decision-making</u>”</p>					
52.	FIN/4	Para 3.5		<p>Please try to clarify; What is the meaning or difference between dossiers, <b>two separate</b> ones?</p> <p>A complete retrievable <b>dossier</b> 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 <b>dossier</b> documenting the entire regulatory experience feedback management process.</p>	X			Please see the revised text in comment 50.
53.	FIN/5	Para 3.5., line 4	...The regulatory body may complement	Please consider using the same terminology throughout the text:	X			Please see the revised text in comment 50.

			the information recorded in management system by creating a separate retrievable dossier documenting the entire <b>regulatory experience feedback management arrangements.</b>	regulatory experience feedback management <b>process</b>				
54.	CAN/12	Figure 1		To match the revised text in paragraph 3.4 and 3.6, possibly add clarity to figure 1 by re-labeling each “box” as “key elements” for managing REGEX.			X	
55.	GER/26	Figure 1 (after 3.5)	<i>We suggest to modify this figure. To our understanding it should show: 1) where is the interface with operating experience 2) how regulatory experience is used and taken into account in the integrated management system as a separate process with links to other processes or as an element of individual processes.</i>	Figure 1 (after 3.5)			X	Appendix-I describes the comprehensive list of sources including operating experience. The figure is kept simple to show the typical arrangements for managing REGEX. The detailed linkage of these arrangements with different regulatory functions and processes is provided in section 4. Figure I-1 in Annex provides the link between OPEX and REGEX.
56.	CAN/13	3.6	“The <u>regulatory body should collect regulatory experience findings from various sources using appropriate tools and techniques of knowledge</u>	By starting with the "should" statement and clearly delineating the responsibilities of the regulatory body, this proposed revised text establishes a direct and active tone. This makes the guidance more		X The regulatory body should collect regulatory experience findings from various sources using		This addressed comments 57 and 58 as well.

			<p><u>management as per recommendations of GSG-12. first element of managing regulatory experience feedback is the collection of regulatory experience findings<sup>2</sup> from various sources utilizing appropriate tools and techniques for knowledge management. The collection of Collecting findings is the first typical element of managing regulatory experience feedback. The regulatory body should ensure that the collection process clearly identifies how to recognize and document</u> relevant information including clarity on how to collect, record, <del>and</del> store, <del>and</del> screen, and categorize them.”</p>	<p>actionable and easier to measure. This eliminates ambiguity and reinforces accountability.</p>		<p>appropriate procedures or arrangements, tools and techniques for knowledge management as per recommendations of GSG-12.</p>		
57.	GER/27	3.6	<p>The first element of managing regulatory experience feedback is <u>the definition of regulatory experience findings, followed by</u> the collection of regulatory experience findings<sup>2</sup> from various sources utilizing appropriate tools and techniques for knowledge management. The <del>collection of findings</del> <u>retrievable</u></p>	<p>1) The footnote 2 gives a very rough definition, furthermore every regulatory body using this process should define findings, taking para 3.2, 5.4 (bullets 1 and 2), 6.7 g) and thus potential existing regulatory processes into account a definition serves to identify processes feeding into the regulatory experience process or which processes need to be defined along with the regulatory experience process (because they don't exist yet).</p>			X	<p>The first element is not the definition of findings, it is the ‘collection’ as illustrated in figure 1 also and whole of the safety guide. Further detailed guidance on ‘findings’ could be sought from the IAEA TECDOC-1899.</p> <p>. Re: retrievable dossier. The retrievable</p>

			<p><u>dossier</u> should clarify how the relevant information is identified; collected, recorded and stored <u>for appropriate time frames and knowledge on its use is preserved</u>; and screened and categorized.</p>	<p>- the footnote includes information relating to issues, difficulties, inefficiencies, as well as good practices of the regulatory process as “regulatory experience findings”, however it remains unclear if this also includes regular outputs of already established processes which warrant a follow-up</p> <p>- examples of findings should be included in the annex along with examples of regulatory experience, e.g. in Appendix II and/or Annex II see comment on para 2.4</p> <p>2) It is not clear, what exactly is meant: does “The collection of findings” or the aforementioned “retrievable dossier” contain these information?</p> <p>3) In particular in geological disposal situations, storage of data is a long term issue (&gt;&gt;100 yr) and even information on the significance of the knowledge might become lost</p>				<p>dossier is not the process of how the relevant information is identified, it is merely a record of information.</p> <p>Section 3.5 has been revised to clarify and address these comments. Para 3.5 is linked to documentation guidelines provided in GSG-12.</p>
58.	FIN/6	Para 3.6 lines 2-3	<p>Please add procedures or arrangements in the text for possible clarification...from various sources utilizing appropriate <b>procedures or arrangements</b>, tools and techniques <b>for knowledge management</b>.</p>	<p>There must be a defined <b>procedure or arrangements</b> for collection of regulatory experience findings. These procedures can be carried out by using different tools and techniques. Additionally: please clarify does knowledge management refer to another process (knowledge management) process or procedures for collecting findings in a certain way?</p>	Accepted			<p>Agree to add Procedure or arrangement as suggested. See comment 56 for redraft.</p>

59.	GER/28	3.7	<p>The management of the regulatory body should promote positive attitude <u>towards the regulatory experience</u> in the personnel of the regulatory body through training activities, coaching and mentoring, and providing appropriate tools for documenting and communicating potential findings. <u>The attitude towards “Without findings there are no lessons to be learned” should be supported.</u> Therefore, guidance and training should be provided to personnel on how to recognize, <u>categorize</u> and document potential findings, internal and external, <u>national and international</u>, that can be used, <u>fast and efficient</u>, 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. <del>This</del> <u>Such</u> training and guidance can also help to optimize the resources of the organization for management of regulatory experience <u>and to optimize resources</u></p>	Clarification		<p>X Para 3.7 deleted as para 3.9 includes all the relevant information. The training part is covered in section 7.</p>		
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			<u>of regulatory body in general as well.</u>					
60.	CAN/14	3.7	<p><del>“The management of the regulatory body should establish and maintain arrangements to promote positive attitude in the amongst its personnel in recognizing and documenting regulatory findings. These arrangements should include the provision of the regulatory body through training activities designed to enhance the understanding and importance of regulatory experience feedback management. Training activities may include, coaching and mentoring sessions as methods to support and reinforce learning, and providing appropriate tools for documenting and communicating potential findings. Without findings there are no lessons to be learned. The regulatory body should ensure that personnel are equipped with the necessary tools for documenting and communicating. Therefore, guidance and training should be provided to personnel on how to recognize and document potential findings effectively.</del></p>	<p>The revised text addresses the challenge of measuring compliance with the original text. It sets measurable expectations by requiring the regulatory body to have training arrangements in place, while leaving the specific approaches, such as coaching and mentoring, as optional guidance. Separating requirements and guidance provides clearer expectations. The "should" statements define the mandatory actions, whereas the "may" portion offers recommendations that support implementation but are not obligatory. The revision maintains the emphasis on promoting positive attitudes and capturing findings but does so in a way that is practical for implementation and assessment.</p>		X		
						Para 3.7 deleted as para 3.9 includes all the relevant information. The training part is covered in section 7.		

			<p><u>Guidance and training should focus on fostering the ability to identify and document</u>, internal and external <u>findings</u> that can <del>be used to</del> improve the regulatory functions and processes, <del>and to ensure that relevant regulatory experience is captured in a timely manner and can be used for improving regulatory effectiveness.</del> This training and guidance can also help to optimize the resources of the organization for management of regulatory experience. <u>By implementing these arrangements, the regulatory body ensures that relevant regulatory experience is captured in a timely and systematic manner.</u>”</p>					
61.	FIN/7	Para 3.7	<p><del>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</del></p>	<p>Not relevant to identifying findings.</p> <p>Please consider adding a separate paragraph/section to promote open transparent environment and motivation of personnel.</p>	X			<p>Para 3.7 deleted as para 3.9 includes all the relevant information. The training part is covered in section 7.</p>

			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.					
62.	PAK/8	Page 6, Section 3.7	Availability of nuclear safety culture shall be discussed in this section which includes existence of strong reporting culture.	To highlight the importance of reporting culture			X	Safety Culture is covered in paragraph 1.2, 4.2, 4.3, 4.4, 6.7 (h).
63.	FIN/8	para 3.7, lines 8-9	This text: “This training and guidance can also help to optimize the resources of the organization for management of regulatory experience.”; is applicable for all steps in the REGEX, but here it is under para “ <b>Identifying findings</b> ”.	Please consider is it necessary under this paragraph.	X			Para 3.7 is deleted and the content on training of personnel is already covered under section 7.
64.	FIN/9	para 3.7 and 3.8	Please consider changing order of the paragraphs	First scope (para 3.8) and then details (para 3.7)	X			Para 3.7 is deleted and the content on training of personnel is already covered under section 7.
65.	FIN/10	Para 3.8		Which appendix, I or II?	X			New text, corrected the Appendix numbers.

				<i>The <b>Appendix</b> provides additional guidance for the regulatory bodies to assist the personnel in identifying potential findings.</i>				See comment 66 for revised text.
66.	CAN/15	3.8	<p>“The <u>regulatory body should identify findings-sources that can be used for identification of findings include-</u> information from its internal activities <del>of the regulatory body,</del> <u>information from</u> regulat<u>ing</u>ed facilities and activities, and <u>information from</u> external sources of regulatory experience. The regulatory body should define the <del>most</del>-relevant external sources whose lessons <u>learn</u><del>ed</del> are to be followed. Further information on the sources of findings is provided in Appendix-II. <u>Additional guidance is also available in-</u>The Appendix <del>II provides additional guidance for the regulatory bodies</del> to assist the personnel in identifying potential findings.”</p>	<p>Starting with the "should" statement immediately emphasizes the regulatory body's responsibilities, creating a more actionable and direct tone.</p> <p>The revised text provides a clear flow by first addressing the first key element of identification of findings, then specifying the sources, and finally referencing additional guidance.</p> <p><b>Also corrected the reference from incorrect Annex II to Appendix I and II.</b></p>	X	The regulatory body should identify findings from its internal activities, regulated facilities and activities, and external sources of regulatory experience. The regulatory body should define the relevant external sources whose lessons learned are to be followed. Further information on the sources of findings is provided in Appendix-I. Additional guidance is also available in Appendix-II to assist the personnel in identifying potential findings.		
67.	GER/29	3.8	The sources that can be used for identification of findings include information from internal activities of the regulatory body, information from	By using “most relevant sources” there is an inherent chance to neglect sources of Regulatory Experience and miss findings, lessons learned and opportunities for improvement.			X	Additional information on sources is provided in Append-I. It includes information on national and international sources of regulatory

			<p>regulating facilities and activities, and information from external sources of regulatory experience, <u>such as national, international, interface with operational experience etc.</u> The regulatory body should define <del>the most relevant</del> external sources <u>to follow and ensure, that external sources are frequently checked, especially but not limited to those sources to be identified to be of high relevance</u> whose lesson learnt are to be followed. Further information on the sources of findings is provided in Annex II. The <b>Appendix</b> provides additional guidance for the regulatory bodies to assist the personnel in identifying potential findings.</p>	<p>Please specify more clearly.</p> <p>Which Appendix? There are 2 of them, please specify.</p>				<p>findings including operating experience. Further, it is with the Member States as per their own national system to implement the recommendation on identifying findings from external sources (highlighting key/most relevant sources, frequency to check periodically and access etc.).</p> <p>The comment to delete ‘most’ is accepted. Please see comment 66.</p>
68.	GER/30	3.9	<p><i>References to GSG-12 are missing</i>  <i>All bullets are already covered by GSG-12 (e.g. GSG-12 para 5.43).</i>  <i>Please add references to GSG-12.</i></p>			X		<p>The following is a redraft based on comments 68, 69, 70, 71, 72 and 73, all on paragraph 3.9:</p> <p>“The Regulatory Body should establish arrangements to foster an environment that actively encourages personnel at all levels to identify and report findings. Key elements</p>

