

DS513 Leadership, Management and Culture for Safety (DPP)

| COMMENTS BY REVIEWER | | | | RESOLUTION | | | |
|--|---------------------------------|---|----------------------|------------|-----------------------------------|----------|---|
| Reviewer: | | Page 1 of 3 | | | | | |
| Country/Organization: China /China Atomic Energy Authority | | Date: 09.05.2018 | | | | | |
| Comment No. | Para/Line No. | Proposed new text | Reason | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |
| 1 | Page 2 Line 27 | The full stop at the end of “Developing practices in management, leadership and culture for safety in regulatory organizations.” should be a semicolon. | Editorial correction | x | | | This section has been edited and simplified . |
| 2 | Page 2 Last Paragraph | The full stop at the end of this paragraph should be a comma. | Editorial correction | x | | | See above note |
| 3 | Page 3 Line 2 | There should be a comma at the end of this sentence. | Editorial correction | x | | | See above note |
| 4 | Page 3 Line 4 | The full stop at the end of “Application of defence-in-depth and strength-in-depth in the area of management, leadership and culture for safety.” should be a comma. | Editorial correction | x | | | See above note |
| 5 | Page 3 Penultimate Paragraph | The case of the initials should be consistent through out the “outline of the proposed structure of the document” part, e.g. in page 4 line 6 “2.5.1 Senior Leadership accountability.”, the initial of “accountability” should be capitalized. | Editorial correction | x | | | See above note |
| 6 | Page 4 Line 2 | | | x | | | See above note |
| 7 | Page 4 Line 6, etc | | | x | | | See above note |
| COMMENTS BY REVIEWER | | | | RESOLUTION | | | |
| Reviewer: Zhang Hong, Zhang Li | | Page 2 of 3 | | | | | |
| Country/Organization: China /China Atomic Energy Authority | | Date: 09.05.2018 | | | | | |

| Comment No. | Para/Line No. | Proposed new text | Reason | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |
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| 8 | Page 4 Line 16 | The blank space between clause numbers and subsequent words should be consistent, e.g. there should be a blank space between “3.2.2” and “Management”. | Editorial correction | x | | | See above note |
| 9 | Page 4 Line 20 | | | x | | | |
| 10 | Page 4 Line 21 | | | x | | | |
| 11 | Page 4 Line 29 | | | x | | | |
| 12 | Page 4 Line 34 | | | x | | | |
| 13 | Page 4 Line 15 | The first clause number“3.2.2” should be “3.2.1”. | | x | | | See above note |
| 14 | Page 4 Line 7 | The content of clause 2.5 should be “2.5.2 management leadership responsibility. 2.5.3 individual responsibility. 2.5.4 regulatory organization responsibility.” | Logical correction, and “Regulatory organizations” are mentioned in Page 3 the penultimate Paragraph but not in subsequent clauses of Section 2. | x | | | See above note Regulatory bodies will be included in the guide but at generic level and the specific guides will be referenced to avoid repetition of content. |
| 15 | Page 4 Line 8 | Clause 2.5.3 should be changed to 2.6. | The content of clause 2.5.3 is not related to “2.5 responsibility”. | x | | | This section has been edited and simplified. |
| COMMENTS BY REVIEWER | | | | RESOLUTION | | | |
| Reviewer: Zhang Hong, Zhang Li | | | Page 3 of 3 | | | | |
| Country/Organization: China /China Atomic Energy Authority | | | Date: 09.05.2018 | | | | |
| Comment No. | Para/Line No. | Proposed new text | Reason | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |

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| 16 | Page 4 Line 24 | The full stop before the word “system” in “4.2 Management for safety and responsibility for integration of safety into the management system,” should be deleted. | | | | | See above note |
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DS513 Leadership, Management and Culture for Safety (DPP)

| COMMENTS BY REVIEWER | | | | RESOLUTION | | | |
|--|---------------------------|---|---------------------------------|------------|-----------------------------------|----------|-----------------------------------|
| Reviewer: Dr. Sertan YEŞİL Country/Organization: Turkey / Turkish Atomic Energy Authority | | | Page 1 of 1 Date: 24.04.2018 | | | | |
| Comment No. | Para/Line No. | Proposed new text | Reason | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |
| 1 | Page 2 Third Paragraph | “Two recent Agency publications refer to this area; Performing safety culture self-assessments, IAEA Safety Reports Series 83 (2016) and Independent” should be deleted | Editorial correction | agreed | Edited to simplify | | |
| 2 | General | Font of the text should be consistent through-out the document. | Editorial correction | agreed | Edited to simplift | | |

