

Form for Comments
Operating Experience Feedback for Nuclear Installations (DS479)

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: Mr. M. Smit Country/Organization: The Netherlands / ANVS (RB)		(1 page) Date: July 2016					
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	p.6 footnote 1	Add the red words in the next sentence: “OE includes for example reportable and non-reportable (including low level) events, operational records, near misses, good practices, organizational factors with direct relevance for safety , and all other information pertaining to the nuclear installation”	To stress that OE is not only about technical topics (as outcomes). For example bad engineering or a bad license application by the operator, could influence safety or could be a precursor for more organizational issues.			x	In line with position of editor, an event definition from IAEA Safety Glossary was used in the revised draft that covers also OE, see footnote 3 page 6
2	p.10 Req 2.8	Delete the words “among installation personnel”		X			
3	p.14 footnote 8	Check footnotes 7 and 8. Double wording.	Typo. Extent of condition?	Definition were transferred into the text, see 2.48			

GP changes due to missing rows, missing comments, late arrived comments and resolution position

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: M-L Järvinen, M. Kaijanen Country/Organization: Finland, STUK		Page.... of... Date: 30 th June 2016					
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1.	General	The safety guide for operating experience is well structured and clear. It reflects the current practices.		X			
2.	General	Quotations of the safety requirements should be included into the text.	Enhancement of the user friendliness of the safety guide.	Adopted as appropriate			

			Examples: 1.9, 2.1, 2.5, 2.8, 2.31, 2.46, 2.58, 2.70, 2.82, 2.83, 2.84, 2.89, 3.1, 3.6 3.9, 3.11 and 3.26	throughout the guide.			
3.	Fig. 1	See Attached proposal for updated Figure 2 and reasoning.	<p>The figure should be in line with the text. The updated figure in in line with the text and follows the structure of the safety guide.</p> <p>The example of Fig 2. Is given for the regulatory body. For the Fig. 1. this figure should be modified to reflect the licensees actions.</p>			X	<p>The designation for figure 1 and 2 is changed to ... schematic diagram ... That expresses better the intent of these figures to allow a general conspectus of chapter 2 and 3 at a glance.</p> <p>Member states might have different flow charts in use to reflect the necessary actions according to their management system.</p> <p>Basis for the the proposed flowcharts can be found in several IAEA publications, e.g PROSPER Guidelines, TECDOC 1653.</p>
4.	Fig. 2	See Attached proposal for updated Fig.2.	The figure should be in line with the text. The updated figure in in line with the text and follows the structure of the safety guide.		X		The texts in 3.7 and in the Figure 2 were aligned.
5.	2.2	All organisations involved in nuclear safety related activities should implement or participate in an effective OE system. A graded approach should be used in line with the risks associated with the activities at the installation and with the role of the organization. <i>The on site investigation of the events should not affect the safety of the installations.</i>	<p>Shift from 2.53 the last sentence to 2.2.</p> <p>See. also 2.53</p>		x		Adopted in 2.47
6.	2.3	... Identification and recording of internal OE;	Clarity,	Adopted in 2.4			

		<ul style="list-style-type: none"> • Collection of external OE4; • Screening of OE— primarily on the basis of relevance and actual or potential safety significance; • Investigation complemented by in-depth analysis of relevant OE, including causal analysis; • Recommended actions resulting from the investigation and analysis, including approval, implementation, tracking and evaluation of effectiveness; • Wider consideration of trends; • Dissemination and exchange of information, including by the use of international reporting systems; • Continuous monitoring and improvement of processes by use of OE; • A storage, retrieval and documentation system for OE. 	Add evaluation of effectiveness				
7.	2.7	The <i>management system</i> should include procedures for the control of activities at the installation for the feedback of operating experience.	To clarify, the meaning of 2.7 was unclear.	Adopted in 2.10			
8.	2.12	Management should ensure that sufficient, dedicated, suitably qualified, and experienced staff is appointed to <i>participate for</i> the defined scope of the OE programme.	Clarity, Change deliver to participate for.	Adopted in 2.16			
9.	2.19	Management should analyse, review and oversee the adequacy of OE process on a regular basis (commensurate with the type of installation and number of OE issues arising).	Clarity, The review and the assessment are the key point not the meeting.	Adopted in 2.22			
10.	2.22	... Within the OE system issues involving non-conforming, counterfeit, fraudulent or suspect items (<i>NCFSI</i>) or parts should also be identified and reported.	Typo NCFSI	The abbreviation is not used in the revised draft			
11.	2.23	Operating organizations should develop <i>procedural guidelines</i> outlining appropriate reporting criteria specific to the type of	Clarity <i>procedural guidelines</i>	Adopted in 2.25			

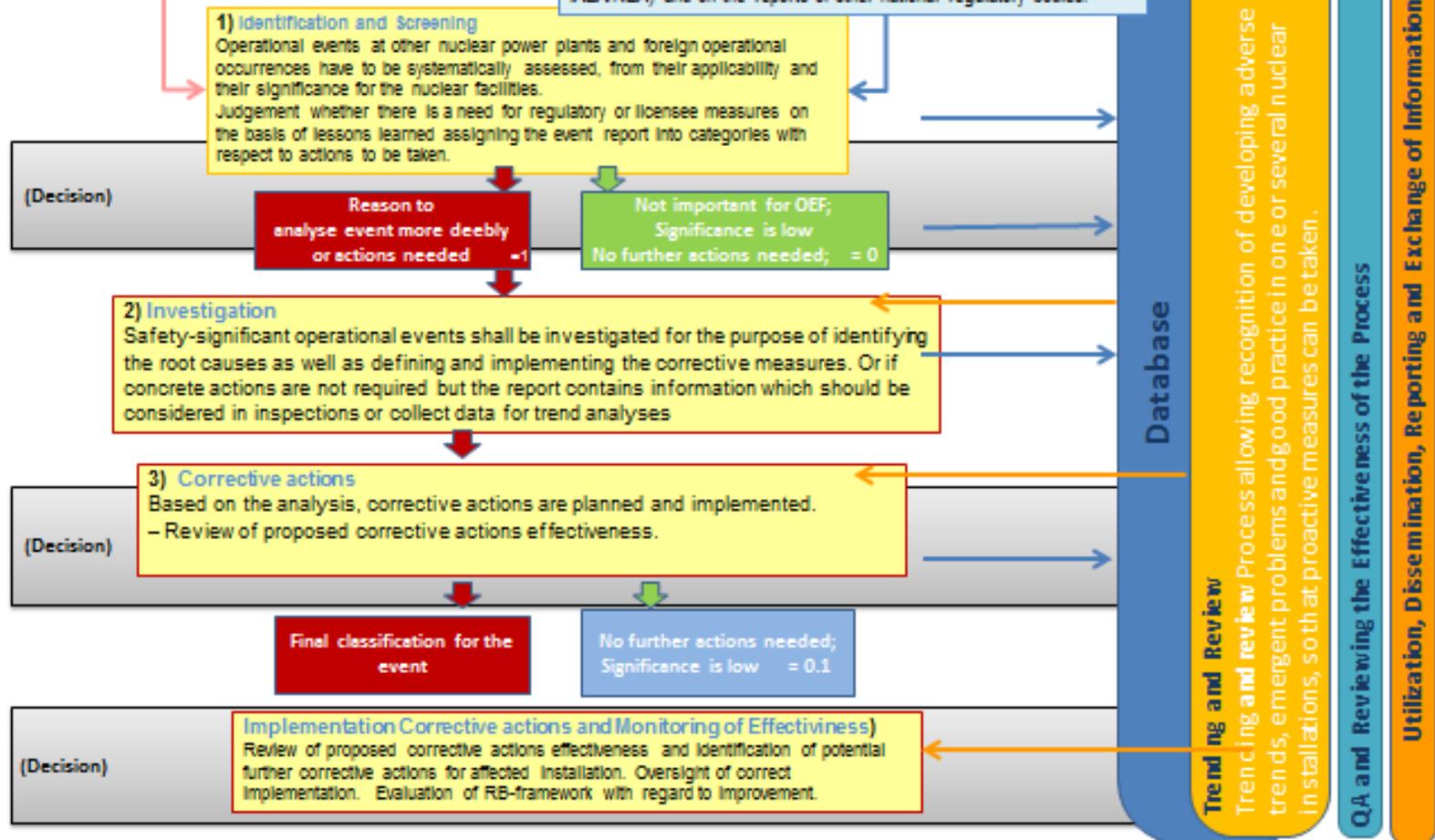
		installation being operated and consistent with national regulatory requirements (see appendix 1).	Add reference to appendix 1				
12.	2.32	Potentially relevant external operating experience should be <i>identified and</i> entered into the OE programme of the operating organization. Move to Identification and Reporting part of the Chapter 2.	Clarity, Add: identified and		x		Adopted in 2.37, but kept in Screening part as it has no added value to further split this task into separate sections.
13.	2.43	The results of <i>international and</i> external event screening at the installation level should be recorded and may be used for evaluation in subsequent periodic self-assessments, periodic safety reassessment or peer reviews.	Add: <i>international and</i> Both international and external sources should be covered.		X		The comment was reflected throughout the guide, see additional explanations in 2.37 or 3.7
14.	2.46	Events with • Safety implications should be investigated in accordance with their actual or potential significance; • Significant implications for safety should be investigated to identify their direct and root causes, including causes relating to <i>design of the installation and systems and structures</i> , equipment design, operation and maintenance, or to human and ... organizational factors.	Add: design of the installation and systems and structures, Also the major modifications should be considered. As an example Fukushima Dai-ichi actions.			x	Quotation from SSR 2/2
15.	2.53	The on-site investigation should be commenced as soon as practicable to ensure that information is not lost or diminished and evidence is not invalidated or removed. It is vital that the on-site investigation be performed in a timely manner and should not affect the safety of the installation.	Delete the end of the second sentence. That the on-site investigation shall not affect the safety of the installation is a general remark and could be included in points 2.1 -2.3. Proposal at 2.2.		x		Adopted in 2.47
16.	2.71	To allow further trending and identification of recurring themes, the OE databases should provide a comprehensive coding system covering for	Add: structures Also structures should be considered.	Adopted in 2.55			