							<p>of this approach, in line with the guidance provided in <b>IAEA Safety Standards Series No. GSG-12</b>, include:</p> <p>(d) <b>Guidance:</b> Management should provide clear direction on sources of regulatory experience, criteria for identifying potential findings, and means for collection and reporting.</p> <p>(d) <b>Questioning Attitude:</b> A culture of critical thinking should be promoted, encouraging personnel to proactively seek and recognize potential regulatory findings.</p> <p>(d) <b>Ownership and Commitment:</b> Management should foster the value of accountability, motivation, and continuous learning and sharing of knowledge and experience to ensure sustained effectiveness in regulatory</p>
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								<p>experience feedback.</p> <p><b>(d) Being proactive and avoiding complacency:</b> The management should establish mechanisms to ensure that personnel at all levels are consistently prompted and encouraged to regularly evaluate and enhance regulatory functions and processes.</p>
69.	PAK/9	Page 6, Section 3.9 (a) Line-1	“Provide guidance” may be replaced with “Provide guidance/resources”				X	Resources are covered in paragraph 3.14.
70.	PAK/10	Page 6, Section 3.9 (b)	Importance of blame free environment shall be highlighted in this section.	Questioning attitude can be flourished with blame free environment			X	No-blame working environment is covered in paragraphs 6.7 (e), footnote on page 13 and Appendix II Topic 6,
71.	IRAN/3	3.9 ©	(c) Ownership and commitment: the management <b>should foster a sense of ownership</b> , commitment, motivation, and willingness to learn <b>and sharing of knowledge and experience</b> for sustaining an effective arrangement for managing the regulatory experience feedback among all	<p>Mere emphasis could not be enough and they must take practical steps to promote and foster.</p> <p>Mere learning is not enough, and knowledge sharing must also be considered alongside it.</p>		X		See comment 68 for revised text

			personnel.					
72.	GER/31	3.9 (d)	Regulatory functions inquiry: The management should <del>prompt personnel at all levels to consider if regulatory functions and processes can be enhanced</del> <u>establish structured mechanisms, such as regular review meetings, feedback sessions, and internal audits, to encourage personnel at all levels to propose improvements</u> for more effective and efficient regulation of facilities and activities	Consider opening this statement to personnel at all levels		X (d) <b>Being proactive and avoiding complacency:</b> The management should establish mechanisms to ensure that personnel at all levels are consistently prompted and encouraged to regularly evaluate and enhance regulatory functions and processes.		
73.	IRAN/4	3.9 (d)	<b>Being proactive and avoiding complacency</b> (instead of Regulatory functions inquiry:)	The title of this paragraph is inconsistent with the previous paragraphs. The previous paragraphs imply creating an environment to promote the spirit of identifying findings, while the Regulatory Functions Inquiry is considered a formal and organizational matter.	X			See comment 68 for revised text
74.	GER/32	3.10	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 <u>on the facility or activity</u> as	Are safe circumstances on meant for facility or activity? Please specify, otherwise it becomes misleading and unclear what “safe circumstances” are with regard to the regulatory body.		X Please see response to comment 75		

			soon as possible and <del>report the action to management. The identified finding together with the respective action should enter the system of experience feedback management.</del>	<p>Not only the action should be reported, also the finding.</p> <p>The immediate step after taking action might not be reporting to management</p>				
75.	CAN/16	3.10	<p><u>“The Regulatory Body should take immediate measures to address any safety-significant issue identified through the process for collecting findings. These measures should restore safe conditions as quickly as possible, and the actions taken should be reported to management. 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.”</u></p>	<p>The “should” statement is passive in the draft paragraph. The use of the active form of "should" emphasizes the responsibility of the Regulatory Body while leaving room for flexibility based on context. Replacing phrases like "restore safe circumstances" with "restore safe conditions" may improve readability. Lastly: The qualifier "regulatory findings" was replaced with the term "findings" to align with the explanation provided in footnote 2.</p>		<p>Agreed with modifications from comment 74. The Regulatory Body should take immediate measures to ensure 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.</p> <p>Make this as para 3.4</p>		
76.	FIN/11	Para 3.10, line 1	In case a new safety significant issue is identified from the <b>process -à procedures</b> for identifying...	Please consider leaving the term process and replace with appropriate word for example arrangements/procedures		<p>X</p> <p>Please see response to comment 75</p>		
77.	FIN/12	Para 3.10	In case a new safety significant issue is	Please delete, unnecessary wording.		X		

			identified <del>from the</del> <del>process for identifying</del> <del>regulatory findings</del> , immediate action should be taken to restore safe circumstances as soon as possible and report the action to management.			Please see comment 75		
78.	IRAN/5	3.10	Delete the paragraph or change it in a way that does not lead to abuse of this paragraph to bypass the analysis and action plan stages.	The issue of immediate safety action cannot be raised for regulatory bodies, as it is for facility operators, and the issue of immediate action must be reviewed and implemented in accordance with its process and subsequent paragraphs of this document in a procedure and according to its priority. Therefore, this paragraph can be considered misleading in some way and become an excuse to bypass that process.			X	There might be some actions for the regulatory bodies that may require immediate measures to be taken but putting and exercising the REGEX arrangements might take some time. The inclusion of such kind of issues in the REGEX arrangements is added in the revised text. (please see comment 75)
79.	FIN/13	Para 3.11	The regulatory body should make arrangements for gathering findings, including defining the responsibilities of the personnel of the regulatory body for monitoring various information sources and documenting substantive information related to findings. <b>Once a potential finding has been identified, the next step is to make the finding and accompanying information available</b>	Transfer first sentence to last, because it is referring to the next step, screening. Sentences in more logical order?		X The regulatory body should make arrangements for collecting findings, including assigning the responsibilities for monitoring various information sources and documenting substantive information related to findings to facilitate the subsequent screening.		This comment takes into account comment 80.

			for the organization to undertake the screening process.					
80.	CAN/17	3.11	<p><del>“The regulatory body should ensure that Once a potential findings, once identified, has been identified, the next step is to make the finding and accompanying information are made available for to the organization to undertake the for screening process. The regulatory body should make arrangements for gathering findings, including defining</del></p> <p><u>Arrangements should be established to define</u> the responsibilities of <del>the</del> personnel <del>of the regulatory body</del> for monitoring <del>various</del> information sources and documenting substantive <del>information related to details about</del> findings”.</p>	<p>By beginning with the regulatory body's responsibility, the revised version immediately emphasizes the expectation and accountability.</p> <p>Terms like "monitoring information sources" and "documenting substantive details" may be more straightforward than the original phrasing.</p> <p>The order of actions—identifying findings, making them available for screening, and defining responsibilities—provides a clear narrative.</p>		X	<p>The regulatory body should make arrangements for collecting findings, including assigning the responsibilities for monitoring various information sources and documenting substantive information related to findings to facilitate the subsequent screening.</p>	<p>This comment takes into account comment 79.</p>
81.	GER/33	3.11	<p>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 <del>gathering</del> <u>processing</u> <del>identified</del> findings,</p>	<p>1) We would like ask for a rephrase to better distinguish between identifying potential findings and its preparation to screening process.</p> <p>2) Missing reference to the management system and to GSG-12 para 5.56</p> <p>3) Taking para 3.2 ,5.4 (bullets 1 and 2), 6.7 g) into account information gathering and monitoring various information sources may be already defined</p>			X	<p>The comment is to link this paragraph to paragraph 5.56 of GSG-12 (which mainly focuses on how the Management System should address non-conformances and corrective and take future preventive actions).</p>

			including defining the responsibilities of the personnel <u>or relevant processes to be applied according to the management system</u> of the regulatory body for monitoring various information sources and documenting substantive information related to findings ( <u>see also para 5.56 of GSG-12</u> ).	in other regulatory processes, depending on the “finding”, e.g. existing processes for Operating Experience Feedback, performance of (reactive) inspections, partaking in bi-or multilateral working groups, review of regulatory framework etc., restating every potential source and responsibilities within the regulatory experience process seems redundant in such cases and contradicts the goal of enhancing effectiveness by applying the regulatory experience process.				However, regulatory findings can also be positive and serve as future good practices.  Furthermore, as the typical arrangements shown in figure 1 and whole of this document talks about collection of findings, therefore we changed ‘gathering’ to ‘collecting’. [see comment 79/80). The recommendation on storage and making all the information available for screening and analysis is then covered in the subsequent sections.
82.	GER/34	3.12	The regulatory body should make arrangements for recording and storing the collected findings, including those findings which are communicated informally (e.g. orally or through other informal communication means). <u>in a structured manner.</u>	Clarification	X			
83.	CAN/18	3.13	“The regulatory body should <del>consider integrating</del> <u>integrate</u> findings into <del>the its</del> existing records system within the management system or, <u>if necessary,</u> <del>establishing</del> a new system. <u>This system should account for key factors, taking into</u>	The proposed text simplifies the language to improve readability while retaining all critical information. The proposed text clearly presents the two options—integrating findings into the current system or creating a new one. Separating the paragraph into 2 sentences makes it easier to	X			

			<del>consideration factors</del> such as type <del>of information</del> , and reliability <del>of the information</del> , as well as access, security, retrievability and <del>the required storage</del> duration <del>for storing of</del> the collected findings.”	identify what is mandatory versus what is recommended for implementation.				
84.	CAN/19	3.14	“The regulatory body should <u>develop a system to screen and categorize</u> <del>make the necessary arrangements for screening and categorization of</del> findings. <del>This should include the development of, including</del> clearly defined roles and responsibilities of personnel and <u>identification of</u> 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.”	The proposed text removes ambiguous text such as “necessary arrangements”.	X			
85.	GER/35	3.14	The regulatory body should make the necessary arrangements for screening and categorization of findings <u>or indicate relevant processes according to management system</u> , including clearly defined roles and responsibilities	Missing reference to the management system.  Taking para 3.2, 5.4 (bullets 1 and 2), 6.7 g) and thus potential existing regulatory processes for Operating Experience Feedback, performance of (reactive) inspections, partaking in bi-or multilateral working groups,			X	The existing text seems more appropriate as it is with the MSs own national arrangements how they screen and categorize the findings arising from various processes of the management system.

			<p>of personnel and necessary resources, such as availability of suitably qualified personnel, <del>financial resources, tools and equipment</del>, thresholds for screening the findings <u>should be based on the source of information or within relevant processes to be applied according to the management system. Accordingly, it should be considered to define and</u> criteria for categorization of the findings. <u>Additionally, it should be checked if it is a recurrence of a previous finding. Annex III gives advices of categories to be applied</u></p>	<p>review of regulatory framework etc. into account, which may individually already assign responsibilities and resources to be used.</p> <p>“financial resources, tools and equipment” should be deleted since this requirement pertains to every regulatory processes in general and all steps within a regulatory experience process as indicated by para 6.7 a) too, furthermore it is not explicitly part of screening and categorizing regulatory findings.</p> <p>Recurrence of a finding can point to a different root cause of the finding, or call for a higher categorization of a finding, or point to weaknesses in the action plans.</p> <p>In order to help with international exchange/harmonization a recommendation for categories should be provided in this guide, for instance in an additional annex. Does IAEA plan to implement a portal for regulatory experience feedback similar to others (INES, FINAS etc.)?</p>				
86.	PAK/11	Page7, Section 3.14	Event/ Cause/ Coding of events w.r.t type shall also be included for collection of data for trending purpose.	For annual/ six monthly/ monthly trending or for identification of similar type of event in past.			X	Most of the proposed text is provided in section 3.15
87.	FIN/14	Para 3.15., line 4	Should identify findings which require more detailed analysis by	Please check the consistency in wording	X			

			defining and utilizing clear criteria to ensure verifiable and consistent implementation of the <b>process</b> à <b>arrangements/procedures</b>	(process/arrangements/procedures)				
88.	CAN/20	3.15(a)	<p>“Should <u>clearly define and use criteria to identify findings</u> <del>which that require more detailed in-depth analysis. These criteria should ensure that the arrangements for by defining and utilizing clear criteria to ensure verifiable and consistent implementation of the process for effectively managing the regulatory experience feedback are implemented consistently and can be verified.</del> These criteria will <u>also help estimate</u> <del>determine</del> the workload <u>for subsequent steps, including associated with further steps during the</u> detailed assessment, <u>lessons</u> identification <del>of lessons, and development and implementation of the</del> action plan <u>development and execution.</u>”</p>	<p>The proposed revision simplifies the sentence structure and flow while retaining the original meaning, making it easier to follow.</p> <p>The original text has a long and somewhat cumbersome sentence that packs in multiple ideas. The proposed revision organizes these ideas into a logical sequence, with each thought clearly delineated. This improves readability and ensures the key points are conveyed effectively.</p> <p>The proposed revision uses direct and active language, such as "Clearly define and use criteria" and "These criteria should ensure," making the text more assertive and engaging. Active voice also helps in assigning clear responsibility for actions.</p>		X	Should <u>establish and utilize criteria to ensure consistent implementation of arrangements</u> to identify findings requiring further analysis. <b>Clear criteria are needed to conduct the screening and to set a threshold for screening-in. The criteria could be quantitative (e.g. risk-informed), qualitative (e.g. the finding may affect regulatory practices) or a combination.</b>	
89.	CAN/21	3.15(b)	<p>“Should document <u>details about the screening and categorization process, including information relating to the process</u> <del>such as</del> the name of the <u>person individual</u></p>	<p>The revised version simplifies the structure by breaking down the information into shorter, more digestible sentences. This improves readability and makes the purpose of each element more explicit.</p>		X	Should document <b>the relevant</b> information such as name of the <b>owner or coordinator</b> conducting the	The paragraph is rephrased as proposed and also includes the changes proposed in Comment 90.