DS 513 – Leadership, Management and Culture for Safety

| COMMENTS BY REVIEWER | | | | RESOLUTION | | | |
|---|------------------|---|--|------------|--|----------|-----------------------------------|
| Reviewer: Country/Organization: Belgium – FANC/Bel V | | | Page.... of.... Date: | | | | |
| Comment No. | Para/Line No. | Proposed new text | Reason | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |
| 1 | Pg 2 §5 Scope | The General Safety Guide will also provide <u>specific</u> guidance applicable for the functions and activities of the regulatory body, and for other | As example, requirement 14 of the GSR Part 2 deals with “measurement, assessment and improvement of Leadership | Yes | As the RAS in NSNI have been developing guidance we will include a general | | |

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| | | government organizations as appropriate. | for safety and of safety culture”. Regarding IRRS peer review for Regulatory Bodies, it could be pertinent to include in this safety guide some considerations on how regulatory bodies should comply with leadership for safety and of safety culture” | | section for regulators and reference published guides for regulator | | |
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DPP DS513 Leadership, Management and Culture for Safety, Version 2 Dated 06/10/2017

| COMMENTS BY REVIEWER | | | | RESOLUTION | | | |
|--|---------------|--|--------|---|-----------------------------------|----------|--|
| Reviewer: M-L Järvinen, R. Bly, J. Leino, S. Hellstén, H. Aaltonen; P. Karhu /NUSSC/RASSC/WASSC/TRANSSC/EPreSC/NSNG Country/Organization: STUK | | | | Page.... of.... Date: 8 th May 2018 | | | |
| Comment No. | Para/Line No. | Proposed new text | Reason | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |
| 1. | General | <p>IAEA drew up the top down approach for the development of IAEA Safety Standards in 2008. The aim is to harmonize the approach at different sectors and develop a set of user friendly IAEA Safety Standards. One of the goals is to minimize the number of safety standards. However this goal is not the only driving force of the development.</p> <p>IAEA presented the plans for the development of DPP_DS513 at 44th NUSSC meeting in autumn 2017. NUSSC presented its concern of the proposed wide scope of the guide ranging from radiation practices to nuclear power plants. This concern has not been addressed in the DPP.</p> <p>The challenges on the development of safety requirements for different types of users of radiation sources were evident during the development of GSR Part 2 document.</p> <p>DPP DS513 should be limited to nuclear installations. Most of the</p> | | | | x | <p>The scope of DS513 reflects the GSR part 2 – This will be a high level guide in support to GSR part 2 requirements as requested by member states.</p> <p>The revision of GSG part 3.5 is under discussion and this will specifically address Nuclear Installations.</p> <p>Other Guides to reflect other parts of the industry or other activities has been referred to NSOC.</p> |

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| | | background material referenced and other justifications are from nuclear power sector. IAEA should draw up another DPP for radiation practices, facilities and activities. | | | | | |
| 2. | General | Consider the feasibility of addressing safety and security in a balanced manner in this DPP and the resulting publication/s. This might be achieved either by a more comprehensive approach to security or by using more references to appropriate publications in the NSS. A balanced approach might apply to the title as well as the contents. | Safety and security approach the same objective (protecting people, society, and the environment from harmful effects of ionizing radiation) from different angles: protection against accidental effects and against intentional acts. Both angles are needed in order to achieve the objective. Hence safety and security considerations should be part of all decision making in a balanced manner, and part of an integrated management system and organizational culture in a similar manner. | | X principle agreed | | The interface between safety and security will be included as an appendix to reflect the IAEA development of this area at the time of publication |
| 3. | General | Replace facilities and activities, including nuclear installations with nuclear installations. | The text should be aligned with the scope of nuclear installations. | | | | |