		instance affected systems, <i>structures</i> , components, causes, safety consequences.					
17.	2.83		this paragraph should be on the “identification”. The division of the paragraph for identification to be shifted and for feedback should be considered.	X			
18.	Footnote 9	The IAEA provides <i>review services</i> for the application of this Safety Guide through its PROSPER service...	Clarity, Add <i>review services</i>			x	Explanation is included in the brackets, see footnote 7.
19.	3.8	The OE programme should be executed by appropriately trained, experienced and knowledgeable personnel, and where possible <i>support by experts</i> from different disciplines, to facilitate the determination of appropriate regulatory response to an issue.	Clarity, Add <i>support by experts</i>	Adopted in 3.9			
20.	3.13	As a minimum, the reporting requirements should include: • Early Notification/ <i>Preliminary Report</i> ; Information relating to events that challenge (or have the potential to challenge) nuclear or radiological safety... Main report as stated in the Appendix I / I.2.A Should be before the follow up report - or with it ?	Consistency, Add <i>/Preliminary Report</i> ; Add main report text.		X		To avoid confusion with reporting under emergency preparedness and response, only preliminary reporting is used in the guide.
21.	3.13	Add the bullet points to appendix 1.	3.13 is important also for the operating organization			x	‘deemed significant by operating organisation’ is not a reporting criteria, the idea is addressed in A.9
22.	3.14	Add the bullet points to appendix 1.	3.14 is important also for the operating organization			x	‘deemed significant by the operating organisation’ is not a reporting criteria, the idea is addressed in A.9
23.	3.15.	These reporting criteria should cover the phases of the installation life cycle including design,	For clarity the waste management should be mentioned explicitly.			x	Waste management itself is an activity/ a process linked to

		construction, commissioning, operation and decommissioning. <i>The waste managements should be considered at relevant lifecycle phases.</i>					several lifecycle phases of various nuclear installations. See the scope of the guide, 1.6 – facilities for management of radwaste are included.
24.	3.23	The regulatory body should analyse the information provided from reported events, investigations and other OE sources to identify trends and patterns. These analyses may also include information about low level events, near misses when available and best practices <i>as appropriate</i> .	clarity	Adopted in 3.23			
25.	3.25	The regulatory body should periodically inspect operating organizations to ensure their OE programmes are effective and satisfy the criteria set out in Chapters 2 and 3. The regulatory body should verify that the feedback of OE has been adequately used. Additional inspections should be undertaken when gaps in regulatory requirements and standards are identified.	Clarity. delete of the OE programme or parts of it	Adopted in 3.31			
26.	3.28	The regulatory body should implement a system for storage, retrieval and searching of OE. An effective search should be possible via an appropriate coding system or keywords. Move, this paragraph is more for Storing/Database/Trending/... (before 3.23.)	Move, this paragraph is more for Storing/Database/Trending/... (before 3.23.)			X	For consistency with Section 2 it was left in Documentation part.
27.	subtitle	Storing/Database, Trending and review	Add Storing/Database,			X	To reflect comments from other Member States, the structure in Section 3 was made consistent with the structure in Section 2.

National OE identification / Internal operating experience
National operating experience is based to the reported events by licensee. Reception of reports from licensed nuclear installations and domestic industry where applicable.

International OE Identification
Lessons learned from OE gained and shared by international nuclear community (IAEA, OECD/NEA, EU Clearinghouse etc.)
The evaluation of foreign operational occurrences and incidents is based on the reports of the international Reporting System (IRS - IAEA/NEA) and on the reports of other national regulatory bodies.



- 0 / 0.1. No further actions
- 1. Applicability on information / Particular issues need clarification
- 2. Lessons learned need to be taken into account in certain activities
- 3. Actions required
- 4. Good practice

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: Canadian Nuclear Safety Commission Page..1.. of....16 Country/Organization: Canada				Date:			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	All	<p>This is a general comment regarding the Draft Safety Standard DS479. This standard provides more guidance for implementing a non-conformance and corrective action program than that for the collection, communication and use operating experience information.</p> <p>It is recommended that this safety standard not be published as currently written.</p>	<p>The standard describes operating experience (OE) feedback for nuclear installations. The standard promotes a practice of open and honest communications of OE.</p> <p>The exchange of information includes the regulator and other non-nuclear industries.</p> <p>The standard then provides guidance for implementing a non-conformance and corrective action system with trending. There is no information regarding how information is to be obtained and shared (including confidential information and possible litigation).</p>				<p>The current draft revision provides recommendations for implementing operating experience programme as required by SSR 2/2 Rev. 1.</p> <p>Note: Operating Experience Programme as defined by SSR 2/2 Rev 1 Requirement 24 includes both programmes as generally established at North American nuclear installations, i.e. OE programme as defined by IAEA = CAP + OE as generally established at North American nuclear installations.</p>

2	2.3 line 5	Relevant lessons from other industries should also be taken into consideration, as necessary. Non-nuclear industries should be encouraged to proactively identify OE, including from suppliers that could affect nuclear installations.	The current wording of the para is restrictive to nuclear and applicable industries, none of which are <u>proactively</u> encouraged to provide information. This also needs to apply to suppliers who may not see themselves as having an important and relevant role and may wait until requested to provide information.		x		Comment partially adopted in 2.3 (quotations from relevant Safety Requirements are used). Non-nuclear industries are no in the scope of the guide, but if relevant, they should participate in the OE programme established by nuclear installation – see 1.5, 2.69, 2.70.
3	2.40 line 3	...OE should not be dismissed, for instance, only on the basis of equipment, design differences, or source; all aspects should be considered.	The current wording is inwards looking and does not consider the possibility of OE being excluded solely because it happened in another industry.		x		Adopted in 2.37 (1st line in the brackets)
4	Page 14 note 8	Extent of cause is the extent to which similar causes are present... Delete the second sentence.	Typographical error. The list which calls note 8 in para 2.51 specifies this to be extent of cause. It currently says 'extent of condition' and is a duplicate of note 7.	Adopted in 2.48			
5	General Comment	Delete the term 'near miss' or define the threshold of reportability.	A definition of near miss should be included if it is not considered as part of low level events. This is essential as it could muddy the waters and leave open to interpretation as to the relative significance that needs to be reported. It should be clear and either be reportable, or not as there may be consequences to the licensee if something is later	Adopted in Footnote 5, also in 3.13 (graded approach) and 3.23.			

			deemed reportable. If it cannot be provided, it should be deleted. Additionally, this could result in the licensee needing to report a significant portion of data on their adverse event reporting database. Such a quantity of data would be impractical to analyze, overwhelming in volume and take the responsibility for the analysis away from the licensee, where it belongs.				
6	3.21	Delete this para or replace ‘...should establish...’ in line 1, with ‘may establish’.	Requiring the regulatory body to establish requirements for investigation of events is too prescriptive and removes the flexibility of the regulatory body (which varies from one country to another) to respond appropriately.			X	The recommendation is in 3.22 of the current draft revision. It follows GSR Part 1, Requirement 31. As stated in 3.22, a graded approach should be used in accordance with the significance of findings, providing the needed flexibility of the regulatory body to respond appropriately, depending on the problem safety significance.
7	3.23 line 23	Delete trending best practices	Licensees report on events. Best practices are not reportable. Even if such information was obtained (through different regulatory compliance mechanisms) it is unlikely to produce sufficient data to be of value, or be reliable. This activity should be confined to the licensee.	Adopted in 3.23 (no reference to best practices).			
8	3.26 and 3.27	Delete these paras	While examining regulatory effectiveness is a good idea, it	Adopted in 3.32			

			should be confined to the limits of para 3.25. As currently worded, paras 3.26 and 3.27 exceeds the mandate of the title of the document which is 'operating experience feedback for nuclear installations' not 'monitoring the effectiveness of the regulator'	(only OE).			
9	Scope, 1.7	Add to the paragraph: long-term waste facilities.	To apply to facilities such as deep geological repositories (DGRs)			x	Exceeds the mandate of the DPP, please see point 1.6.
10	Section 2, 2.3	To the applicable industries listed in the parentheses add: mining.	Again, this is relevant to DGRs.			x	Exceeds the mandate of the DPP, please see point 1.6.
11	Section 2, 2.3	The diagram on page 9 does not agree with the description in 2.3		Adopted in 2.4 and Fig. 1			
12	2.22	In the first line, after "installation documents", add "decommissioning and dismantlement documents"	If this document is applicable to the entire lifecycle, then opex from these activities is also important to like facilities or activities.	Adopted in 2.24			