			conducting the <del>review screening and categorization</del> , dates of screening and investigation, a file title <u>that follows a clear (following a file naming convention that allows ease of reference) for easy reference. Provide a concise and a brief</u> description of the finding along with <del>the relevant justification explaining why the finding was screened in or screened out for future reference and record</del> <u>for whether it was included or excluded for further analysis. In addition, for screened in</u> For findings <u>that are included (screened-in), record their the</u> categorization <del>of the finding should be included</del> to <u>facilitate allow for</u> further analysis.”	By using clear phrases such as "concise description" and "easy reference," the redraft ensures the text is practical and avoids ambiguity.		screening and categorization, the dates of screening, and a file title that follows a clear and consistent naming convention for easy reference. <del>A</del> <u>concise description</u> of each finding should be included, along with the relevant justification explaining why the finding was screened-in or screened-out for future reference and record. In addition, for screened-in findings, the categorization of the finding should be included to allow for further analysis.		
90.	FIN/15	Para 3.15 (b)	Should document information relating to the process <b>(FIG. 1.)</b> such as the name of the person conducting the screening and categorization, dates of screening and investigation, a file title (following a file naming convention that allows ease of reference) and a brief description of the finding along with the relevant justification	Please refer to the FIG 1 process diagram.		X Should document the relevant information such as the....		

			explaining why the finding was screened-in or screened-out for future reference and record. In addition, for screened-in findings, the categorization of the finding should be included to allow for further analysis.					
91.	PAK/12	Page7 Section 3.15 (b) Line 1	Should document information relating to the process such as the name of the <b>committee members</b> conducting the screening and categorization	To ensure reliability of screening process, instead of an individual, a committee may conduct the screening and categorization etc.		X Should document information relating to the process such as the <b>owner or coordinator</b> conducting the screening and categorization		
92.	CAN/22	3.15(c)	“Should identify <u>instances</u> where similar findings have been raised previously. <u>It should then be determined and if so determine</u> whether there are existing action plans to address these <u>se</u> findings or <u>if additional analysis and action are required a need for further analysis.</u> ”	The revised version proposes slight editing for clarity while preserving the original meaning.		X Should identify <u>instances</u> where similar findings have been raised previously. <u>It should then be determined and if so determine</u> whether the existing action plans are sufficient to address these <u>se</u> findings or <u>if additional analysis and actions are required.</u>		This comment also takes into account Comment 93.
93.	GER/36	3.15 (c)	Should identify where similar findings have been raised previously, and if so determine whether there are	It is not sufficient to just check, if there are action / improvement plans concerned with such a finding. Possibly the action plan has not been as effective as		X Should identify <u>instances</u> where similar findings have been raised		This comment also takes comment 92 into consideration.

			existing action / <u>improvement</u> plans to address the findings <u>and if these plans possibly need adjustment or if there is</u> a need for further analysis	envisioned and needs improvement itself.		previously. <u>It should then be determined and if so determine</u> whether the existing action plans are sufficient to address these <u>findings or if additional analysis and actions are required.</u>		
94.	GER/37	3.15 (d) and (e) New issues	<u>(d) Should identify, with regards to integrated management system, processes affected and process owners</u>  <u>(e) Should carry out categorization with regard to actual or potential impacts on safety and on the effectiveness of the regulatory body (see GSG-12 para 5.61)</u>	<p>The goal of the screening should be to identify:</p> <ul style="list-style-type: none"> <li>- Processes affected and process owners</li> <li>- Categorization with regard to actual or potential impacts on safety and on the effectiveness of the regulatory body (see GSG-12 para 5.61).</li> </ul> <p>In GSG-12 para 6.18 reference is made to an individual or a team who/which should be appointed to be responsible for the management processes. These persons should be included in the screening process.</p> <p>The detailed analyses should further be carried out by the process owner or by the responsible person for the IMS</p>		X Added new paragraph: “Should establish a structured method for categorizing findings based on predefined criteria. These criteria shall ensure effective classification by type, significance, and relevance to regulatory objectives. Categorization shall facilitate prioritization, trend analysis, and appropriate response measures to enhance the management of regulatory experience.”		The further elaboration of screening and categorization is covered in Section 4 of IAEA TECDOC-1899 providing practical insights as well. Furthermore, para 3.17 covers aspects related to the involvement of multidisciplinary personnel including process owners for multifaceted analysis of the findings.
95.	CAN/23	3.16	“The <u>regulatory body should conduct a comprehensive analysis of the purpose of analysing the regulatory-experience feedback</u>	There is no “should” statement in this paragraph. The use of “should” directly emphasizes the regulatory body's responsibilities, providing clear guidance.		X The <u>regulatory body should conduct</u> a comprehensive analysis of the		This comments also takes into consideration Comment 96.

			findings <del>that are is to undertake a comprehensive analysis of the</del> screened-in <u>by regulatory experience feedback screening.</u> <u>Based on this analysis, it should findings, and to</u> develop an action plan to address the gaps and <del>identify seize</del> opportunities for improving the regulatory framework, <u>functions and processes.</u> ”	Also, the proposed redraft clearly separates the two primary actions—analysis of findings and development of an action plan—ensuring a logical flow. Added clarity surrounding findings that are screened-in, linking specifically to findings screened in by “regulatory experience feedback screening”.		screened-in findings, <u>taking into account the applications of a graded approach.</u> Based on analysis, an action plan should be developed to address the gaps and seize the opportunities for continuous improvement.		
96.	GER/38	3.16	<del>The purpose of analysing the regulatory experience feedback findings</del> <u>should be investigated</u> <del>is to</del> undertake a comprehensive analysis of the screened-in findings, and to develop an action / <u>improvement</u> plan to address the gaps and identify opportunities for improving the <del>regulatory framework</del> <u>effectiveness and efficiency of the integrated management system and its processes for carrying out the regulatory functions.</u> <u>Analyses should be carried out using a graded approach in accordance with the findings of the screening process.</u>	Even though Section 5 of this draft addresses graded approach it should specifically state at this point as well, as an analysis/investigation may be comprehensive even with less depth, as it depends on the type of finding, the impact on the regulatory processes and further stakeholders among other things. E.g. improving the efficiency of a single process in the regulatory body’s management system may need less analysis compared to amending a gap in the regulatory framework, which in itself may be spur several parallel or subsequent regulatory experience feedback processes as part of the analysis.		X  “The <u>regulatory body should conduct a comprehensive analysis of the screened-in</u> findings, taking into account the application of a graded approach. <u>Based on analysis results,</u> an action plan should be developed to address the gaps and <del>identify seize</del> <u>the</u> opportunities for continuous improvement.”		Investigating findings may be too much in some cases. “Analyse” is used in line with the methodology presented in this document.
97.	PAK/13	Page 8, Section 3.17	<u><b>Review process of cause(s) and action</b></u>	For SMART action plans			X	SMART is a current trend and may not be relevant in a few years.

			<p><u>plans before finalization shall be existed.</u>  <u>Actions plans before finalization shall be reviewed by implementing units to check whether actions are SMART or not.</u></p>					<p>3.17 does a good job of providing guidance that will likely result in a SMART product. Further, the aspect of approval is covered in para 3.17 (d) which requires this plan to be approved by the senior management.</p>
98.	GER/39	3.17 a)	<p><del>Involvement of suitably Assurance that qualified personnel conduct a comprehensive analysis of findings considering technical, operational and organizational aspects.</del></p> <p>This analysis should <del>comprise a comprehensive and thorough examination of the findings from multiple perspectives such as</del> technical, operational and organizational, <del>should involve experts from various disciplines and should take into consideration the impact of findings on regulatory functions and processes.</del> <u>assess potential impacts on regulatory functions and involve relevant internal and external stakeholders.</u></p> <p><b>Alternative:</b></p> <p><u>Commensurate with the screening process and the potential impact a finding on different processes of</u></p>	<p>The process owner should analyze the changes needed in order to take into account/react on the regulatory finding and propose changes to the process.</p> <p>Our suggestion is, that this guidance should be rewritten and then based and linked to the review of the management system based on GSR Part 2 para 6.2 and GSG-12 para 5.40 – 5.54.</p>			X	<p>The existing text seems clearer and more detailed. The same was discussed during the CS and the relevant reviewer agreed to stick with the original text.</p>

			<p>the IMS might have the process owner should include suitably qualified personnel, if needed in the analysis, for conducting a multifaceted analysis. This analysis should comprise a comprehensive and thorough examination of the findings from multiple perspectives such as technical, operational and organizational, should involve experts from various disciplines and should take into consideration the impact of findings on regulatory functions and processes.</p> <p><u>The analysis should assess potential impacts on regulatory functions and involve relevant internal and external stakeholders.</u></p>					
99.	CAN/24	3.17(a)	<p><u>“The regulatory body should involve involvement of</u> suitably qualified personnel <u>to conduct for conducting</u> a multifaceted analysis <u>of findings</u>. This analysis should <u>include comprise</u> a <u>comprehensive and</u> thorough examination <u>of the findings</u> from multiple perspectives, such as technical, operational and organizational. <u>It should also</u> involve experts from</p>	<p>Proposed revision using active voice and repeating the action is on the RB in each of these subparagraphs as each is a separate requirement. Each idea is separated in their own distinct sentence for better flow and readability.</p>		<p>X</p> <p>“Involvement of suitably qualified personnel <u>to conduct</u>—a multifaceted analysis <u>of findings</u>. This analysis should <u>include comprise</u> a <u>comprehensive and</u> thorough examination <u>of the findings</u> from multiple perspectives, such</p>		<p>The opening statement “the regulatory body should...”) is already there in the text in the start of para 3.17. No need to repeat again in 3.17 (a). Rest of the changes are accepted.</p>

			<del>various diverse</del> disciplines and <del>should take into consideration</del> <u>account for</u> the impact of <u>the</u> findings on regulatory functions and processes.”			as technical, operational and organizational. <u>It</u> should <u>also</u> involve experts from <del>various diverse</del> disciplines and <del>should take into consideration</del> <u>account for</u> the impact of <u>the</u> findings on regulatory functions and processes.”		
100.	FIN/16	Para 3.17 (a)	Involvement of suitably qualified personnel for conducting a multifaceted analysis. This analysis should comprise a comprehensive and thorough examination of the findings from multiple perspectives such as <b>safety significance</b> , technical, operational and organizational, should involve experts from various disciplines and should take into consideration the impact of findings on regulatory functions and processes.	Please consider including assessment of safety significance as a part of this analysis, either to 3.17 (a) or (b).			X	The aspect of safety significance is covered in technical and operational perspectives.
101.	FIN/17	para 3.17 (b)	The findings’ safety significance should be defined in the assessment of findings	Please consider should there be a requirement for the findings’ <b>safety assessment/ definition on safety significance in this section/paragraph?</b>			X	As above
102.	CAN/25	3.17(b)	“ <del>The regulatory body should assess. Assessment of each finding to identify covering</del> the	Proposed revision using active voice and repeating the action is on the RB in each of these		X Assessment of each finding to <b>identify covering</b>		The opening statement of para 3.17 covers the initial change proposed.