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| 4. | for Example: | <p>Delete the example. Reference to the documents mentioned above below the examples is adequate..</p> <p>In addition, a number of projects were started in 2016 which are developing aspects of the requirements in GSR Part 2 and recommendations incorporating their outcomes will need to be included in the proposed new Safety Guide along with information from recently published guides and reports.</p> <p>For example:-</p> <p>□ Safety culture framework harmonization project work is being carried out with WANO and INPO to harmonize the safety culture frameworks in order to assist Member States in their safety culture improvement programmes and the application of assessment tools. [4 global workshops and 2 CS meetings]-</p> <p>□ Leadership for safety project as part of the Leadership project in NP-section, safety leadership is being defined and good practices identified. [4 CS meetings]-</p> <p>The proposed Safety Guide will be developed from existing tested practices applied by IAEA, and from Member States' experience. Two recent Agency publications refer to this area; Performing safety culture self-assessments, IAEA Safety</p> | <p>It is great that WANO and INPO are working to enhance assessment of safety culture. However IAEA should make reference to IAEA documents. Highlighting the WANO and INPO activities might mislead to making a presumption of the use of WANO or INPO methodologies.</p> | | x | | Section simplified and edited. |
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| | | Reports Series 83 ‘ (2016) and Independent safety culture assessment, IAEA Services Series 32 (2016), and there are publications in progress relating to self-assessment of leadership for safety for nuclear installations, facilities and activities. | | | | | |
| 5. | Objective | The objective of the proposed Safety Guide is to provide recommendations to nuclear installations, facilities and activities (licensees and/or registrants), regulatory bodies and other relevant governmental organizations , to support the implementation of the requirements of GSR Part 2. | Please clarify the scope. The scope should be limited to nuclear installations and as appropriate the related supply chain. DS472 and DS473 safety guides on the organization and processes of the regulatory body were approved in the last CSS meeting in April 2018. Those safety guides should cover the aspects of GSR Part 2 for the regulatory body. | | x | | Reference to appropriate specific guides will be made to avoid duplication of detail. |
| 6. | 6. PLACE IN THE OVERALL STRUCTURE OF THE RELEVANT SERIES AND INTERFA | ... As such, the new Safety Guide will interface with other IAEA Safety Standards containing requirements, recommendations and guidance on: <input type="checkbox"/> Compliance with Fundamental Safety Principle No. 3; | Please clarify and make the reference to relevant IAEA Safety Standards Series Documents, even though several documents needs to be presented. | | x | | An interface grid was published on the standards web site. This is a living document and will be updated as other guides are published. |

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| | CES WITH EXISTING AND/OR PLANNED PUBLICATIONS | <input type="checkbox"/> Management of safety, including the graded approach and integrated management systems; <input type="checkbox"/> Leadership for Safety; <input type="checkbox"/> Culture for Safety; <input type="checkbox"/> Measurement, assessment and improvement of safety performance; <input type="checkbox"/> New standards and guides under revision (e.g. DS 492 and the NS-G 2 series under the safety standard SSR 2/2 rev 1); | | | | | <p>DS513 guide will aim to provide a road map to other IAEA documents</p> <p>The question of other specific guides has been referred to NSOC.</p> |
| 7. | Outline of the Proposed Structure of the document: | <p>Section 2: Overview of Management and Leadership for safety in nuclear installations and activities that give rise to radiation risks, and the regulatory organizations.</p> | <p>See above.</p> <p>The scope should be limited to nuclear installations and as appropriate the related supply chain.</p> <p>DS472 and DS473 safety guides on the organization and processes of the regulatory body were approved in the last CSS meeting in April 2018. Those safety guides should cover the aspects of GSR Part 2 for the regulatory body.</p> | | x | | <p>This section had been edited and simplified.</p> <p>Reference to appropriate specific guides will be made to avoid duplication of detail.</p> |