13	2.45 to 2.57	The entire section on Investigation (2.45 to 2.57) seems out of place and should be removed.	This document is about operating experience, not event investigation. The details of performing an investigation are not necessary here to be able to use opex information, which is the result of investigation, not doing the investigation itself.			X	OE scope as defined by the agency covers investigations, see SSR 2/2 Rev.1, Req. 24.
14	2.57	If you do leave in the whole part about investigation, I would remove 2.57.	The organizational aspects are often the systemic root causes of events and should be considered along with other possible causal factors during an investigation.	Removed and the idea of independence in investigation on organizational issues addressed in 2.46.			
15	2.60 to 2.62	Remove these items.	These are points that would be more likely found in a licensee procedure document, not this high-level document.		X		2.60 removed, wording in 2.62 changed to better fit the level of SG - see current 2.63.
16	2.67	The word “at” should be removed from the first sentence.	The way it is now has a different meaning than what you want.		X		Adopted in new 2.62
17	2.70	It is not clear what is meant by “monitor the diffusion”. What is diffusion supposed to mean here?	It’s confusing. I don’t know what it means.	Deleted			
18	2.87	In the parentheses also add: “design level”.	This document also applies to design.	Adopted in 2.70			

19	2.92	Instead of just talking about indicators it might be useful to add criteria as well. So “criteria and indicators...” Instead of the word “indicators” you could use “performance measures”.	Seem to be better choice of words.	Adopted in 2.77			
20	Section 3, 3.4	At first read I thought this meant that the regulator should capture all the OE from the operating organizations. For some countries this would be a huge amount of information. Perhaps this should be limited to reportable events. The regulator would then decide what they want as reportable events.	The volume of information to manage could be overwhelming.	Adopted in 3.4 and throughout the Section 3.			
21	3.5	Instead of talking about the “events of daily life” perhaps call them the “typical types of events experienced” or something like that.	Choice of words.	Adopted in 3.5			
22	3.7	The regulator wouldn’t necessarily want to do regular investigations of licensee events. Perhaps in unusual circumstances they might want to, but for regular events that could also become very overwhelming. Also, the licensee does investigations of their events.	The licensee does investigations so the regulator shouldn’t have to do an investigation again except in unusual circumstances.	Adopted in 3.7 c) – in a graded approach (only events with significance for safety)			
23	3.9	It is not clear what is meant by “The regulator’s management system should integrate the outcomes of the OE in the regulatory processes.” What is this referring to? Also, the third sentence mentions requirement 19 but while it is important in general, I don’t see the relevance to the topic of OE.	Do you mean the regulator should incorporate OE about, say, radiation protection in the boiler room into its processes? Confusing. For 3.9 and 3.10 why is the focus only on the regulator?		X		Addressed by rewording 3.10 and 3.11. Section 3 describes regulatory OE.

24	3.11	You could say “For both the licensee and the regulator the management system...”				X	Section 3 deals with regulatory management system.
25	3.14	Instead of using the word “installation” (which I read as meaning something different at first) perhaps say “nuclear facility”.	Clarity.			X	Nuclear installation = any nuclear facility... see IAEA Safety Glossary 2016
26	3.29	To the end of the sentence add “where applicable.”	Gives a bit of flexibility.			X	Quotation from GSR Part 1
27	3.31	At the end of the first sentence add “where applicable.”	Gives a bit of flexibility.			X	Quotation from GSR Part 1
28	2.3	The diagram on page 9 does not agree with the description in section 2.3	Section 2.3 and the diagram in Figure 1 do not agree. They need to agree.	Adopted in 3.7 and Fig. 2, also both schematic diagrams and descriptions of OE elements were aligned			
29	2.5	This section does not fit here.	This section talks about operating experience but this first bullet quotes the management system on safety culture. It does not fit.	Deleted.			
30	2.8	The management does not instill a safety culture. The culture is already there. They can foster a desirable (hopefully healthy) safety culture but that’s it. As well, the expression “the reporting of” is incorrect English. Changing a verb to a gerund weakens the sentence. Just say “encourages reporting all events”.	Change the first part of the sentence to say “management of operating organizations should foster the desirable safety culture among station personnel that encourages reporting all events...” As well, remove “in the sense of” and replace it with “pursuant to”. (to correct the translation)		Adopted in 2.11.		Quotation from SSR SSR 2/2 Rev 1, 5.31, includes ‘instilling an attitude’..
31	2.9	This sentence describes the reporting culture and not a just culture (which also is not hyphenated). Also, in the footer,	Change this to a reporting culture.		X		Adopted in current 2.11 and 2.12 - text modified accordingly to

		decisions are made, not taken. That is a poor translation. As well, the IAEA uses characteristics not traits. You have contradicted them here. A questioning attitude is not a characteristic.	Clear up the confusion between characteristics and traits.				differentiate between reporting and just culture.
32	2.10	This sentence should include a well-structured safety management program where safety performance is the priority. (the word overriding is redundant with priority).	Sentence to read Management's decisions regarding the activities of the ...driven by maintaining a well-structured safety management program where safety performance is the priority.			x	The recommendation is in current 2.13. The text has passed through editorial process.
33	2.11	The OE program should be an integral part of the management system where a safety management program includes OE as part of it. Safety culture is the outcome measure of a good safety management program. The sentence needs to properly identify the inputs without mixing them up with outputs.	Confusing safety culture with a safety management program.	Adopted in 2.10 and 2.15 (expectations split into two points – as understood, the original 2.11 mixed up two different expectations).			
34	2.12	Management should ensure that the staff is trained. Dedication is a behavior and not a role requirement. Remove it.	Change sentence to include trainer staff, not dedicated staff.			X	Meaning here is that staff is assigned to OE programme implementation.
35	2.16	It is important to have corrective actions that are implemented with follow-up to ensure their effectiveness.	Sentence should include "management should ensure that corrective actions resulting from the OE program are implemented with follow-up to ensure their effectiveness, and given the	Adopted in 2.20			

			appropriate priority within budgets and staffing plans.”				
36	2.20	This sentence describes a safety management program yet you only include its elements without defining it. Therefore the last sentence should read “the communication of expectations should be made through the establishment of a safety management program. As well, degrading trends is not the correct translation into English. It should be negative or declining trends. Degrading does not have the appropriate meaning when used in the context of trends.	Introduce a safety management program instead of listing things. As well, use the correct adjective that describes the downward direction of trends.		X		The comment was partially adopted in 2.19, but IAEA prefers listing practical means for communication of expectations instead of referring to a safety management programme.
37	2.21	It may be very difficult to input data about human performance shortcoming into a database. What would be the criteria for their inclusion? Also, the last sentence should read “...as well as opportunities identified, for improvement..” You have introduced an action through a verb in the middle of list of nouns: deficiencies; good practices, etc.	“Shortcomings in human performance” needs to be described better and inclusion criteria need to be determined. Otherwise, many spurious ‘shortcomings’ may get into the database through individual bias, or determine to be highly interpretable. The list should be consistent with nouns and not verbs.		X		Adopted in 2.23, terms used in the draft guide are from SSR 2/2, see e.g. 5.31.
38	2.22	Define the term “receipt inspection documents”. This is not a familiar term. Or use another term. As well, this section should start with “the sources of information on OE should include, but not be limited to the following examples:” then list them in bullets. There are a lot of items included in this list so it requires bullets for easier reading.	Define “receipt inspection documents”. Do you mean results from inspections? Rephrase this sentence and use bullets since this list is so long.		x		Adopted in 2.24
39	2.25	This section is a duplicate of 2.21. Remove it.	Remove this section or combine it with 2.21 since it is redundant.			x	Original 2.21 and 2.25 equal to 2.23 and 2.27 in the current draft revision. 2.27 is more specific about encouragement

							and provides explanation why such expectations is important.
40	2.29	This section is a duplicate of 2.9.	This is a duplicate of 2.9 which is a reporting culture, not a just culture. If you want to say something about feedback, add this sentence to 2.9.			x	Original 2.9 and 2.29 equal to 2.12 and 2.29 in the current draft revision. In the opinion of IAEA, just culture (2.12) and feedback to individual who reported issues (2.29) are different means for encouraging reporting.
41	2.30	This is a duplicate of the corrected version of 2.9 which is a reporting culture. “the reporting of” is not a correct phrase in English. Just say “reporting”.	Remove this section. Correct bad grammatical mistakes.		X		2.30 = preliminary reporting of significant issues either within the organization or outside (RB). 2.30 is different from 2.9 which discusses just culture.
42	2.31	“in the sense of” is a poor translation. Use the phrase “pursuant to”, which is correct English.	Correct the translation into proper English.			x	Original 2.31 equals to 2.32 in the current draft revision. 2.32 was re-worded and addresses also the comment.
43	2.32	This was already stated. Remove this.	This is a duplicate.	Duplicate d text was deleted.			
44	2.35	This was already stated in 2.12 so this is duplication. If you want to specify human and organizational factors, you can add that to 2.12.	Remove this section or add the last sentence only to 2.12.			x	2.32. It is important to emphasize that screening, as one of very important activity in overall OE, should be performed by experienced, knowledgeable, multidisciplinary team.
45	2.38	This sentence needs to be reconstructed to read correctly. It should read “screening should include the follow-up actions, by priority with their safety significance, potential for recurrence.....”	This sentence needs to be corrected to convey the correct meaning.		x		Adopted in 2.35.