			relevant elements potentially affected, <del>by the finding, including such as</del> human, technical, legal, financial and managerial <del>elements-aspects</del> . <u>It should consult Consultations may be held with</u> internal parties, <u>including</u> (e.g. process owners, senior management, <u>and</u> technical experts, <del>within the organization</del> ) <u>and as well as</u> external interested parties, <u>such as</u> (e.g. authorized parties, vendors, <u>and</u> other regulatory bodies), to gather diverse perspectives and feedback on the findings.”	subparagraphs as each is a separate requirement. Each idea is separated in their own distinct sentence for better flow and readability.		the relevant elements potentially affected <del>by the finding</del> such as, <del>including</del> human, technical, legal, financial and managerial <del>elements-aspects</del> . It should <del>Consultations may be held with</del> internal parties <del>including, such as</del> (e.g. process owners, senior management and technical experts <del>within the organization</del> ) <del>and</del> as well as external interested parties, such as (e.g. authorized parties, vendors and, other regulatory bodies) to gather diverse perspectives and feedback on the findings		Rest of the changes are accepted.
103.	GER/40	3.17 (b)	<del>Assessment of each finding covering the relevant elements potentially affected by the finding, including human, technical, legal, financial and managerial elements. Consultations may be held with internal (e.g. process owners, senior management, technical experts within the organization) and</del>	Delete, as issue is covered by 3.17 a)			X	Para 3.17 (b) covers certain other factors that should be considered while analysing the findings and gives direction to consult with internal and external parties.

			external interested parties (e.g. authorized parties, vendors, other regulatory bodies) to gather diverse perspectives and feedback on the findings.					
104.	GER/41	3.17 (c)	Development of an action / <u>improvement</u> plan, which may result in ranging from minimal to substantive changes in the regulatory <del>framework</del> , functions or processes. The action / <u>improvement</u> plan should identify the personnel responsible for its implementation <u>and monitoring the implementation. If the management system already defines process owners or further responsible personnel, it should be checked whether there is a reason to re-assign responsibility in individual cases.</u>	Please use consistently, in compliance with GSG-12: - “regulatory functions or processes” - improvement plan instead of action plan, or at least both terms parallel		X Development of an action plan <u>to address the findings which may include-</u> actions ranging from <u>minor adjustments</u> to <u>significant</u> changes in the regulatory functions or processes. The action plan should identify the personnel responsible for its <u>timely</u> implementation <u>and monitoring.</u>	Last part not accepted	Its with the Member States own national arrangements as per their management system to assign/reassign the responsibilities. This comment also takes comment 105 into consideration.
105.	CAN/26	3.17(c)	<u>“The regulatory body should develop</u> <del>Development of</del> an action plan <u>to address the findings. This plan may include, which may result in-</u> actions ranging from <del>minimal</del> <u>minor adjustments</u> to <del>substantive</del> <u>significant</u> changes in the regulatory <del>framework</del> , functions or processes. The action plan should <u>clearly assign responsibilities for</u>	Proposed revision using active voice and repeating the action is on the RB in each of these subparagraphs as each is a separate requirement. Each idea is separated in their own distinct sentence for better flow and readability.		X Development of an action plan <u>to address the findings which may include-</u> actions ranging from <u>minor adjustments</u> to <u>significant</u> changes in the regulatory functions or processes. The action plan should identify the		This comment also takes comment 104 into consideration.

			<u>implementation to specific personnel</u> <del>identify the personnel responsible for its implementation.</del>			personnel responsible for its <b>timely</b> implementation <u>and monitoring.</u>		
106.	FIN/18	Para 3.17 (c)	Development of an action plan, which may result in actions ranging from minimal to substantive changes in the regulatory framework, functions or processes. The action plan should identify the personnel responsible for its implementation <b>and timeframe for completing it /or in timely manner.</b>	Please consider adding timeframe/timely manner in completing the action plan. Can also be stated under the next paragraph “Implementing the action plan”		X See comment 104 and 105 above.		
107.	CAN/27	3.17(d)	<del>“The regulatory body should review and approve. Review and approval of the action plan by the through senior management, of the regulatory body taking into account factors such as the</del> <u>The review should prioritize safety, implications of the identified actions; incorporate consultation outcomes, include the outcomes of consultations;</u> a cost-benefit analysis; <u>consider</u> the impacts on interested parties; <u>and identify</u> follow-up actions <del>giving safety the highest priority as necessary.”</del>	Proposed changes for clarity. We propose using active voice and repeating the action is on the RB.			X	The original text seems appropriate. The same was discussed during the consultancy meeting with the relevant reviewer and agreed upon to stick with the original text.

108.	GER/42	3.17 (d)	<p>Review and approval of the action plan by <del>the</del> senior management <u>or specific committees/ decision-making bodies</u> of the regulatory body taking into account factors such as the safety implications of the identified actions; the outcomes of consultations; <del>a cost-benefit analysis</del>; the impact on interested parties; <del>and</del> follow-up actions giving safety the highest priority <u>and finally estimation of results</u>.</p>	<p>Taking into account para 3.2, 5.4 (bullets 1 and 2), 6.7 g) and potentially existing processes in regulatory bodies, as well as different organizational structures “specific committees” and/or “decision-making bodies” should be added. These may be defined in existing processes, organizational hierarchy or other functions already.</p> <p>However, it should be added to account for the fact, that an action plan needs to be approved and the responsibility for review and approval may rest with another decision-making body than senior management. Of course, responsibility again depends among other things on the type of regulatory experience finding. Giving safety the highest priority and doing a cost-benefit analysis is a contradiction. If safety is impacted by the implementation plan, then a cost-benefit analysis should not be a decisive factor. However, given the wide range of potential regulatory experience findings and corresponding implementation plans it makes sense for some to explicitly utilize cost-benefit analysis in review and approval.</p> <p>Additionally, a final estimation of results belongs to the process as well.</p>			X	<p>The original text seems appropriate. The intent is to get the action plan reviewed and approved by the senior management as it may result into minor to substantive changes in regulatory framework requiring additional resources.</p> <p>Furthermore, there might be some actions having no impact on safety but to improve the work practices, in that case, cost-benefit analysis may be carried out to implement actions. The same is also highlighted in the comment made by Germany.</p>
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109.	CAN/28	3.18	“The <u>regulatory body should document the</u> decision-making process and <del>the</del> rationale for <del>the</del> finalization <u>ationing of</u> the action plan <del>should be documented for to ensure</del> transparency and <u>provide a reference for</u> future reference.”	The proposed text clarifies that the responsibility is on the RB. Was missing “who” should do this action. For added clarity.			X	The original text seems more appropriate.
110.	GER/43	3.18	The decision making process and the rationale for the finalization of the action / <u>improvement</u> plan should be documented for <del>transparency and</del> future reference.	It is not necessary to add the word transparency, as it is not explained to whom this should be transparent. As this documentation should be a document for the regulatory body, the respective national rules and regulations regarding transparency apply. Additionally, we suggest to add term “improvement plan”, to be in line with para. 5.62 of GSG-12.		X The decision making <del>process</del> and the rationale for the finalization of the action plan should be documented for <del>transparency and</del> future reference.		Not necessarily to align with GSG12 but more to maintain consistent terminology throughout this document.  This comment also takes comment 111 into account.
111.	FIN/19	para 3.18, line 1	The decision-making <b>process</b> and the rationale for the finalization of the action plan should be documented for transparency and future reference	Please consider replacing the term process or leave it: “The <b>decision making and</b> the rationale for the finalization of the action plan should be documented for transparency and future reference.	X			This comment also takes comment 110 into account.
112.	GER/44	3.19	The approved action / <u>improvement</u> plan should consider specific instructions for <u>communicating changes to the processes of the IMS to the relevant personnel of the regulatory body</u> <del>disseminating the lessons learned</del> , when necessary.	It is not clear, what is meant by “disseminating the lessons learned”.  A distinction should be made between the action plan for implementation and the action plan for dissemination. The dissemination is a separate step in the process		X The approved action plan should <u>include</u> specific instructions for disseminating the lessons learned <u>to ensure that the relevant findings and associated actions are effectively communicated to</u>		To align with comment 113.

						<u>internal and external stakeholders</u> , when necessary.		
113.	CAN/29	3.19	“The <u>management of the regulatory body should include approved action plan should consider</u> specific instructions <u>in the approved action plan</u> for disseminating the lessons learned <u>to ensure that the relevant findings are effectively communicated to internal and external stakeholders</u> , when necessary.”	Simplifies the sentence structure, making the actions required by the management of the regulatory body more direct and comprehensible though the use of active voice rather than passive. Note: Added text is proposed for further clarification, if needed. It adds clarity around the “why” of the requirement to further assist in implementation.		X The approved action plan should <u>include</u> specific instructions for disseminating the lessons learned <u>to ensure that the relevant findings and associated actions are effectively communicated to internal and external stakeholders</u> , when necessary.		
114.	PAK/14	Page8 Section 3.19	<b><u>Lesson learned should be specific and also generic.</u></b>				X	It depends on the nature of findings and associated actions.
115.	CAN/30	3.20	“ <u>The management of the regulatory body should assign approved actions from After approval of the action plan to designated personnel who will be responsible for their ,the actions- should be assigned to the personnel responsible for its implementation.</u> ”	Proposed to clearly state the authority of this action is the management of the regulatory body.			X	Initial text is also clear. There might not be the management of the regulatory body, it could be the process owner’s responsibility. We propose to keep the original text.
116.	GER/45	3.20-3.21	<i>Guidance of para 5.61.- 5.62 of GSG-12 should be referenced and be taken into account.</i>				X	The requirements are referenced from GSRs and SSRs and detailed guidance is provided on how to implement those. As the highlighted recommendations in

								GSG-covers certain aspects, we understand that these are covered on appropriate places in the course of this safety guide. For instance, para 3.17, 3.21 and 6.7 of DS547 covers for all the aspects of para 5.61 and 5.62 of GSG-12.
117.	CAN/31	3.21(a)	<p><del>“Coordinating the execution of The regulatory body should ensure effective coordination in executing the action plan by confirming ensuring the availability of the necessary resources and involving, as well as ensuring the involvement of third parties or external interested parties stakeholders when required, if necessary. This coordination might include collaboration with multiple authorities responsible For example, when there is more than one authority with responsibility for safety, when cooperation with regulatory bodies of other countries, or engagement with external technical support organizations is envisaged.”</del></p>	<p>The use of active voice (e.g., "Ensure effective coordination...") enhances clarity and avoids ambiguity, making responsibilities and actions more direct. The revised phrasing creates a smoother reading experience by presenting information in a logical sequence. For example, beginning with "Ensure effective coordination..." immediately sets the focus on the central action.</p>		<p><del>X</del></p> <p><u>Effective coordination in executing the action plan by confirming ensuring the availability of the necessary resources and involving, as well as ensuring the involvement of third party or external interested parties when required, if necessary. This coordination might include collaboration with multiple authorities responsible For example, when there is more than one authority with responsibility for safety, when cooperation with regulatory bodies of other countries, or engagement with external</u></p>		

						technical support organizations.		
118.	CAN/32	3.21(b)	<p><u>“The regulatory body should monitor the progress. Monitoring the implementation of the action plan implementation by systematically which includes tracking each action’s status, resolving any delays or obstacles, and ensuring timelines and responsibilities are adhered to effectively. This monitoring process should involve regular status updates, documentation of progress, and communication of any significant deviations to senior management the implementation progress.”</u></p>	<p>This version offers a more structured and precise explanation of monitoring activities while maintaining the original intent.</p>		<p>X</p> <p>Monitoring the progress of the action plan implementation by systematically which includes tracking each action’s status, resolving any delays or obstacles, and ensuring timelines and responsibilities are adhered to effectively. This monitoring process should involve regular status updates, documentation of progress, and communication of any significant deviations to appropriate management level.</p>		
119.	CAN/33	3.21(c)	<p><u>“The regulatory body should evaluate. Evaluating the impact of the actions on the regulatory functions and processes, assessing their effectiveness by analyzing performance metrics, gathering feedback from the target audience, and comparing results to baseline data, and providing updates to senior management. This</u></p>	<p>This proposed version is clearer and more structured, emphasizing key steps in evaluating the impact while maintaining the original meaning.</p>			X	<p>As the opening sentence starts with “the regulatory body should...”. Original text seems more clearer. Further elaboration for improving the arrangements for managing regulatory experience feedback are discussed in detail in section 6.</p>