Japan NUSSC Comments on DPP-DS513, “Leadership, Management and Culture for Safety”

| COMMENTS BY REVIEWER | | | | RESOLUTION | | | |
|-----------------------------------|---|---|--|------------|--|----------|-----------------------------------|
| Reviewer: Japan NUSSC Member | | Page..1.. of...1 | | | | | |
| Country/Organization: Japan / NRA | | Date: 29 May, 2019 | | | | | |
| Comment No. | Para/Line No. | Proposed new text | Reason | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |
| 1. | Sec. 2 3 rd bullet, 2 nd sentence | Consequently, it focused primarily on the management system and safety culture, and did not address <u>the new topics introduced in GSR Part 2.</u> | Specify for the new topics introduced in GSR Part 2. | Yes | Modified as indicated | | |
| 2. | Sec.4 4 th line | The recommendations, especially general recommendations for regulatory body in order to meet the requirements on leadership, safety culture, responsibility etc. established in GSR Part 2 are already captured in GSG-12 Sec.12. Please clarify how the duplications between recommendations in proposed DPP and those of SSG-12 will be avoided. | | Yes | As the RAS in NSNI have been developing guidance we will include a general section for regulators and reference published guides for regulator. Duplication of Details will not be included. | | |
| 3. | Sec.6 | Please confirm the coverage of this proposed safety guide, using the table attached. https://www-ns.iaea.org/committees/files/draftcomments/1848/CopyofSafetyGuidessupportingGSRPart218-06-21.xlsx It is understanding that this proposed guide cover the blue-painted columns. | | Yes | It is intended to develop a ‘road map’ for the pre-existing requirements and guides. DS513 will be a high level document and will avoid duplication of detail. | | |

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| 4. | Sec.6 | <p>In the table attached, some columns are left blank, which implies that some separate guides will be developed. At the very beginning of producing general safety guides on management system, it would be essential to develop a clear vision for the future as overall structure of MS-related Guides first.</p> <p>Please clarify how many additional safety guides specific to each facility and/or activity will be proposed.</p> | | | No | <p>This will not be covered in the guide – as GSR part 2 is generic all future proposed guides and revisions should take GSR part 2 and DS513 into consideration.</p> |
| 5. | Sec.6 | <p>Please clarify relationship between this proposed SGs and DS477 (The Management System for the Predisposal Management and Disposal of Radioactive Waste, revision of GS-G-3.3 and 3.4).</p> | | | | <p>DS513 is a generic guide, DS477 is a specific guide. DS513 will have guidance on the core principles for all nuclear and radiation facilities, DS477 will have specific guidance and. identify and interpret core principles into context specific guidance for pre-disposal and disposal of radioactive waste.</p> |

DS513 - DPP Leadership, Management and Culture for Safety

| COMMENTS BY REVIEWER | | | | RESOLUTION | | | |
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| Reviewer: | | Page.1... of..1.. | | | | | |
| Country/Organization: ONR/UK | | Date: May 2019 | | | | | |
| Comment No. | Para/Line No. | Proposed new text | Reason | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |
| 1 | Section 5 | <p>The objectives of the DPP, namely updating of GS-G-3.1 to take account of the new or strengthened requirements introduced by GSR Part 2 and incorporating the elements of GS-G-3.5 as much as possible are welcomed.</p> <p>Additional two items to the list:</p> <ul style="list-style-type: none"> • Concept of governance • Cultural aspects of transition programmes during a facility lifecycle, e.g. transition from operations to decommissioning | We would suggest including within the scope the identified emerging practices to the list of items within the scope. | Noted | The General Safety Guide will also provide guidance applicable for the functions and activities of the regulatory body,, during transition , and for other government organizations as appropriate. | | Oversight and Governance will be included in the content of the guide. Maintaining safety, and Safety culture during transition will be included and will have a specific appendix. |

DS513, DRAFT Standard ‘Leadership, management and culture for safety’.