46	2.33	Grammar needs to be corrected. “approach to processing...” is not correct. Change to “approach to process operating experience information”. A verb should be used, not a gerund.	Correct grammar mistake.		x		Adopted in 2.31.
47	2.40	The inclusion of screening items was discussed in a previous section, so the last part of the first sentence (after the semicolon) is redundant with what already been discussed in a previous section. As well, the 4 th bullet should read “the possible recurrence (not reoccurrence) of a similar event”. Recurrence means more than once, so “one or more times” is redundant.	Explaining what should and should not be included in the OE database was already discussed in a previous section. Inclusion is more positive instead of warning the user what not to dismiss. Correct reoccurrence to recurrence.		x		Original 2.40 equals to 2.37 in the current draft revision. 2.37 is reworded and addresses also the comment.
48	2.41	This is redundant with a previous section. Remove.	Remove this redundant section. It was already discussed.			X	Original 2.41 equals to 2.36 in the current draft revision. Repeating in the previous section is avoided by revising previous sections.
49	2.58-2.59	This issue was already discussed on corrective actions in a previous section.	These sections were already discussed elsewhere.		X		Text modified to differentiate from previous sections. Original 2.59 paragraph is deleted to avoid duplication and repeating.

50	2.63	Remove this section. This is becoming too prescriptive.	This section was discussed elsewhere and is becoming too prescriptive.		x		Original 2.63 equals to 2.65 in the current draft revision. 2.65 is reworded and addresses also the comment.
51	2.66-2.69	These sections were covered in other sections. Remove these sections.	These sections were already covered in previous sections.		x		Previous sections were revised to avoid duplication. Original sections 2.66-2.69 are revised. Original section 2.66, 2.67, 2.68 and 2.69 equal to sections 2.63, 2.62, 2.68 and 2.65 in the current draft revision.
52	2.71	This section and section 2.73 should be combined. Also, don't use "for instance". The coding system was discussed elsewhere, so it might be better just to eliminate the section on trending and review, and indicate in the previous sections on the database that trending and review are included. That will eliminate a lot of the redundancy.	Combine 2.71 with 2.73 and eliminate words like "for instance". It just seems like you are saying the same things over and over again. Combine some of these sections under a more comprehensive title to eliminate this duplication.		x		Original text from sections 2.71 and 2.73 is revised and adopted in the sections 2.55 and 2.56 in the current draft revision.
53	2.74	Facilities should have some latitude about how the databases should be connected. The word "harmonized" does not express the integration of all databases.	This section is rather prescriptive for integrating databases.		X		Original text from section 2.74 is revised and adopted in the section 2.56 in the current draft revision.
54	2.75	This section should begin with the second sentence with slight editing - "The types of <i>trends</i> [add the 's'] to be identified and reviewed are the following:"	This sentence reads better without the first sentence. This whole section might be better at the beginning of a subject area instead of in the middle.		X		Original text from section 2.75 is revised and adopted in the section 2.57 in the current draft revision.
55	2.78	The last sentence of this section should be corrected to read "For significant trends, an RCA should be conducted to identify causal and contributing factors ...". The expression "so as to" is very poor English	Correct the last sentence to make the English better.		X		Original text from section 2.78 is revised and adopted in the section 2.58 in the current draft revision. It

		and should never be used.					addresses also the comment.
56	2.79	Who are appropriate levels of managers? Do you mean appropriate levels of management? The last sentence should be removed. Mult-unit stations don't need to be told to trend reports for each installation."	"Appropriate levels of managers" is poor English. Correct it to "appropriate levels of management". Trending of multi-unit stations is understood and should not be expressed. It appears to insult those stations.	Original text from section 2.79 is revised and adopted in the section 2.59 in the current draft revision. It addresses also the comment.			
57	2.81	This sentence does not make sense. This issue was expressed somewhat in 2.77 and does not need to be repeated here.	Remove 2.81 since it was already discussed in 2.77 and elsewhere.	Text from original section 2.81 is deleted.			
58	2.82	The title of this section needs to be changed to "Use, Dissemination, Reporting and Exchange of Information" "Utilization" is unnecessary when a simpler word will do.	Change the title of the section to make it simpler.	The title is changed: COMMUNICATION: USE, DISSEMINATION AND EXCHANGE OF INFORMATION.			
59	3.6	It is not clear what you are trying to say here. Ensuring stability of OE regulations is not a clear concept. Explain what is meant by this section.	Clarify what is meant by this section.		X		Original text from section 3.6 is revised and adopted in the section 3.5 in the current draft revision.

60	3.7	This section should be the first section of the standard to introduce the concept.	The concept of OE should be very clear and this section would help if it were to be placed in the introduction instead of being buried here.			X	The first sections of the chapter provide requirements to establish OE. The section 3.7 introduces the concept.
61	Figure 2	This figure should agree with the list on page 19.	The list on page 19 is different from this figure. They should agree to eliminate confusion.	The Figure 2 is revised.			
62	3.17	The penultimate word in this section reads “topical”. The correct word is “topic”. It does not change when it’s an adjective. A topical is an ointment.	Use correct word.			X	The safety guide passed IAEA established editorial review.
63	3.22	The regulatory body is singular. Therefore procedures are for <i>its</i> own independent investigations; not <i>their</i> own. In line has no hyphen. It is not an adjective.	A singular subject must have a singular verb. A hyphen makes this an adjective, which it is not.	The text is revised.			
64	3.25	Unless the word “ensure” is followed by a noun, if you are going to continue with another phrase that contains a verb, “ensure” must be followed by “that”. There is no exception to this rule.	“ensure that” is the proper phrase here.	Original text from section 3.25 is revised and adopted in the section 3.31 in the current draft revision. It addresses also the comment.			
65	3.27	This section is not appropriate for a regulatory body. Under a management system, any process must be demonstrated to be effective.	Remove this section.		X		Original text from section 3.27 is revised and adopted in the section 3.32 in the

							current draft revision.
66	3.28	<p>Change the title of this whole section to <i>Dissemination and Use</i>. Again, a simpler word is more appropriate here.</p> <p>Also, keywords needs the word “method” at the end to match “coding system” so the proper phrase should be “keyword search”. Keyword is singular.</p> <p>Also, for all of the mixes of nouns and gerunds to match, this sentence should read “the regulatory body should implement a system for storing, retrieving and searching operating experience. You can’t end a sentence with the acronym. Or re-phrase the sentence “the regulatory body should implement an OE system for storage, retrieval and searches.”</p>	<p>Simplify words wherever possible.</p> <p>Re-phrase the sentence so that it reads better.</p> <p>Re-phrase the sentences so that it reads better English.</p>		X		<p>The title is changed: COMMUNICATION: USE, DISSEMINATION AND EXCHANGE OF INFORMATION.</p>
67	3.29	Combine this section with 3.31.	Combine all OE information use into one section, i.e. use and dissemination.		X		Original text from sections 3.29 and 3.31 is revised and adopted in the sections 3.28 and 3.30 in the current draft revision.
68	3.30	<p>Restrictions on the information to be disseminated should be minimized appropriately. Add the words “as appropriate” after “minimized” in the 2nd sentence.</p> <p>Also, the last sentence should end with “assessments or investigations”. Make them agree with each other.</p> <p>The last sentence is incomplete and doesn’t read well. It should read “The information shared should include what, if any, regulatory experience was used to make enhancements <i>to the</i> regulatory body’s regulatory framework in accordance with...”</p>	<p>Each country will have its own appropriate restrictions.</p> <p>“Investigatory efforts” is not a common expression in English.</p> <p>Remove “that” from the sentence. It does not belong. Add “to the” after “enhancements”.</p>	Original text from section 3.30 is revised and adopted in the section 3.29 in the current draft revision. It addresses also the			

69	Annex I Introduction.	<p>The 3rd sentence says “this information is to promulgate root cause analysis..” The word “promulgate” does not belong here. Change it to “This information is for root causes analyses and lessons learned...” Make the word “analysis” plural into “analyses” to agree with “lessons learned.”</p> <p>WANO is just WANO; not “the WANO”.</p>	<p>One promulgates rules, not information for dissemination to other countries.</p> <p>The definite article is not used in front of WANO. It is used if you spell out the acronym.</p>	<p>comment.</p> <p>The text is revised and addresses the comment.</p> <p>The safety guide passed IAEA established editorial review.</p>			
70	Annex I History of the IRS bullet No: 1 and 2	<p>The first bullet should be restructured so that it reads better. “Avoid the recurrence elsewhere of incidents taking place in one country”.</p> <p>Bullet 2 has mixed nouns and gerunds together in the same sentence. The sentence should read “facilitate analyzing general safety issues and sharing experience” so that they both agree.</p>	<p>The way the bullet was originally written makes “from recurring elsewhere” an orphan.</p> <p>Better grammar.</p>		x		<p>The text is revised and addresses the comment. The safety guide passed IAEA established editorial review.</p>
71	Description of the IRS page 30, paragraph 4	<p>The 3rd sentence does not make sense, specifically “contains preventive respectively corrective actions ...” What are preventive respectively? From the context I suggest you mean “That database also contains <i>preventative</i> information as a result of corrective actions taken at other NPPs both inside and outside of the reporting Member states.” The word “preventive” is a noun. The word here that you are looking for is “preventative,” which is an adjective that describes the noun “information.”</p> <p>There are other grammar mistakes in this annex which need to be corrected. E.g. page 33 “the reporting of” needs to be</p>	<p>This sentence needs a clear rewrite to make your message clear. A suggestion is given.</p> <p>Correct grammar mistakes in this Annex.</p>		x		<p>The text is revised and addresses the comment.</p> <p>The safety guide passed IAEA established editorial review.</p>

		changed to just “reporting”. “Event reporting” on page 34 is not hyphenated, but “risk-reducing measures” is hyphenated.					
72	General Comment	The title of this standard is operating experience feedback. The document contains instructions on Root Cause Analysis, Corrective Actions and rules for regulators. This is misleading. Where is OE feedback?	Review the title of this document. The content does not reflect the title.			X	OE as defined by IAEA in SSR 2/2, Req.24 covers all listed activities. The title of the guide followed approved DPP

COMMENTS BY REVIEWER Reviewer: ONR OPEX Lead TRIM 2016/308502 Page...1...of...5. Country/Organisation: UK Office for Nuclear Regulation Date:July 2016				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/ rejection
1	Page 6 footnote line 3	Add ... learning outputs from regulatory body and operating organisation nuclear safety assessment and review processes after ...,good practices and before... all other information	Explicit addition to all other information wording. These are key OE inputs that allow data to be turned into learning/knowledge and intelligence They are referenced in 2.22		x		Original text from footnotes is revised and adopted in the sections 1.7 and 2.24.
2	Page 6 footnote line 6-7	Replace lines 6-7 with It is essential that OE information collection efforts be systematic to ensure completeness and accuracy of records. It is also essential that this information is integrated with all relevant learning, to allow effective analysis and translation of OE information into knowledge and intelligence for effective utilisation.	OE data and information needs to be analysed with key additional learning derived from the assessments and reviews proposed as additions at comment 1				Original text from footnotes is revised and adopted in the sections 2.9 and A-41 and A-42.