			<u>evaluation process should ensure the effectiveness of the actions, identify potential improvements, and provide comprehensive updates to senior management for informed decision-making.”</u>					
120.	FIN/20	Para 3.21 c	Evaluating the impact of actions on the regulatory functions and processes, assessing their effectiveness by <b>for example</b> analysing performance metrics...	Is there a reason to limit assessing the effectiveness only to certain measures; their might be some other as relevant measures existing.		X ....functions and processes, assessing their effectiveness by <b>using methodologies such as</b> analyzing performance....		
121.	FIN/20	Para 3.21 (c)	Evaluating the impact of actions on the regulatory functions and processes, assessing their effectiveness by <b>for example</b> analyzing performance metrics, gathering feedback from the target audience, and comparing results to baseline data, and providing updates to senior management.	Please add “for example”; there might be also other ways of assessing the effectiveness.		X See above		
122.	CAN/34	3.24	<del>“Furthermore, p</del> Para. 2.8 of GSR Part 1 (Rev. 1) [2] states: ...”	Section 3.24 could benefit from starting directly with the point it conveys, rather than using the transitional word "Furthermore.". This would be consistent with 3.22, 3.23 and 3.25.	X			
123.	CAN/35	3.26	“The regulatory body should <del>disseminate make-arrangements for-dissemination of the</del>	The proposed version is clearer with superfluous text removed.		X The regulatory body should <b>establish</b>		To make it in line with para 2.33 of GSR Part 3.

			lessons learned from the regulatory experience feedback management <u>mechanisms</u> <del>arrangements</del> for their use by <del>other</del> regulatory bodies with the responsibility for safety and other relevant organizations, nationally or internationally....”			<del>mechanism</del> for dissemination.....		
124.	GER/46	3.26	The regulatory body should make arrangements for dissemination of the lessons learned from the regulatory experience feedback management arrangements for their use by other regulatory bodies with the responsibility for safety and other relevant organizations, nationally <u>and/or</u> internationally. The lessons learned might be useful for authorized parties, vendors, designers and supply chain organizations <u>and should be considered to be made available.</u>	If deemed possible, information should be made available to external parties		The regulatory body should <del>establish</del> <del>mechanism</del> <del>make-</del> <del>arrangements</del> for dissemination of the lessons learned from the regulatory experience feedback management arrangements for their use by <del>other-</del> regulatory bodies with the responsibility for safety and other relevant organizations (e.g. authorized parties, vendors, designers , technical support and supply chain organizations), nationally <u>and/or</u> internationally.	Last part not accepted .	It is already covered in the opening sentence of this para.
125.	FIN/21	Para 3.26, lines 4-5	The lessons learned might be useful for authorized parties, vendors, <b>technical support organizations,</b>	Please consider adding technical support organizations (TSO)		The regulatory body should disseminate the lessons learned from the regulatory experience		

			designers and supply chain organizations.			feedback management arrangements for their use by <del>other</del> regulatory bodies with the responsibility for safety and other relevant organizations (e.g. authorized parties, vendors, designers, technical support organizations and supply chain organizations), nationally <u>and/or</u> internationally.		
126.	GER/47	3.28	<p>The regulatory body's <u>information on regulatory experience to be shared</u> <del>plan for disseminating lessons learned from regulatory experience</del> should include, at a minimum, the following <del>four</del> elements:</p> <ul style="list-style-type: none"> <li>- <u>information for which recipient the regulatory experience might be of interest</u> <del>Target recipients: Identifying and defining the recipients of the shared information,</del> which may include the personnel of the regulatory body, licence holders, other national authorities and relevant international organizations.</li> </ul>	<p>The focus should be on the content of the information to be shared.</p> <p>Potentially a link to relevant processes of the IMS could be made.</p>		<p>X</p> <p>The regulatory body's <del>plan</del> <u>mechanism</u> for disseminating lessons learned from regulatory experience should include, at a minimum, the following <del>four</del> elements:</p> <ul style="list-style-type: none"> <li>– Identify the lessons learned to be shared: Establishing arrangements to determine when a regulatory experience findings and associated actions qualify</li> </ul>		

			<p><u>- Information on the regulatory finding and on necessary measures</u></p> <p><del>—Means and channels for dissemination: Deciding on the best approach to reach the target recipients, considering factors like purpose for sharing the lessons learned, needs of the target recipients, and means of sharing.</del></p> <p><u>- Information on the implementation of measures due to the regulatory finding.</u></p> <p><del>— Implementing the action plan: Establishing clear instructions for implementing the action plan to effectively disseminate the lessons learned from regulatory experience.</del></p> <p><del>—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</del></p>			<p>for dissemination.</p> <p>— Target recipients: Identifying and defining the recipients of the shared information, which may include the personnel of the regulatory body, licence holders, other national authorities and relevant international organizations.</p> <p>— Means and channels for dissemination: Deciding on the best approach to reach the target recipients, considering factors like relevance for compliance, safety significance, urgency of actions etc.</p> <p>— <del>Implementing the action plan: Establishing clear instructions for implementing</del></p>		
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			achieved the intended purpose. This can be achieved, by analyzing performance metrics, gathering feedback from the target audience, and comparing results to baseline data.			<p>the action plan to effectively disseminate the lessons learned from regulatory experience.</p> <p>— 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</p>		
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						<del>audience, and comparing results to baseline data.</del>		
127.	FIN/22	Para 3.28	<del>Implementing the action plan: Establishing clear instructions for implementing the action plan to effectively disseminate the lessons learned from regulatory experience.</del>	Is this in the wrong place? Should it be under chapter “Implementing action plan”? Implementing the action plan: Establishing clear instructions for implementing the action plan to effectively disseminate the lessons learned from regulatory experience.	X			
128.	FIN/23	Para 3.28	This can be achieved, by analyzing performance metrics, gathering feedback from the target audience, and comparing results to <b>baseline data</b> .	What does “baseline data” mean in this context. Needs clarification	X	The relevant para is deleted.		
129.	GER/48	3.29 New issue	<u>The regulatory body should decide on developing and implementing measures to facilitate access to potential sources of experience (e.g. hosting peer review missions, encouraging personnel to participate in international training and to enroll in fellowship programmes or scientific visits) or to remove access barriers to such sources (e.g. engaging in international research, concluding bilateral agreements with other countries). The regulatory body can</u>	Please move statements from Appendix I/ I.2 here. This para. contains significant guidance information relevant for Section 3.			X	The information is more relevant in the Appendix as it provides additional details on provision for accessing the sources. Appendix is considered to form an integral part of the safety standard. Material in an appendix has the same status as the body text.

			<u>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.</u>					
130.	GER/49	3.30 New issue	<u>Research and development is an important source of lessons for regulatory experience and, as such, a regulatory body should explore how to effectively utilize lessons identified from research and development in keeping their framework and regulatory functions and processes up to date and effective. Regulatory bodies, though, may need to establish arrangements to address the specific characteristics of this source of regulatory experience.</u>	We suggest moving the statements from Appendix I/ I.3 here. This para. contains significant guidance information relevant for Section 3.			X	All sources of regulatory experience, including R&D are important and are provided in Appendix-I as additional details to the existing recommendation in section 3. Appendix is considered to form an integral part of the safety standard. Material in an appendix has the same status as the body text.
131.	CAN/36	4	<u>“INTEGRATION OF THE ARRANGMENTS FOR MANAGING REGULATORY EXPERIENCE FEEDBACK INTO THE MANAGEMENT SYSTEM”</u>	This version streamlines the title while maintaining its focus on the integration of feedback and management.		X <del>INTEGRATION</del> G THE <u>ARRANGMENTS</u> FOR MANAGING REGULATORY EXPERIENCE FEEDBACK INTO THE MANAGEMENT SYSTEM		
132.	PAK/4	Page 10 Section-4 Title	"ARRANGEMENTS"	"ARRANGMENTS" (misspelled)	X			

133.	CAN/37	4.3	<p><del>“The regulatory body</del>  <u>Regulatory bodies with established management systems</u> should integrate <del>the</del> regulatory experience feedback management <del>arrangements within its</del> <u>into their current</u> management systems.  <u>This ensures a coherent,</u>  <del>to foster a</del> systematic approach to capturing, analysing and applying lessons learned <del>from regulatory experience</del> <u>while aligning these efforts.</u>  <del>These arrangements should be effectively interconnected with all processes contributing to regulatory experience and should be consistent and well-aligned</del> 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].”</p>	<p>Possible confusion/contradiction between section 3.2 and 4.3.</p> <p>Section 4.3 emphasizes that the regulatory body <b>**should integrate**</b> the arrangements for managing regulatory experience feedback directly into its management system.</p> <p>In contrast, section 3.2 provides <b>**two options**</b> for addressing regulatory experience feedback. The first option suggests establishing a distinct, specific process for identifying lessons learned from regulatory functions and processes. The second option allows for embedding these arrangements within existing regulatory functions and processes or within an existing Management System.</p> <p>These two sections may appear contradictory because section 4.3 firmly advocates for integration into the management system, while section 3.2 offers flexibility by presenting an alternative approach of creating a separate, dedicated process. This discrepancy could create confusion regarding the preferred method for managing regulatory experience feedback.</p> <p>This proposed text attempts to address and clarify this discrepancy by clearly stating this paragraph is aimed at “RBs with existing IMS”.</p>			X	<p>The original text is clear and in line with the IAEA GSR Part 2 and GSG-12 which requires the establishment of the management system by the Member States.</p>
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134.	CAN/38	4.5	<p><del>“The s</del>Senior management of the regulatory body should <u>demonstrate commitment to regulatory experience feedback management by allocating</u> allocate the necessary resources to develop, implement and sustain <del>regulatory-experience-feedback-management-arrangements the</del> <u>program. This includes</u> fostering an enabling environment <u>that motivates by motivating-</u> the personnel and <u>reinforces the importance of effective feedback management arrangements through leadership actions</u><del>demonstrating-commitment by its actions.</del>”</p>	<p>This version simplifies the language while preserving the intent, emphasizing the role of senior management and their commitment to enabling successful implementation.</p>		X		<p>The term ‘arrangements’ is used in this Safety Guide based on the input received from Member States and is also inline with the Requirement 15 of GSR Part 1.</p>
135.	CAN/39	4.6	<p>“The regulatory body should ensure that knowledge management <u>systems effectively captures</u>, retains and <u>make accessible the</u></p>	<p>This revision replaces "visible outcomes" with a clearer and more specific description of what the regulatory body should aim to achieve and retain.</p>	X			

			<p><del>results and benefits keeps visible outcomes of the</del> regulatory experience feedback management arrangements <del>and vice-versa</del>. <u>These results may include documented lessons learned, identified improvements in regulatory function and processes, and tangible actions that enhance safety and regulatory effectiveness.</u></p>	<p>It also includes the word “systems” to qualify knowledge management as a system that could be measured rather than a concept.</p>				
136.	GER/50	4.6	<p>The regulatory body should ensure that knowledge management captures, retains and keeps visible outcomes of the regulatory experience feedback management arrangements <del>and vice-versa</del>.</p>	<p>It is clear that also through knowledge management the lessons learned and so on of the regulatory experience should be transported. The reverse is less clear. It is suggested to elaborate on this or to leave out the vice versa.</p>	X			
137.	GER/51	4.7	<p>The regulatory body should promote the collection of information and knowledge resulting from experience at all levels in the organization to ensure that all learning opportunities are successfully managed. Therefore, a proactive attitude of individual process owners is an important contributing factor to successfully manage the regulatory experience. The owner of a specific regulatory process should proactively take</p>	<p>Suggestion as to not repeat the ideas too often.</p>	X			

			<p>regulatory experience feedback into account in reviewing the process <del>to keep it up to date and effective</del> <u>and bring it to the attention of senior management</u>. The <del>process owners can play an important role by proactively raising findings to the attention of senior management</del>. The senior management would be expected to use regulatory experience feedback as one of the inputs when completing a review and updating the regulatory framework and processes. This approach also encourages dialogue on the benefits to be gained from effective management of regulatory experience throughout the organization and promotes its daily utilization</p>					
138.	CAN/40	4.7	<p>“The regulatory body should <u>actively</u> promote the collection of information and knowledge <del>resulting</del> from experience <u>across</u> <del>at</del> all levels <del>in</del> <u>of</u> the organization to ensure <u>effective management of</u> <del>that all</del> learning opportunities <del>are successfully managed</del>. <u>This requires fostering</u> <del>Therefore</del>, a proactive</p>	<p>Proposed revision to improve clarity.</p> <p>It organizes the content into a clear sequence, starting with the active promotion of information collection, followed by the role of process owners, and concluding with the involvement of senior management. This logical progression enhances understanding.</p>		<p>X</p> <p>The regulatory body should <u>actively</u> promote the collection of information and knowledge from experience <u>across</u> all levels <u>of</u> the organization to ensure <u>effective management of</u> learning opportunities. <u>This</u></p>		This comment takes into account above comment as well.