COMMENTS BY REVIEWER Reviewer: ONR OPEX Lead TRIM 2016/308502 Page...2...of...5. Country/Organisation: UK Office for Nuclear Regulation Date:July 2016				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/ rejection
3	2.3 Pg8	Additional bullet after wider consideration of trends <ul style="list-style-type: none"> Synthesis or integration of OE inputs to generate knowledge and intelligence to inform operating organisation improvement and intervention strategies. 	Highlights the key point that OE data and information needs to be process integrated to generate outputs that allow improvement opportunities to be identified and actioned	X			Text is adopted in the sections 2.9 and A-41 and A-42.
4	Mgt system Section 2 P11	Addition of new bullet <ul style="list-style-type: none"> 2.21 Management should ensure that the effectiveness of the OE programme is subject to review and is supported by the introduction and review of OE performance indicators 	Effectiveness of OE needs to be measured explicitly and OE system performance reviewed at appropriate managerial level			x	Chapter Reviewing the Effectiveness of the Process (sections 2.75– 2.78) covers that suggestion

COMMENTS BY REVIEWER Reviewer: ONR OPEX Lead TRIM 2016/308502 Page...3...of...5. Country/Organisation: UK Office for Nuclear Regulation Date:July 2016				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/ rejection
5	2.75 p16	Addition of new bullet <ul style="list-style-type: none"> Trends in causation 	Causation trending is a core component of identification and development of improvement opportunities and actions	x	Trends of causes		Original text from section 2.75 is revised and adopted in the section 2.55 in the current draft revision. It addresses also the comment.
6.	2.92 p18	Add further text Examples of indicators include <ul style="list-style-type: none"> Sustainability of corrective actions Repeat event frequency OE cultural maturity and awareness Use of OE learning in new projects Visibility of OE performance indicators at organisation leadership level 	Guidance on the type of OE effectiveness indicators is a useful clarification .			x	Para 2.93no examples at the level of safety guide

COMMENTS BY REVIEWER Reviewer: ONR OPEX Lead TRIM 2016/308502 Page...4...of...5. Country/Organisation: UK Office for Nuclear Regulation Date:July 2016				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/ rejection
7.	3.7 p19	Bullet 5 Replace text with “wider consideration of trends and integrated review with other nuclear safety learning inputs”	The need for OE to be integrated with other nuclear safety learning inputs such as Regulatory Body assessments and emergent Nuclear Safety trends and identified improvement requirements, to generate OE intelligence This gives clarity to the management system comment at 3.9 where the word integrate is used in the context of the regulator’s management system		x		Original text from section 3.7 is revised and adopted in the section 3.7 in the current draft revision. The need for OE to be integrated with other processes is adopted in section 3.11.

<p>COMMENTS BY REVIEWER Reviewer: ONR OPEX Lead TRIM 2016/308502 Page...5...of...5. Country/Organisation: UK Office for Nuclear Regulation Date:July 2016</p>				<p>RESOLUTION</p>			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/ rejection
8.	3.24	<p>Add</p> <p>These reviews should follow a formal process designed to integrate operational learning with that generated by relevant subject matter experts. This process needs to generate outputs that meet end user requirements for identifying evidence based nuclear safety improvement opportunities.</p>	<p>This section needs strengthening it is the key reason for undertaking OE and formality in the design of the trending and review process is vital to the translation of OE data and information into knowledge and intelligence, for use in determining integrated and prioritised improvement actions</p>		x		<p>Recommendation on integration of operational learning is provided in the section 3.11. The recommendation to learn from OE is also provided in the section 3.4, where is cited text from Req. 15 from GSR Part 1.</p>

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COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: CNSQ Country/Organization: Indonesia/National Nuclear Energy				Page 1 of 1			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	2.2/2	A graded approach should be used in line with risks <u>and consequences</u> . Associated with the activities at the installation and with the role of the organization.	Not only the risk but also consequences			X	Risk takes already consequences into account.
2	2.3/4	... to draw <u>lessons to be learned</u> for its own operations.	To be cleared	Section 2.3 is reformulated and it is cited original text from Req.24 from SSR 2/2			
3	2.6/1	Within the management system, management should <u>plan and</u> establish an OE programme...	Before establish an OE programme should be planned	Original text from section 2.6 is revised and adopted in the section 2.9 in the current draft revision. It addresses also the comment.			

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: ENISS Country/Organization: ENISS		Page 1 of 5 Date: 2016-07-22					
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	1.5.	... from design through decommissioning. A graded approach should be used in line with the radiological risks associated with the activities at the installation and with the role of the organization.	We consider the graded approach for OEF is an important point, which should be mentioned in chapter 1. E.g. in the decommissioning phase, and for small installations, the radiological risk will decline or be lower and the OEF system should be adaptable in an appropriate way.		X		Comment is addressed in the section 2.2. and throughout the current draft revision.
2	2.3	The OE system should include the following: (add a bullet, second from last) Evaluation of the effects of actions taken	Evaluation of effects of the actions taken is important for "continuous learning"	Comment is addressed in the section 2.4.f)			
3	2.3	It should obtain and evaluate information on relevant OE at other nuclear installations and, as far as achievable with commensurate effort , applicable industries (e.g. chemical plants, air/sea/land transportation) to draw lessons for its own operations.	There might be various restrictions in obtaining OE information from other industries. This should reflect in the guide.	Comment is addressed in the section 2.3			
4	2.3 3 rd bullet	primarily on the basis of relevance and, i.e., actual or potential safety significance	For clarification: OE is relevant if there is actual or potential safety significance.		x		Original text from section 2.3 3 rd bullet is revised and adopted in the section 2.4 (c) in the current draft revision.
5	2.3 7 th bullet	Dissemination and exchange of information on internal OE , including by the use of international reporting systems	For clarification		x		Original text from section 2.3 7 th bullet is revised and adopted in the section 2.4 (g) in the current draft revision.

6	2.3 8 th bullet	Continuous monitoring and improvement of processes by use of OE of the OE system;	OE systems are normally based on events and therefore not suitable for continuous monitoring of processes; Probably, a continuous improvement of the OE system itself is meant here, which is also in line with §§2.89 – 2.93	Original text from section 2.3 8th bullet is revised and adopted in the section 2.4 (h) in the current draft revision.			
7	2.3/ Fig 1	Clarify that the box “Results coded and stored in database for further use.” is updated following “Investigation”. Also “corrective actions” and “trend” should be included in the database.	The box “Results coded and stored in database for further use” is not an action that is performed only once (after screening), this is an action that is performed also after “Investigation”. (also “Corrective Actions” and “Trend and review” should be included in the OE database.		x		Figure 1 is revised.
8	2.4	“Operating organizations that have multiple installations may have a centralized OE system ... at least deal with the following centralized OE functions:”	“a centralized OE system” is a physical tool, which is different of a “function”. This guide shall stick to functional recommendations.		x		Original text from section 2.4 is revised and adopted in the section 2.6 in the current draft revision. It addresses also the comment.
9	2.6	...so that relevant operating experience can be gathered, analyzed and disseminated throughout the lifecycle of the installation including decommissioning, as long as there is a significant radiological risk arising from the installation.	In the decommissioning phase, a point may be reached where the maintenance of a OE system as described in the guide is no longer appropriate.			x	The scope of the safety guide is to cover OE throughout the lifetime of nuclear installations from design to decommissioning what includes also any time when there is any kind of risk from the installation.
10	2.7	The OE programme should include procedures for the control of related activities at the installation for the feedback of operating experience.	For clarification		x		Original text from section 2.7 is revised and adopted in the section 2.10 in the current draft revision.

11	2.12	“are appointed to define the content of the OE program deliver the defined scope of the OE program”	For clarification		x		Original text from section 2.12 is revised and adopted in the section 2.16 in the current draft revision.
12	2.22	The sources of information on OE may use, should include for instance	List of example can change from case to case, and is not suitable with “should” but more with “may”, under responsibility of licensee to use on the best way.			x	The safety guide passed IAEA established editorial review.
13	2.29	Feedback should be given to the person who initiated the report and all other relevant personnel where appropriate. Examples of a strong reporting culture should be widely communicated within the installation to encourage reporting, questioning attitude and promote a ‘just-culture’. Trends should be communicated.	Events used for trending needs to be communicated to the reporting personnel to avoid a reputation of OE as “an empty hole” where events are input but no useful information come out.			x	Sections 2.53-2.59 are related to trends. Particular section 2.59 is related to communication about trends.
14	2.30	Prompt notification and reporting of significant issues and events process should ensure that events they are reported to relevant internal and external organizations	For clarification		x		Text is deleted due to duplication
15	2.31	The information on OE events should	For clarification			X	Events are part of operating experience.
16	2.34	Screening criteria should consider consequences or potential consequences with regard to nuclear safety, radiological safety, environment issues and non radiation related safety	The focus of the OE system should clearly be on nuclear and radiological safety. Other aspects (like HSE) are covered by other requirements or guidance and not specific to nuclear installations.			x	OE takes all aspects into account.
17	2.35	A suitably experienced, knowledgeable, and multi-disciplinary team should be assigned to the screening task. The team should preferably include personnel with knowledge of relevant technical matters and matters concerning human performance and	It is difficult to systematically ensure that all the skills are present in the team			x	Original text from section 2.35 is revised and adopted in the section 2.32 in the current draft revision. Personnel should be knowledgeable.

18	2.40, line 4	all relevant aspects should be considered	For clarification	Original text from section 2.40 is revised and adopted in the section 2.37 in the			
19	2.48 Footnote no.8	Editorial: Text is identical to footnoteno 7, no 8 should be on “extent of cause”		Footnotes no 7 and 8 are deleted. Text is adopted in the section			
20	2.55	Individuals performing investigations should be knowledgeable in investigation techniques. At least one individual on the team performing root cause or apparent cause analysis should have received formal training, regular retraining and or have recent experience in the conduct of investigations.	A person which have regular practice on such investigations has already received formal training			x	Expert in conducting root cause analysis should have received formal training, regular retraining and should have experience in the conducting root cause analysis.
21	2.57	Organizational issues should be investigated by a group independent from the line organization to ensure objectivity with the results of the investigation.	To clarify independence notion consistently with para 2.35		x		Original text from section 2.57 is revised and adopted in the section 2.46 in the current draft revision. It addresses also the comment.
22	2.61	The person responsible for implementation of the corrective action should be involved in its definition or at least agree to implement it	For clarification			x	Original text from section 2.61 is revised and adopted in the section 2.63 in the current draft revision.
23	2.75	Abnormal trends related in g to work groups of in the installation	For clarification			x	Original text from section 2.75 is revised and adopted in the section 2.57 in the current draft revision.

24	2.75	Information from all reported issues including low level events and near misses should be trended. Examples of trend to be identified and reviewed are: ... Short term trends that develop quickly ...	This may be difficult. If trends develop quickly, they may be missed on short term because time to identify and characterize them may be longer than the short term trend. Moreover, it is only a specific type of trend which is encompassed in other trends.		x		Original text from section 2.75 is revised and adopted in the section 2.57 in the current draft revision.
25	2.75 1 st bullet	Recurring issues derived from all a significant number of reported events	For clarification		x		Original text from section 2.75 is revised and adopted in the section 2.57 in the current draft revision.
26	2.76	Under graded approach concept , trend analysis should be performed appropriate systematically	Some trend analyses may be of poor efficiency, and could divert human resources		x		Text is adopted in the section 2.54 in the current draft revision.
27	2.83	Relevant lessons from other industries, as far as information can be obtained with commensurate effort , should also be taken into consideration, as necessary in the sense of requirement 24 para. 5.27 of SSR-2/2 [1]	There might be various restrictions in obtaining OE information from other industries. This should reflect in the guide.		x		Section 2.3 includes recommendation to use OE and lessons learned from different industries. It is relevant for all activities within OE.
28	2.86	Paragraph to remove	As it is a basic objective of OE implementation, we propose to delete it here.		x		Original text from section 2.86 is revised and adopted in the section 2.72 in the current draft revision.

29	2.90	The effectiveness of the OE programme should be assessed using the following methods such as: Self-assessment; Benchmarking; Independent peer review.	The original text is focused on three methods and excludes the application of possible new developments	Original text from section 2.90 is revised and adopted in the section 2.76 in the current draft revision. It addresses also the comment.			
30	3.4	The regulatory body should establish an internal OE process. The information disseminated should include other information that is not necessarily captured by operating experience programmes (e.g. actions	For clarification most of the given examples, except those that connected to research and development activities, are OE related and	Section 3.4 is revised and it addresses the comment.			
		pursuant to research and development activities, inspection findings, international forums, licensing activities, Integrated Regulatory Review Service Mission findings, regulatory experience from other industries, etc.) but which would result in improving the regulatory framework.	should be captured by OE programmes. OE issued from R&D activities may not be relevant for industrial installations (less formal procedures, temporary solutions, etc.)			x	OE issued from R&D activities may be relevant also for industrial installations.
31	3.6	It is a good practice to discuss modifications to regulations, procedures and arrangements should be submitted for observation to stakeholders before implementation	For clarification		x		Section 3.6 is revised and it addresses the comment.
32	3.12	The regulatory body should specify the reporting arrangements for events, incidents or accidents considered significant to safety and security .	This document describes the OEF for safety significant issues. Security specific issues should be mentioned in a Nuclear Security document.	Original text from section 3.12 is revised and adopted in the section 3.13 in the current draft revision. It addresses also			

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: Andres Rodriguez Hernandez		Page 1 of 1					
Country/Organization: Mexico		Date: 2016-07-2016					
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	2.25	This paragraph should be clarified, is confusing when it refers to low level events/near misses and their relationship with significant events.	This message in this paragraph is not clear.	Para reworded in current 2.27 to make the message clearer.			
2	Page 11	Section Identification and reporting should include a paragraph for recurrence assessment.	An OE programs should include actions to evaluate recurrent events revealing lack of effectiveness of the corrective actions, including the safety significance of the recurrent events.			X	See para 2.46, 2.76, 2.78 of the current draft revision.
3	Page 14	Footnote 8	Footnotes 7 and 8 are the same. Replace the text of footnote 8 wotj a definition of “extent of cause”.	X			

4	Page 12	“Screening” section. This section should have more specific suggestions on the safety significance of the events.	Suggestions should be provided on the use of defense-in-depth philosophy, vulnerability analysis, probabilistic risk assessment or any other tool to make a categorization of events in terms of safety.			x	See paras 2.31, 2.32, 2.33, 2.34 ... This suggestion could be addressed in a TECDOC level document /see TECDOC 1581/, achieving consensus with Member States on how to address this suggestion in Safety Standards is considered to be not feasible.
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COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: Rastislav Menus Country/Organization: Slovak Republic		Page 1 of 1 Date: 2016-05-19					
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	2.4/Line No.10	Delete line No. 10	Centralized OE cannot perform investigation of event due to personal structure, skills, experience, etc.			X	Relevant recommendation can be found in 2.6 of the current draft revision. An organization that has multiple installations may judge it appropriate to centralize some of the OE functions and this may include also independent investigations.

2	Under line Comment No. 6/Line No. 2	Change wording from “previous nuclear industry event(s)” to “previous event(s)”	Original wording is very wide and it is not possible consider all previous nuclear industry events. Also it can happen that nearly all events will be recurred because of similar causes especially human factor.	X			
3	Under line Comment No. 8	Insert definition of extent of cause	There is a definition of extent of condition (the same as comment No.7) but there should be extent of <i>cause definition</i>	X			
		LATE COMMENTS	JAPAN				
Reviewer: Page.... 1of 8 Country/Organization: Japan/NRA Date: July, 2016				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	1.11	Delete the whole description. Otherwise, merge the description into para 1.7 with small modification as follows; 1.7. This Safety Guide is applicable to all types of nuclear installations. This includes	Para 1.11 is universal description which could be applied in all of the Safety Standard publications. Also, the referred web page is general research page of IAEA publications and is not dedicated to OE system.	X			

			description of footnote 5 of draft DS479 without using the wording “just-culture”, as well as the description of INSAG-15.				
3	2.22/ L5	involving non-conforming, counterfeit, fraudulent or suspect items (CSFI)	Editorial. Generally abbreviation “CSFI” is used.		X		Abbreviations deleted from the draft revision
4	2.26	Delete whole description of this paragraph.	Reporting in this document is not nature of empowerment. Everyone should be encouraged to report proactively and voluntarily		X		Addressed in current 2.28 – wording changed/ expanded to better explain the recommendation aim.
5		Current text; 2.29. Feedback should be given to the person who initiated the report and all other relevant personnel where appropriate. Examples of a strong reporting culture should be widely communicated within the installation to encourage reporting, questioning attitude and promote a ‘just-culture’. Proposed new text; 2.29. Feedback should be given to the person who initiated the report and all other relevant personnel where appropriate. Examples of a strong reporting culture should be widely communicated within the installation to encourage reporting <u>and</u> questioning attitude and promote a ‘just-culture’ .	(See comment No. 2)		X		Adopted in 2.29 ‘Individuals who report issues should receive feedback, due acknowledgment and recognition from management to encourage future reporting. Good examples of reporting should be widely communicated within the installation to encourage future reporting and a questioning attitude.’
6	2.37/ L2	Screening should consider generic implications of the issue being screened and how it can affect other areas of the installation or <u>organization</u> utility .	Wording.	Adopted in 2.34			

7	Fig. 1	Please consider of replacing current Fig.1 with proposed amendment (See attached) then refer to the below comments No.8 to No.10.	Amendment to make this flow chart consistent with the main text. - The relationship between each box is modified but the descriptions in each box are left as original. - However, some practice indicated as “box” does not accompany any recommendation in main text.			X	The proposed Figure can be found in other IAEA publications such as PROSPER Guidelines (used also in OSART reviews) and all OE related TECDOCs.
8	Fig. 1	Merge the box “ External OE Identification ” into the box “ Screening ”.	Concerning the box “External OE Identification”, the relevant descriptions of external operating experience identification (e.g. paras 2.31, 2.40, 2.43) are found under the subtitle “Screening”. This means the practices on “External OE Identification” are ones of the “Screening”. If this understanding is wrong then create new subtitle “External OE Identification” and move the relevant description to the new subtitle.				See previous comment
9	Fig. 1	Delete the box “ Immediate event review of specific interest ”	No description is found in main text on this issue. If this box needed, some recommendation on this issue should be added with creating subtitle “Immediate event review of specific interest” .		X		Adopted in 2.4 c) and Screening section, e.g. see 2.35.