			<p><del>approach among attitude</del> of individual process owners <del>is an important contributing factor to successfully manage the regulatory experience.</del> The owner of a specific regulatory process <u>who</u> should <del>proactively</del> take regulatory experience feedback into account <del>in</del> <u>when</u> reviewing <del>the</del> processes to keep <del>it up to date</del> <u>them current</u> and effective. <del>The p</del>Process owners <del>can</del> play <del>an important</del> a key role by <u>bringing relevant</u> <del>proactively raising</del> findings to the attention of senior management, <u>including facilitating continuous improvement.</u> <del>The s</del>Senior management <del>is would be</del> expected to <u>incorporate use</u> regulatory experience feedback as <u>a valuable input one of the inputs</u> when <del>completing a review</del> <u>reviewing</u> and updating the regulatory framework and processes. This approach <del>also</del> encourages <u>organization-wide</u> dialogue on the benefits <del>to be gained from of</del> <u>effectively managing</u> <del>of managing</del> regulatory experience <u>and promotes its integration into daily operations throughout the</u></p>	<p>The revised version clearly defines the responsibilities of process owners and senior management, emphasizing how each contributes to the effective management of regulatory experience feedback.</p>		<p><del>requires fostering</del> a proactive <u>approach among</u> individual process owners <u>who</u> should take regulatory experience feedback into account <u>when</u> reviewing processes and <u>bring it</u> to the attention of senior management, <u>including facilitating continuous improvement.</u> Senior management <del>is</del> expected to <u>incorporate</u> regulatory experience feedback as <u>a valuable input</u> when <u>reviewing</u> and updating the regulatory <del>functions</del> and processes. This approach encourages <u>organization-wide</u> dialogue on the benefits <u>of</u> <u>effectively managing</u> regulatory experience <u>and promotes its integration into daily operations.</u></p>	
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			<del>organization and promotes its daily utilization.”</del>					
139.	PAK/15	Page 11 Section 4.7, Line 6	The process owners can play an important role by proactively raising findings to the attention of senior management, <b><u>free from the fear of consequences of such reporting.</u></b>	Reporting culture should be open and free from the fear of consequences. Also to achieve alignment with Para 6.7.e			X	This aspect is already covered in section 6 (para 6.7)
140.	IRAN/6	4.8	Adding this paragraph: <b>4.8. Since the proposing of alternatives in an organizational unit could sometimes create conflicts of interest within organizational units, managers need to periodically or randomly supervise the details of the process of collecting, analysing, and implementing action plans to prevent such effects.</b>	Theoretically, the emphasis on creating a learning organization could lead to create a strong political and informal atmosphere and provoke conflicts of interest, so they must be managed.			X	This aspect is already covered in section 6 (para 6.7)
141.	GER/52	5.3	The regulatory body should <u>design</u> , develop and implement the management of regulatory experience feedback in line with Requirement 16 <b><u>“Organizational structure of the regulatory body and allocation of resources”</u></b> of GSR Part 1 [2] and Requirement 7 <b><u>“Application of the graded approach to the management system”</u></b> of GSR Part 2 [10]. The regulatory body should	Please make the issue more balanced and richer in content.		X .....The regulatory body should take into account the criteria, used to grade the development and implementation of the management system, as mentioned in para. 4.15 of GSR Part 2 [10] to identify and analyse the finding.....Para		The ‘design’ is covered in the ‘development’. There are appropriate references added already in the text. The original text seems appropriate, providing not too much details but referencing.

			<p>take into account the criteria, <u>used to grade the development and application of the management system, as mentioned in para. 4.15 of GSR Part 2 [10]</u> 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.</p> <p><u>According to para. 4.15 of GSR Part 2 [10] “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”.</u></p>			<p>4.15 of GSR Part 2 states that: “The following shall be taken into account:</p> <ul style="list-style-type: none"> <li>(a) The safety significance and complexity of the organization, operation of the facility or conduct of the activity;</li> <li>(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;</li> <li>(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.”</li> </ul>		
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142.	CAN/41	5.4	<p>“The <u>regulatory body should develop the</u> management of regulatory experience feedback <del>should be developed</del> commensurate with <del>the its</del> context, objectives, needs and priorities <del>of the regulatory body</del>. <u>This design should also consider</u> <del>Other</del> factors, such as the size <del>of the regulatory body, its and</del> organizational structure <u>of the regulatory body, as well as</u> the <del>overall</del> design and structure of <del>the its</del> management system <del>should also be considered in the design</del>. <del>The</del>The regulatory body should consider additional factors, <u>including when designing the management of regulatory experience feedback which may include the following:</u></p> <ul style="list-style-type: none"> <li>- The <u>presence</u> <del>existence</del> of other <del>processes of the</del> management system <u>processes</u> that <del>can contribute to support</del> the establishment and <del>application</del> <u>implementation</u> of <del>the</del> regulatory experience</li> </ul>	By starting with "The regulatory body should," the statement immediately highlights the main responsibility, ensuring the message is both clear and directive.As		<p>X</p> <p>The regulatory body should develop the arrangements for managing regulatory experience commensurate with its objectives, needs, priorities and other factors, such as its size and organizational structure, the overall design and structure of the management system. The regulatory body should consider additional factors such as:</p> <ul style="list-style-type: none"> <li>– The existence of other processes of the management system that can contribute to the establishment and implementation of the arrangements for managing regulatory</li> </ul>		
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			feedback management arrangements; - <u>The integration of regulatory experience feedback</u> with other information management systems <sup>3</sup> ; - <u>The allocation of sufficient Provision of adequate human and financial resources to support effective feedback management.</u>			experience feedback; – Integration with other information management systems <sup>1</sup> ; – Provision of adequate human and financial resources.		
143.	GER/53	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, <del>cost-benefit analysis,</del> impact on <del>stakeholders,</del> <u>interested parties</u> as well as when and how to do it giving safety the highest priority.	Giving safety the highest priority and doing a cost-benefit analysis is a contradiction. If safety is impacted by the action plan, then a cost-benefit analysis should not be a decisive factor. However, given the wide range of potential regulatory experience findings and corresponding action plans it makes sense for some to explicitly utilize cost-benefit analysis in review and approval.  Additionally, IAEA Safety Glossary uses “interested parties” instead of “stakeholders”	X Para 5.5 deleted.			Please see response to comment 144.

<sup>1</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.

144.	JPN/4	5.5.	<p>The regulatory body should apply a graded approach in assessing the findings, <del>and defining actions and the implementation of the implementing actions and the implementation of the actions taking into account factors such as safety implications, external consultations, cost-benefit analysis, impact on stakeholders,</del> commensurate, to the extent practicable, with the likelihood and possible consequences of, and the level of risk associated with, the actions, as well as when and how to do it giving safety the highest priority.</p>	<p>In IAEA Nuclear Safety and Security Glossary (2022 (Interim) edition), “graded approach” is defined such that “For a system of control, such as a regulatory system or a safety system, a process or method in which the stringency of the control measures and conditions to be applied is commensurate, to the extent practicable, with the likelihood and possible consequences of, and the level of risk associated with, a loss of control.”</p> <p>Consideration of factors, such as “external consultations”, “cost-benefit analysis” and “impact on stakeholders” are not derived from this definition, and then suggested these factors to be deleted.</p> <p>Proposed new text comes from the definition of graded approach in the Glossary.</p>	X Para 5.5 deleted.			<p>The proposed change is to include the definition of graded approach as per IAEA safety glossary. There is no need to reproduce the same here. Many factors are already discussed in the safety guide (in paras 5.3 and 5.4). Therefore, para 5.5 is deleted.</p>
145.	GER/54	5.6	<p>The regulatory body should disseminate the lessons learned from the regulatory experience feedback management arrangements <del>considering that the</del> <u>The</u> significance of the findings may have a different degree of relevance, both inside and outside the organization of the regulatory body, nationally or</p>	<p>Clarification: A clear connection between the sentences and a conclusion has been missing.</p>			X	<p>Original text seems fine and more reader friendly as the connection will make the sentence too long to follow.</p>

			internationally, depending on how the lessons learned will contribute to enhance the regulatory framework, functions and processes and, ultimately, to improve safety of the regulated facilities and activities.					
146.	FIN/24	Para 5.6	The regulatory body should disseminate the lessons learned from the regulatory experience feedback management arrangements. <b>The regulatory body should define the most significant findings to be disseminated.</b> The significance of the findings may have a different degree of relevance, both inside and outside the organization of the regulatory body, nationally or internationally, depending on how the lessons learned will contribute to enhance the regulatory framework, functions and processes and, ultimately, to improve safety of the regulated facilities and activities.	The chapter needs further explanation (pls see bolded text) for its context under Application of a Graded Approach to...		X The regulatory body should apply a graded approach when disseminating lessons learned, ensuring that dissemination efforts are commensurate with the safety significance of the findings and their relevance both within the organization and externally, at national and international levels.		The para was reproduced with mutual consensus during the consultancy meeting to include the inputs from Finland and Canada. Comment 147 is also addressed.
147.	CAN/42	5.6, line 2	<del>“...The significance of the findings may have a different degree of relevance, both inside and outside the organization of the</del>	The original version is not clear on who the REGEX should be shared with. Propose this revised text for 2 reasons:		X  The regulatory body should apply a graded approach when		

			<del>regulatory body, nationally or internationally, depending on how the lessons learned will contribute to enhance the</del> <u>These lessons should be shared with various stakeholders, including authorized parties, vendors, designers, and supply chain organizations, as well as other regulatory bodies responsible for safety and relevant organizations at both the national and international levels. Sharing these lessons ensures that improvements contribute not only to the enhancement of</u> regulatory framework, functions and processes, <u>but also to the overall and, ultimately, to</u> <del>improve</del> safety of the regulated facilities and activities.”	The revised version separates the ideas logically, which helps the reader grasp the key points more effectively.  Clarifies Target Audience: By explicitly listing the stakeholders (e.g., authorized parties, vendors, regulatory bodies), the revised version clearly defines who should receive the shared information.		disseminating lessons learned, ensuring that dissemination efforts are commensurate with the safety significance of the findings and their relevance both within the organization and externally, at national and international levels.		
148.	CAN/43	6.1	<u>“The regulatory body should continuously evaluate the management of regulatory experience feedback for its effectiveness and integrate this evaluation into its assessments of authorized party’s safety performance.</u> Requirement 19 of GSR Part 1 (Rev.1) [2] states that “The regulatory	Recommend starting with the "Should" Statement: By beginning with the directive, the key action is highlighted immediately, making the guidance clear and actionable from the outset.	X			