15	Fig. 2	Modify the title of the center box to “ Screening and Analysis ” from “ Screening ”.	To keep consistency with main text of para. 3.17 – 3.20.			X	See previous comments.
16	Fig. 2 Proposing new para corresponding to Fig.2	Modify the descriptions in the box “ Immediate review of events of specific interest ” as follows; “ Immediate supervision over licensees ” At the same time, create new para to indicate this action as follows; <u>3.18A Regulatory body should notify the licensees to respond specific issues and supervise their response.</u>	No recommended practices are found in main text on the “Immediate review of events of specific interest.” However, some immediate actions may be necessary for some specific events to prevent their recurrence in other similar installations.			X	See previous comments.
17	Proposing new para corresponding to Fig.2	Create new para describing the recommended practices corresponding to the box “ Corrective actions ”. <u>3.24A. The regulatory body should review the proposed corrective actions and identify potential further corrective actions for affected installation. The regulatory body should also to oversight the outcome of corrective implementation.</u>	Amendment to keep consistency between main text and Fig.2, using the description in the box. However, “Evaluation of RB-framework with regard to improvement” is another nature of action, and should be included under the “OE Effective Review”.	Adopted in 3.25 and 3.26.			
18	New box in Fig. 2	Create the box “ Regulatory Effectiveness ”	Amendment to keep consistency between main texts paras. 3.26 - 3.27 and Fig.2.			X	See previous comments.
19	Fig. 2	Modify the subtitle of the box from “ Reviewing the effectiveness of the OE process should be executed ” to “ OE Effective Review ”.	Amendment to keep consistency between main texts and Fig.2.			X	See previous comments.

20	3.26A (Proposing new para)	Create new para as follows to refer to the description in the box “ Regulatory Effectiveness ” as follows; <u>3.26A Regulatory body should evaluate its framework with regard to improvement and enhance their rules and standards.</u>	Adding description to make it consistent with proposed amendment of Fig.2.		X		Adopted in several paras – see current 3.11, 3.27, 3.32.
21	Fig. 2	Delete the box “ Implementation of workflow and in particular of required actions should be tracked. ”	No recommended practices found in the main text which corresponds to this box				See previous comments.

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: Mr. Eddie Singer Country/Organization: ISRAEL, Nuclear Licensing and Safety Office Date: 30 July, 2016							
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	General Comment	<p><u>The title of the document</u></p> <p>The term "Operating Experience" is defined under footnote 1 of the document, and limits the term to "nuclear installations", although one may find that such key-definition should be included in the central part of the introduction and not under a footnote. At the same time this term could be expected to be defined in the IAEA Glossary.</p> <p>Under footnote 2 of the document any nuclear facility is mentioned, in a broader scope than "just nuclear installation".</p> <p>The term "Nuclear Installation(s)" is also a well-defined term (in the IAEA Glossary) and according to this definition a "nuclear installation" is "any nuclear facility subject to authorization that is part of the nuclear fuel cycle..."</p> <p>When analyzing the basic IAEA requirements related to the "operating experience" we can find a much broader scope, which includes, for example, under par 3.17 of [3] the following: "the feedback of operating experience from facilities and activities – and, where relevant, from elsewhere – is a key means of enhancing safety. Processes have to be put in place for the feedback and analysis of operating experience, including initiating events, accident precursors, near misses, accidents and unauthorized acts, so that lessons may be learned, shared and acted upon."</p> <p>Therefore, we suggest the following as the main elements defined in the IAEA</p>	Accurate reflection of the basic IAEA safety requirements.		X	X	<p>The title of the document and its scope follow approved DPP 479.</p> <p>In line with the DPP (see DPP Objective and Scope), the document provides recommendations to nuclear installations and their regulatory bodies.</p> <p><i>Note:</i> <i>Recommendations to all facilities and activities, not included in the definition of nuclear installation, will be provided in revisions of GS-G-3.1 and 3.5.</i></p> <p>As correctly mentioned, definition of nuclear installation can be found in IAEA Safety Glossary, thus was deleted from the document.</p> <p>Current 2.3 of the document defines objectives of the OE programme (to learn from events) with reference to Req 24 of SSR 2/2 and definition of OE was included in</p>

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		<p>requirements, related to the "operating experience":</p> <ul style="list-style-type: none"> The operating experience is from (instead "for) facilities and activities . The operating experience from facilities and activities is expected to be put into a system for feedback and analysis of such type of information. <p>Following the comments listed above we suggest to consider changing the tittle of the document to better reflect the purpose of this guide and prevent limitations.</p> <p>As an optional tittle it is suggested to change the tittle to: "Operating Experience Feedback". The use of the term "installation" could be more precisely used in the document (see for example par. 2.37 where "installation or utility" is mentioned or the box in FIG.1 where it is said "installation (utility)" or par. 2.80 where the following text is used "installation level and utility level".</p>					<p>the Footnote 3. This definition is more general without reference to nuclear installations or facilities, with focus on learning from events.</p> <p>Term 'utility' was deleted from the guide to avoid confusions.</p>
2	2.3/6	<p>In general: it is suggested to replace consistently the term "operating experience" with "OE".</p> <p>For example: the description of FIG.1.</p>	Consistency			X	IAEA editorial position (not in line with IAEA standard)
3	FIG. 1	<p>We suggest to replace the text beginning with "The OE system should include..." with the following: "The main elements of the OE system should provide:"</p> <p>1. We suggest to consider deleting both sentences within the upper and lower</p>	Clarity	Adopted in current 2.5			
			This boxes are not part of			X	Text in the boxes relates

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		<p>boxes, starting with "Reviewing..." and "Implementation..." will be deleted.</p> <p>2. It is suggested to replace the word "coded", in the box starting with "Results...", with the word "classified"</p> <p>3. Addition "the" in the text within the Box starting with "Prior", after the words "review of"</p> <p>4. It is suggested to clarify the words "<i>e.g. low Level Events, Near misses</i>" which are included over the line connecting the Screening Box with the "Trending and review" Box. Suggest to clarify or delete.</p>	<p>the flow chart.</p> <p>The intention is to classify the event (with relevant "flags") while "coding" is probably the programming means to achieve it.</p> <p>Clarity</p> <p>Clarity</p>	<p>Adopted in the relevant box of Fig. 1.</p> <p>X</p>	<p>Text in the box was reworded to make the style consistent with text in other boxes.</p>		<p>to monitoring and reviewing operating experience programme effectiveness and such activities are important to ensure continuous improvement of the OE programme.</p>
4	2.4/3	<p>"...all functions of an OE programme."</p> <p>It seems better to have the definition of such</p>	Clarity	Text reworded to make			

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		"All functions" as a part of the guide. Also, we suggest to clarify the statement calling for Operating Organization with a single nuclear installation to perform all functions of an OE programme. Such statement might be misinterpreted as to Operating Organizations that have <u>multiple</u> nuclear installation are released from the performance of all functions of an OE programme.		the recommendation more clear.			
5	2.4/3	It is suggested to consider to delete the whole sentence starting with "The exchange...."	Relevance/Clarity		The recommendation was reworded and moved to a separate point, see 2.7.		
6	2.4/10	The bullet starting with "Independent investigation": Is it really the intention to include the independent investigation of significant events" only for Operating Organization that have multiple installations?	Clarity			X	The para (2.6 in the current draft revision) list examples of corporate functions. In case of single installation, all functions should be met by the operating organization, as described in the para.
7	2.4/5	It is suggested to correct "Operating organization's" to "Operating organizations"	Clarity		Reworded – see 2.6 (singular used)		
8	2.7	We find unclear the meaning of "procedures for the control..."	Clarity		Wording changed to, see current 2.10 'The management system should include procedures for activities...'		
9	2.13	2.13. Management should ensure that all staff is effectively informed about the role and expectations of the OE programme.	Clarity		The text was reworded to make it more clear and merged with original 2.20 which discussed		

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					similar recommendation – see current 2.19.		
10	2.14/2	"...."all staff easy access"". Probably it should be mentioned that access-rights to the OE information might be limited and not "all staff" has the free access rights.	Statement accuracy	Adopted in current 2.17.			
11	2.17	It is suggested to integrate the relevant elements of this paragraph into paragraph 2.14	Accuracy			x	Clear separation of the recommendations.
12	2.28	"Although information can be captured in different information systems, they should be considered to be integrated into one OE reporting system, in order to ensure their exhaustiveness and uniqueness.	Statement accuracy			x	This part of the recommendation was deleted, recommendation on integrating all information reporting systems into one OE system was considered too specific for the level of Safety Guide, see current 2.28. Recommendation on collecting OE related data in one database for trending purposes can be found in 2.55 of the current draft revision.
13	2.48	"Events involving human or organizational performance issues should be investigated using relevant tools" It is suggested to be more specific what are such "relevant tools".	More clarity is suggested			x	This part of original 2.48 was moved to current 2.42 (due to relevance and to avoid duplication). Appropriate analysis techniques are not discussed in the Safety Guide, additional

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							information is available within other IAEA documents, e.g. TECDOC 1756.
14	2.51	It is suggested to decide whether the issue of the proper Root Cause Analysis (RCA) documentation should be part of this document.	Relevance			X	Information on 'proper' RCA is available within other IAEA documents, e.g. TECDOC 1756.
15	2.58	"... Coding should be reviewed and checked against additional insights." We suggest to better explain what is recommended here to be reviewed.	Clarification is suggested		The sentence was deleted from the original 2.58 – the para referred to SSR 2/2 para 5.30, however, there is no such expectation in 5.30. In 2.60 of the current draft revision (replacing original 2.58), quotation from SSR 2/2 para 5.30 can be found. Furthermore, coding is discussed in 'Trending and review' part, thus having an expectation on coding in original 2.58 was obviously a mistake.		
16	2.60	".... A review of open corrective actions should be..." It is suggested to better explain what for the term "open corrective actions" stands for.	Clarification is needed		This recommendation was deleted – after additional consideration it was		

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					found too specific/prescriptive for the level of Safety Guide.		
17	2.66	The terminology used in this paragraph: "Personal at the appropriate management level" may lead into problematic "foggy" responsibility identification. It is recommended to rephrase the terminology and to better define the hierarchy of the management which is considered to be accountable for the effective actions.	More precise definitions are suggested			x	Original 2.66 can be found in 2.63 of the current draft revision. 'Line management' was added to provide better explanation what is meant by appropriate management level (assigned manager in the line management responsible for implementation).
18	2.69	"An effectiveness review of corrective actions should be performed after completion of the implementation phase."	Clarity		X		Adopted in 2.66 as follows: '... The effectiveness of important corrective actions should be reviewed after their completion.'
19	2.72	The demand for "experienced individuals" should be a general requisite for the personal dealing with OE and not specific to Trending and Review only.	Relevance - Is this relevant to the present guide?	General requisite is addressed in para 2.16 in the current draft revision.			
20	2.77	"Data from other relevant installation..."	Prevention of the "events" is already included in "improved safety".			X	After additional consideration it was found that recommendation on

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							trending all data from all installation databases exceeds the scope of OE programme. Expectation on trending OE related data e.g. event causes or consequences for safety (industrial, radiological, fire...) can be found in current 2.55.
21	2.80	It is unclear what is the meaning of the two levels mentioned here.	Clarity		X		The recommendation can be found in 2.54 of the current draft revision. Utility level was replaced with organization level – to be aligned with Req 9 of SSR 2/2. Those two levels are for an organization operating more installations. An organization operating only one installation does not necessarily have to have those two levels.
22	2.86	"Personal should use OE information to improve safety . "... concerned organizations..." Same comments as for Fig 1 • "Early Notification: Information..."	Clarity	Adopted in current 2.72			
						x	Second part of the

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		<ul style="list-style-type: none"> "Supplementary Reporting: OE..." 					comment is not clear (same comments as for Fig 1...).
23	2.88	<p>"... concerned organizations..."</p> <p>Same comments as for Fig 1</p> <ul style="list-style-type: none"> "Early Notification: Information..." "Supplementary Reporting: OE..." 	Clarity			X	Position of the editorial. Second part of the comment is not clear (same comments as for Fig 1...).
24	Fig 2	Same comments as for Fig 1	See comment 3		x		The Figure 2 was revised to make it consistent with current Fig 1 (that was modified revised to reflect comments from Member States).
25	3.14	<p>"...events, incidents and accidents;:</p> <p>"...of activity that resulted from the operational limits and conditions"</p> <p>"...releases of toxic materials and radioactive releases."</p> <p>"...authorized party or the regulatory body."</p>	Clarity	X		X – editorial position X	<p>Incidents and Accidents are included in the Event definition, see IAEA Safety Glossary 2016, page 61. To avoid confusion, terms Incident and Accident were deleted from the text.</p> <p>Reporting criteria can be found in Appendix A1. The current list follows the original list from NS-G-2.11, and the list of events to be reported according to NUREG1022. The last 'criteria' was deleted as</p>

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							this was considered not to be a criteria / 'deemed significant' cannot be considered as a criteria/

TITLE

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Reviewer: Country/Organization: European Commission 2016		Page 58 of 6 Date: 18 July					
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	1.1	(At the end of paragraph): In 2010 the Incident Reporting System was renamed to International Reporting System for Operating Experience (see Annex 1).	"The joint IAEA/NEA Incident Reporting System Guidelines have been published by the IAEA." It should be added that IRS was renamed to International Reporting System to avoid confusion with the old name		X		The original 1.1 was split into 1.2 and 1.3 in the current draft revision. The points provide a general background without referring to IRS, this specific information about IRS renaming was included in the Annex A-13.
2	2.3	It should obtain and evaluate information on relevant OE <i>including lessons learned from</i> other nuclear installations and applicable industries ...	The proposal simplifies the text, and the phrase "Relevant lessons from other industries should also be taken into consideration, as necessary." can be cancelled.			X	The original 2.3 was split into 2.3 and 2.4 in the current draft revision. The current 2.3 provides quotations from relevant Safety Requirements, which state 'Relevant lessons from...'
3	Fig. 1	If reporting criteria <i>are</i> reached <i>it is</i> reported as appropriate: ...	Center box upper row: "If reporting criteria reached reported as appropriate: ..." In most places full phrases are used but here not.		X		Taking into account other comments, more general phrasing was included: 'Events are reported as appropriate..', as not only those events are reported which meet reporting criteria.
4	Fig. 1	... and shared with other external organisations.	Left box lower row: "... with other external organizations." <i>Other</i> can be omitted; applies to all external org.	Adopted in Fig. 1			
5	Footnote 5 / page 10	A 'just-culture' is a culture where front line operators and others are not punished for	The definition of 'just-culture' appears complicated to read.		X		The definition was simplified, currently the

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		actions, omissions or decisions taken by them, that are commensurate with their experience and training. <i>In this culture</i> second victims of events (people who could be blamed for the event and could suffer psychological damage due to the investigation amplifying the guilt) are cared for, but where <i>and</i> gross negligence, willful violations and destructive acts are not tolerated.	Better to split up in several phrases.				definition widely used in aviation (e.g. ICAO) and by other high risk organizations is used, see footnote 6.
6	2.16	2.16. Management should ensure that corrective actions <i>and related follow-up activities</i> resulting from ...	Corrective actions in a wider sense including follow-up activities (2.60, 2.61 and 2.65)	Adopted in 2.20.			
7	2.22	The sources of information on OE should include for instance construction, Installation walk-downs, ...	The list is rather long. What is not included which would justify writing 'for instance'? Proposal: Cancel it out. Most items in the list are in plural. Mention also walk-downs in plural.	Adopted in 2.24.			
8	2.24, 2.30	Prompt notification and reporting of significant issues and events should ensure <i>timely screening and follow-up and reporting</i> to relevant internal and external organizations.	Present 2.24 and 2.30 together or combine them.		X		Information on timely screening and follow up was added into current 2.26 (note: screening is discussed in 2.31-2.40). Wording in 2.30 was changed to distinguish between two expectations.
9	2.32		Further advice (reference) which options exist to perform this would be helpful.		X		Original 2.32 was combined with current 2.37. 2.37 provides aspects to be considered in screening of external OE, Activities related to external OE process were added to relevant

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							parts of the guide, e.g. 2.52, 2.61, 2.64. More detailed advice on such process can be found in TECDOC1580.
10	2.46		The phrase after 2.46 'Installation event reports and non-radiation-related...' does not have a paragraph number. Intentional or not?	Original 2.46 was split into current 2.41 and 2.43.			
11	Footnote 8		Footnotes 7 and 8 (Extent of cause) are identical.	Adopted in 2.48 (g) and (h)			
12	2.79	OE trend reports should be provided to appropriate levels of management managers at regular intervals ...	Management instead of managers seems to be more pertinent.	Adopted in current 2.59.			
13	2.86		This paragraph sounds like an introduction and should be placed before 2.82.			X	Para reworded in current 2.72.
14	2.91	The effectiveness should be assessed by experienced individuals teams familiar with operating experience programmes.	'assessed by experienced individuals' – according to our experience it is more teams than individuals that make assessments.	Adopted in 2.76.			
15	2.93	The operating organization should issue a periodic report that summarizes the effectiveness of the OE process and should identify areas for improvement and corrective actions taken to address the issues	... 'should identify areas for improvement and corrective actions taken to address the issues'... Typically 'corrective action' has been used in connection with events, but here it is applied to the OE process itself. Improvement includes also	Adopted in 2.78.			

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			corrections if necessary. Proposal is to cancel it.				
16	Footnote 9 / page 18	The IAEA provides <i>support</i> for the application of this Safety Guide through its PROSPER service ...	Incomplete sentence.	Adopted in Footnote 7.			
17	3.9	The regulator's management system should make provisions for the inclusion of external expert support in the OE processes if appropriate.	The regulator's management system should also make provisions for inclusion of TSOs and external consultants in the OE process either in 3.9 or as extra paragraph.			X	GSR Part 1 Req 20 provides recommendations on the use of external technical services. If agreed by SSCs, we may add those recommendations (with appropriate modification) also to the guide.
18	3.31	The information shared should include what, if any, regulatory experience that was used to make enhancements <i>to</i> the regulatory body's regulatory framework in accordance with GSR Part 1, Requirement 15 [2].	Incomplete sentence.	Adopted in current 3.30.			
19	Appendix 1	Types of Events Report, Timing, Format and Content	Event report instead of events report	X			