			<p>body shall establish, implement, assess and improve a management system that is aligned with its safety goals and contributes to their achievement.”</p> <p>Requirement 13 of GSR Part 2 [10] states that “The effectiveness of the management system shall be measured, assessed and improved to enhance safety performance, including minimizing the occurrence of problems relating to safety.” <del>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.”</del></p>					
149.	CAN/44	6.5	<p><u>“The regulatory body should establish governance within its An appropriate governance should be established within the management system of the organization to monitor the performance and effectiveness of the regulatory experience feedback management arrangements. This governance framework should support the</u></p>	<p>The directive is placed at the beginning to clarify the regulatory body's responsibility upfront.</p> <p>The word "appropriate" was removed to enhance clarity and precision. While "appropriate" is often used to convey suitability or correctness, it can be ambiguous and subjective, and difficult to measure, as its interpretation may vary depending on the reader.</p>		<p>X</p> <p>“The regulatory body should establish governance <b>framework</b> within its management system to monitor the performance and effectiveness of the regulatory experience feedback management arrangements. This</p>		

			<u>organization's commitment to embracing and to embrace</u> a culture of continuous improvement.”			governance framework should support the organization's commitment to embracing a culture of continuous improvement.”		
150.	CAN/45	6.6	“The regulatory body should periodically <u>assess how effectively evaluate the degree of utilization and proper functioning of</u> the arrangements <u>for managing to manage</u> the regulatory experience feedback <u>are functioning and being utilized. This evaluation should aim to identify opportunities for to explore possible</u> improvements. <u>Tools Methods</u> such as management reviews, self-reflections, self-assessments or external assessments; <u>—</u> including peer reviews and advisory missions; <u>—</u> can be <u>used employed</u> to <u>carry out conduct</u> these evaluations.”	Simplified Language: Replacing “evaluate the degree of utilization and proper functioning” with “assess how effectively...are being utilized and functioning” makes the statement more straightforward and easier to understand. Clear Objective: Explicitly stating that the purpose of the evaluation is to "identify opportunities for improvement" sharpens the focus of the sentence.  The word "evaluate" was replaced with "assess" for consistency with the methods listed for conducting the evaluations—such as management reviews, self-reflections, self-assessments, and external assessments.	X			
151.	GER/55	6.7 (g)	The regulatory body should <del>design the management of</del> <u>rationalize</u> regulatory experience feedback <del>in such a way as to ensure that the workload associated with processing the findings is the minimum necessary</del>	Clarification	X			

			<del>to ensure transparency and traceability</del> <u>management, ensuring transparency and traceability while minimizing administrative burden.</u> <u>The approach should be proportionate to the radiation risks</u> associated with facilities and activities					
152.	GER/56	6.8 New issue	<u>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.</u> <u>Annex-II shows a checklist that could be used for building tools to support personnel in deciding whether there are lessons to be learned to improve the regulatory process, including the identification of good practices.</u>	Please move this statement from Appendix II/II.5 to the main text, as this para. contains significant guidance information relevant for Section 6.			X	<p>Material for which there is no appropriate place in the body text (e.g. material that is subsidiary to or separate from the body text, is included in support of statements in the body text, or describes methods of calculation, procedures or limits and conditions) may be presented in appendices or annexes.</p> <p>An appendix, if included, is considered to form an integral part of the safety standard.</p> <p>Material in an appendix has the same status as the body text, and the IAEA assumes authorship of it</p>
153.	GER/57	6.9 New issue	<u>When designing management tools for identifying findings, the regulatory body should also develop guidelines</u>	Please move this statement from Appendix II/II.6 to the main text, as this para. contains significant guidance information relevant for Section 6.			X	See response to comment 153

			<p><u>to help personnel identify weaknesses that should be addressed as well as strengths that could be shared related to the regulatory framework, functions and processes. At a minimum, guidance should be provided taking into consideration the following three basic dimensions associated with a finding under consideration:</u></p> <ul style="list-style-type: none"> <li><u>– The regulatory function or process: Aspects relating to the framework, structure and constituents of the regulatory process subject to assessment, including the basic principles and methodology; regulatory objectives and criteria; technical soundness, accuracy and relevance of the information;</u></li> <li><u>– 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;</u></li> <li><u>– The organizational aspects: Aspects relating to the conditions under which the regulatory</u></li> </ul>					
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			<u>process is conducted, including working environment, leadership and involvement of management, interfaces and safety culture of the organization.</u>					
154.	PAK/5	Table of contents and Page 14Section -7 Title	"FEEDBACK"	"FFEDBACK" (extra F)	X			
155.	GER/58	7.1	For effective management of regulatory experience feedback, the regulatory body should develop and implement appropriate training for the involved personnel taking into account a graded approach, <u>if applicable.</u>	Clarification: A graded approach is not suitable for all cases, which is indicated by the proposed addition			X	Graded approach should always be applied. Low risk activities may require less effort and vice versa.
156.	GER/59	7.2 Line 5	<del>... The Table 4 in</del> Appendix II provides guidance on essential topics to be covered for training on regulatory experience.	Clarification. Provide more specific information.	X			
157.	CAN/46	7.2	“The regulatory body should <u>provide training to train the personnel to help them so that they can</u> develop knowledge, skills and <u>attitude mindset required to effectively</u> identify, analyse and <u>use utilize</u> regulatory experience feedback. <del>Necessary</del> <u>Essential</u> tools, such as non-conformance reporting mechanisms, sharing <del>of</del> good practices	The revised version uses clearer phrasing, making the content more accessible while retaining all critical information.  Also specified and added the appendix number “Appendix II” as there is more than one appendix.		X “The regulatory body should <u>provide training to</u> personnel <u>to help them</u> develop knowledge, skills and <u>attitude required to effectively</u> identify, analyse and <u>utilize</u> regulatory experience feedback. <u>Essential</u> tools, such as non-		

			and <u>offering</u> opportunities to raise concerns, <u>should be utilized to</u> empower employees <u>and support</u> <del>to contribute towards the</del> continuous <u>process</u> improvement <del>of the process</del> . <del>The</del> Appendix II outlines key topics that <u>should be included in</u> <del>provides guidance on</del> <del>essential topics to be</del> <del>covered for</del> training <u>programs</u> on regulatory experience.”			conformance reporting mechanisms, sharing good practices and <u>offering</u> opportunities to raise concerns, <u>should be utilized to</u> empower employees <u>and support</u> <del>towards</del> continuous <del>process</del> improvement. Appendix II outlines key topics <u>that should be included in</u> training on regulatory experience.”		
158.	FIN/25	Para 7.2	... The Appendix II provides guidance on essential topics to be covered for training on regulatory experience.	Add number of Appendix.	X			
159.	CAN/47	7.3	“The regulatory body should <u>implement appropriate training on the skills to identify</u> <del>make arrangements to train the relevant personnel to recognize these</del> external sources of regulatory experience that <del>are</del> <u>could be more</u> valuable <del>for</del> <u>to</u> the organization. <del>These</del> <u>programs should also encourage personnel to routinely utilize and to motivate them to</u>	Proposed for consistency with paragraph 7.1, use of “implement appropriate training” rather than “make arrangements to train the relevant personnel”.		X “The regulatory body should <u>impart appropriate training to enhance skills of relevant personnel to identify</u> sources of regulatory experience that <u>are</u> valuable <u>to</u> the organization. <del>The regulatory body</del> <u>should also encourage personnel to routinely utilize</u>		

			<del>regularly use</del> these external sources to identify lessons <del>to be</del> learned <u>and integrate them into as part of</u> their duties.”			these sources to identify lessons learned <u>and integrate this practice into</u> their duties.”		
160.	GER/60	7.3	The regulatory body should make arrangements to train the relevant personnel to recognize <del>those</del> external sources of regulatory experience that could be more valuable for the organization and to motivate them to regularly use these <del>external</del> sources to identify lessons to be learned as part of their duties. <u>The Appendix I provides guidance on possible national and international sources for collecting regulatory experience.</u>	Clarification. Which sources are meant? The Tables 1 and 2 in the Appendix I present a list of possible national and international sources for collecting regulatory experience. Furthermore, in Table 3 the list of potential non-nuclear sources of regulatory experience is given.	X (the strikethrough words are deleted)		Last part not accepted .	As it is already referred in Section 3 (para 3.8)
161.	GER/61	7.4 New issue	<u>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.</u>	Please remove this statement from Appendix II/II.2 to the main text, as this para. contains significant guidance information relevant for Section 7			X	See response to Comment 153.
162.	GER/62	7.5 New issue	<u>The regulatory body should provide appropriate guidance and training to personnel to ensure that only relevant regulatory experiences</u>	Please move this statement from Appendix II/II.3 to the main text, as this para. contains significant guidance information relevant for Section 7			X	See response to Comment 153.

			<u>are captured. This approach helps to streamline resources and avoid unnecessary expenditure on assessing findings unsuitable for the regulatory experience management arrangements.</u>					
163.	GER/63	7.6 New issue	<u>The personnel of the regulatory body at all levels play a fundamental role in achieving successful utilization of regulatory experience. Regardless of the source of regulatory experience, whether internal or external to the regulatory body, it is the individual or a group of personnel that will take the initiative to document and submit a finding for screening and analysis. All personnel should be willing to do so, based on their individual commitment to the objectives of the regulatory body and to continuous improvement.”</u>	Please move this statement from Appendix II/II.7 to the main text, as this para. contains significant guidance information relevant for Section 7			X	See response to Comment 153.
164.	GER/64	7.7 New issue	<u>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</u>	Please move this statement from Appendix II/II.8 to the main text, as this para. contains significant guidance information relevant for Section 7			X	See response to Comment 153.

			<p><u>motivate personnel, and at a minimum, should do the following:</u></p> <ul style="list-style-type: none"> <li><u>— 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;</u></li> <li><u>— Involve personnel who raise findings along the process of regulatory experience feedback management;</u></li> <li><u>— 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;</u></li> <li><u>— 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;</u></li> <li><u>— Identify personnel with the necessary skills to motivate and mentor other employees to raise regulatory findings;</u></li> </ul>					
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			<p>— <u>Manage the additional workload on the individuals to promote active contribution towards the process of regulatory experience feedback management;</u></p> <p>— <u>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.</u></p>					
165.	GER/65	7.8 New issue	<p><u>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.</u></p>	Please move this statement from Appendix II/II.9 to the main text, as this para. contains significant guidance information relevant for Section 7.			X	See response to Comment 153.
166.	GER/66	7.9 New issue	<p><u>The education and training of the personnel of the regulatory body on regulatory experience should be tailored to fit the regulatory experience management arrangements. The content of an education and training programme aimed at the effective management of</u></p>	Please move this statement from Appendix II/II.10 to the main text, as this para. contains significant guidance information relevant for Section 7.			X	See response to Comment 153.

			<u>regulatory experience should cover the eight topics presented in Table 4 of Appendix II. 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.</u>					
167.	GER/67	Appendix I/ Table 1	Reg. function: Regulations and guides Bullet 1  Issuance of new <u>national</u> laws and regulations ( <del>National/Federal and Regional/States</del> ) on matters relevant to safety	Clarification: Avoid confusion, “National” is used in the document in a different meaning. The same counts for “State”.	X			
168.	GER/68	Appendix I/ Table 1	Reg. function: Emergency preparedness and response Bullet 2  Coordination committees involving <u>competent national</u> <del>local, regional and State</del> authorities	Clarification: Avoid confusion, “National” is used in the document in a different meaning. The same counts for “State”.	X			
169.	FIN/26	Appendix I Table 1	Please add under Review and assessment: <b>Incident investigations.</b>		X			
170.	GER/69	Appendix I/ I.2	<del>The regulatory body should also decide on developing and implementing measures to facilitate access to potential sources of experience (e.g. hosting peer review missions,</del>	Adapt wording and move to Section 3.  This para. contains significant guidance information relevant for Section 3			X	This aspect is somehow covered in para 3.8 and 3.9.

			<del>encouraging personnel to participate in international training and to enroll in fellowship programmes or scientific visits) or to remove access barriers to such sources (e.g. engaging in international research, concluding bilateral agreements with other countries). The regulatory body can enable reaching the external sources and the personnel of the regulatory body needs to maintain an open mind and exercise judgement on what information might or might not be useful.</del>					
171.	FIN/27	Appendix I chapter I.2	The regulatory body <b>may</b> also decide ...	The regulatory body <b>should</b> also decide ... Is this obligatory for the regulatory body? (requirement in Appendix). Please review complete document for should statements.			X	Should statements be appropriate for Appendix.
172.	GER/70	Appendix I/ I.3	<del>Research and development is an important source of lessons for regulatory experience and, as such, a regulatory body has to should explore how to effectively utilize lessons identified from research and development in keeping their framework and regulatory functions and processes up to date</del>	Adapt wording and move to Section 3.  This para. contains significant guidance information relevant for Section 3.			X	See response to Comment 153.

			<del>and effective. Regulatory bodies, though, may need to establish arrangements to address the specific characteristics of this source of regulatory experience.</del>					
173.	GER/71	Appendix II/II.2	<del>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.</del>	Move to Section 7. This para. contains significant guidance information relevant for Section 7			X	See response to Comment 153.
174.	GER/72	Appendix II/II.3	<del>The regulatory body should provide appropriate guidance and training to personnel to ensure that only relevant regulatory experiences are captured. This approach helps to streamline resources and avoid unnecessary expenditure on assessing findings unsuitable for the regulatory experience management arrangements.</del>	Move to Section 7. This para. contains significant guidance information relevant for Section 7.			X	See response to Comment 153.
175.	GER/73	Appendix II/II.4	This appendix provides <u>more detailed advices</u> <del>recommendations</del> to regulatory bodies for developing and providing appropriate guidance and training to personnel to recognize and document potential findings that	Clarification: Recommendations should be provided in the main part of the Guideline Document, not in Appendix (see our comment General 3).			X	Safety Guides provide recommendations and guidance on how to comply with the safety requirements, indicating an international consensus that it is necessary to take the measures

			can improve the regulatory process.					recommended (or equivalent alternative measures). The Safety Guides present international good practices, and increasingly they reflect best practices, to help users striving to achieve high levels of safety. The recommendations provided in Safety Guides are expressed as 'should' statements.  See response to Comment 153 related to Appendices
176.	GER/74	Appendix II/II.5	<del>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 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</del>	Move to Section 6. This para. contains significant guidance information relevant for Section 6.			X	See response to Comment 153 related to Appendices

			identification of good practices.					
177.	GER/75	Appendix II/II.6	<p>When designing management tools for identifying findings, the regulatory body should also develop guidelines to help personnel identify weaknesses that should be addressed as well as strengths that could be shared related to the regulatory framework, functions and processes. At a minimum, guidance should be provided taking into consideration the following three basic dimensions associated with a finding under consideration:</p> <ul style="list-style-type: none"> <li>— The regulatory function or process: Aspects relating to the framework, structure and constituents of the regulatory process subject to assessment, including the basic principles and methodology; regulatory objectives and criteria; technical soundness, accuracy and relevance of the information;</li> <li>— The personnel: Aspects relating to the individuals in charge of the implementation of the function or process, including their qualifications, the available resources, and</li> </ul>	<p>Move to Section 6.</p> <p>This para. contains significant guidance information relevant for Section 6</p>			X	See response to Comment 153 related to Appendices

			<p>the availability of guidance and support by the management;</p> <p>—The organizational aspects: Aspects relating to the conditions under which the regulatory process is conducted, including working environment, leadership and involvement of management, interfaces and safety culture of the organization.</p>					
178.	GER/76	Appendix II, II.7	<p>The personnel of the regulatory body at all levels play a fundamental role in achieving successful utilization of regulatory experience. Regardless of the source of regulatory experience, whether internal or external to the regulatory body, it is the individual or a group of personnel that will take the initiative to document and submit a finding for screening and analysis.</p> <p><u>All personnel should be willing to do so, based on their individual commitment to the objectives of the regulatory body and to continuous improvement."</u></p>	<p>The 1<sup>st</sup> sentence in para. II.8 is the direct continuation of the text in para. II.7 and cannot be understood in an isolated manner. Consequently, this sentence should be moved to the end of para. II.7.</p> <p>Additionally, we suggest moving this statement to Section 7.</p>	X First part		X 2nd part	See response to Comment 153 related to Appendices
179.	GER/77	Appendix II/II.8	<p><u>All personnel should be willing to do so based on their individual commitment to the objectives of the</u></p>	<p>The 1<sup>st</sup> sentence in para. II.8 is the direct continuation of the text in para. II.7 and cannot be understood in an isolated manner. Consequently, this</p>	X First sentence deleted.		X 2nd part	See response to Comment 153 related to Appendices

			<p><del>regulatory body and to continuous improvement.</del></p> <p>The management of the regulatory body should explore opportunities to motivate personnel, and at a minimum, should do the following:</p> <ul style="list-style-type: none"> <li>— 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;</li> <li>— Involve personnel who raise findings along the process of regulatory experience feedback management;</li> <li>— 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;</li> <li>— 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;</li> </ul>	<p>sentence should be moved to the end of para. II.7.</p> <p>The best solution, in our opinion, is to move both Appendix II, II.7 and II.8 to Section 7, as this statement contains significant guidance information relevant for Section 7.</p>				
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			<p>— Identify personnel with the necessary skills to motivate and mentor other employees to raise regulatory findings;</p> <p>— Manage the additional workload on the individuals to promote active contribution towards the process of regulatory experience feedback management;</p> <p>— 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.</p>					
180.	PAK/16	Page20, Section 11.8 Bullet-5	"employees"	"employees" (misspelled)	X			
181.	GER/78	Appendix II/II.9	<p>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.</p>	<p>Move to Section 7.</p> <p>This para. contains significant guidance information relevant for Section 7.</p>			X	See response to Comment 153 related to Appendices

182.	GER/79	Appendix II/II.10	<del>The education and training of the personnel of the regulatory body on regulatory experience should be tailored to fit the regulatory experience management arrangements. The content of an education and training programme aimed at the effective management of regulatory experience should cover the eight topics presented in Table 4. Regulatory bodies can use the guidance provided under these eight topics to develop their specific training programme as appropriate while meeting the purpose of each topic.</del>	Move to Section 7.  This para. contains significant guidance information relevant for Section 7.			X	See response to Comment 153 related to Appendices
183.	GER/80	Appendix II, Table 4	<b>Topic 1: Basic Principles</b> right column:  ... the regulatory process, including liaison with other national authorities and <del>stakeholders</del> <u>interested parties</u>	Please put in line with IAEA Glossary, which defines and uses the term ‘interested parties’ instead of “stakeholders”.	X			
184.	GER/81	Appendix II, Table 4	<b>Topic 3: Arrangements for managing regulatory experience</b>  <b>Internal sources:</b> — Core regulatory processes and functions	Please consider research and developments as an external source (national as well as international) – move to the bullet 2.	X	The same will be included in external sources but could also be the part of internal sources.		

			<p>— Other regulatory functions and processes</p> <p>— Management system</p> <p>— Operating experience</p> <p>— <del>Research and development in the field of nuclear and radiation safety</del> Advisory bodies and technical support organizations</p> <p><b>External sources:</b></p> <p><u>National and international</u></p> <p>— <u>Research and development in the field of nuclear and radiation safety</u></p> <p>National:</p> <p>— Non-nuclear legislation and policy</p> <p>— Non-nuclear regulatory bodies....</p>					
185.	GER/82	Appendix II, Table 4	<p><b>Topic 4: Arrangements for managing regulatory experience</b></p> <p>Possible subjects to cover as appropriate:</p> <ul style="list-style-type: none"><li>• Approach and modality</li><li>• Roles and responsibilities in managing regulatory experience</li><li>• Integration within the management system and interfaces with relevant processes</li></ul>	Please include consideration of internal sources in the management of regulatory experience.	X			

			<ul style="list-style-type: none"> <li>• Management of <u>internal and</u> external sources of regulatory experience ...</li> </ul>					
186.	GER/83	Appendix II, Table 4	<p><b>Topic 4, Purpose</b></p> <p>This Section is the bulk of the programme and its purpose is to provide step-by-step information on how to complete a sound analysis of the regulatory experience findings. <del>identified by the staff of the regulatory body, including findings from external sources of experience.</del></p>	We suggest generalizing the formulation in order to avoid excluding some aspects.	X			
187.	GER/84	Appendix II, Table 4	<p><b>Topic 6: Engaging personnel</b> <b>Bullet 5</b></p> <p>Possible 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><del>• Recognition of personnel contributing to the management of regulatory experience</del></li> <li>• Means available to personnel for handling and communicating findings</li> </ul>	<p><i>“Recognition of personnel contributing to the management of regulatory experience” can be misunderstood. It can lead to the competition between personnel and can be misused by the management for the performance monitoring. Please delete.</i></p>		<p>X</p> <p><del>Recognition</del> <b>acknowledgement</b> of personnel contributing to the management of regulatory experience</p>		

188.	PAK/17	Page27	Regulatory action plan implementation block not mentioned in Fig 1.1					
189.	GER/85	Annex I/I.3 Line 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 <u>Member</u> States.	We think that “Member States” is more appropriate here, similar to para. 2.3 and Table 4.  Alternative – leave every-where “States” (without Member) as in GSR-1(Rev1). Please verify.	X			We used the terminology ‘States’ as reflected in other IAEA safety standards as well.
190.	GER/86	Annex I, I.1, Footnote 6	An event is “any occurrence unintended by the operator, including operating error, equipment failure or other mishap, and deliberate action on the part of others, the consequences or potential consequences of which are not negligible from the point of view of protection and safety” [8 <u>5</u> ]. This also includes initiating events, accident precursors, near misses, accidents, as well as unauthorized acts. Operating experience includes experience from such events.	The given definition of the term ‘event’ is found in the IAEA Nuclear Safety and Security Glossary [5] and not in SSR-2/2 (Rev. 1) [8].	X			
191.	FIN/28	Annex I Fig. I-1		Please clarify and add information about the meaning of different types of arrows (dotted or solid), also different colors of boxes and arrows.	X			
192.	FIN/29	Annex I.5.	The relevant lessons learned both from	Sentence is unclear. Please check the meaning.	X			

			regulatory experience and from operating experience are shared and disseminated to national and international organizations. <del>considering general and targeted mechanisms and approaches to ensure effective dissemination of lessons learned.</del>					
193.	GER/87	Annex II/ Table II-1	Opportunities for improvement Bullet 3 Interfaces between <del>different the regulatory process and other</del> regulatory processes are not considered or properly covered	Clarification. Not clear what “other regulatory processes” are	X			
194.	CAN/48	Annex II.1	<del>“The identification of potential findings is the primary driver of the regulatory experience management arrangements. This annex presents an example of a checklist that could be used for building tailor made aid tools to support staff in deciding whether there are lessons to be learned to improve the regulatory process, including the identification of good practices as shown in Table II-1.</del>  <u>Regulatory bodies may find it beneficial to</u>	From our perspective, the purpose and intended application of Annex II is not clearly explained in the introduction. It seems to lack context that is provided in TECDOC 1899 in Appendix V.  As is, Annex II lacks clarity in its purpose and intended application; the introduction does not provide sufficient context of guidance on how regulatory bodies—whether mature or newly established—should utilize this checklist effectively. We propose that the IAEA further clarify the objective and practical usage of Annex II to ensure its		X  <u>This annex presents an example of a checklist that could be used for building tailor made aid tools to support staff in deciding whether there are lessons to be learned to improve the regulatory process, including the identification of good practices as shown in Table II-1.</u> <u>When designing tools for guiding</u>		

			<p><u>design templates, checklists, and other tools to help staff self-assess the relevance of potential findings before initiating their evaluation within the regulatory experience management programme.</u></p> <p><u>When designing tools for guiding staff in self-assessment, the regulatory body should include suitable questions <b>or sample text</b> to help staff identify both weaknesses to address and strengths to disseminate across the organization. This process should consider the interrelation of three key dimensions of a problem: 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).”</u></p>	<p>applicability and usefulness across diverse regulatory contexts.</p> <p>The proposed added 2 paragraphs are intended to add clarity as to the purpose and usefulness of this Annex. The added 2 paragraphs are derived from text from Appendix V of IAEA TECDOC 1899, page 57.</p>		<p><u>staff in self-assessment, the regulatory body should include suitable questions <b>or sample text</b> to help staff identify both weaknesses to address and strengths to disseminate across the organization. This process should consider the interrelation of three key dimensions of a problem: 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)</u></p>		
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