| COMMENTS BY REVIEWER | | | | RESOLUTION | | | |
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| Reviewer: Framatome for WNA / CORDEL Page.14.of. 2 | | | | | | | |
| Country/Organization: WNA Date: 14/05/2019 | | | | | | | |
| Comment No. | Para/Line No. | Proposed new text | Reason | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |
| 1 | Section 4 2 nd paragraph | Shuffle and complete the 2 nd paragraph of section 4 as suggested below : <i>The recommendations are aimed at all parties with responsibilities relevant to leadership and management for safety such as (non-exhaustive list) service providers, specialized consulting companies, standards development organizations, vendors, designers, suppliers and manufacturers of equipment, operating organizations, regulatory bodies (rather than their regulatory oversight activities), emergency response organizations and authorities.</i> | It is recommended to be more explicit regarding the organizations concerned, otherwise, some important parties with responsibilities relevant to leadership and management for safety may be “forgotten” or inadequately covered. For example, §5 says that the full lifetime is concerned. Regarding the ‘Siting’ phase, specialized consulting companies are mostly concerned to effectively characterize the site. Regarding the ‘Design’ phase, SDOs (Standard Development Organizations) as well as, vendors/designers are mostly concerned. Regarding ‘Construction’ phase, suppliers/manufacturers of equipment are concerned ... | yes | <i>The recommendations are aimed at operating organizations, regulatory bodies (rather than their regulatory oversight activities), emergency response organizations and authorities. The guidance can also be used by those who have responsibilities to ensure that the delivery of services, the suppliers and manufacturers eg vendors, consultants and designers, also know the guidance to meet</i> | | Requirement 1 and the FP-1 (3) make clear that first responsibility lies with the customer of services, suppliers, and manufacturers. There is no restriction to using the guidance with the suppliers of services, vendors, manufacturers, designers, and consulting companies. |

| COMMENTS BY REVIEWER | | | | RESOLUTION | | | |
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| Reviewer: Framatome for WNA / CORDEL Page.14.of. 2 Country/Organization: WNA Date: 14/05/2019 | | | | | | | |
| Comment No. | Para/Line No. | Proposed new text | Reason | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |
| | | | Therefore, it is worth being more explicit in section 4 (adding just a few lines to the DPP may prevent disregarding important stakeholders from not being addressed) | | <i>the requirements.in GSR part 2.</i> | | |
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DPP DS513, Step 3, Version 02 dated 06/10/2017

| COMMENTS BY REVIEWER | | | | RESOLUTION | | | | |
|---|-------------|---------------|---|--|----------|--|------------------|---|
| Reviewer: Federal Ministry of the Environment, Nature Conservation and Nuclear Safety (BMU) (with comments of GRS) Pages: 1 Country/Organization: Germany Date: 14.05.2018 | | | | | | | | |
| Relevanz | Comment No. | Para/Line No. | Proposed new text | Reason | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |
| 2 | 1 | 5. Scope | This guide will cover: <ul style="list-style-type: none"> Influence of human, organizational and technology factors (HTO) on human and organizational performance; systemic approach to safety; and culture for safety. Safety and security interfaces | Is not quite clear, why interfaces for safety and security are mentioned in the scope of this DPP. There is no topic like this (viz. this kind of interfaces) in scopes of GSR Part 2, GS-G-3.1 and GS-G-3.5. | | This General Safety Guide will not address leadership and management for nuclear security, although the interfaces between safety and nuclear security will be | Scope simplified | Safety security will be addressed to cover Requirement 12 5.2 (g) |

| COMMENTS BY REVIEWER | | | | | RESOLUTION | | | |
|---|-------------|---------------|---|--|------------|-----------------------------------|----------|-----------------------------------|
| Reviewer: Federal Ministry of the Environment, Nature Conservation and Nuclear Safety (BMU) (with comments of GRS) Country/Organization: Germany Pages: 1 Date: 14.05.2018 | | | | | | | | |
| Relevanz | Comment No. | Para/Line No. | Proposed new text | Reason | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |
| | | | <ul style="list-style-type: none"> Approaches to measurement, assessment, and improvement of safety | If the idea is to highlight some issues then it has also to be addressed as an own topic later, for example in Section 4. Otherwise we suggest to delete this item. | | addressed (in an Appendix). | | |

Leadership, Management and Culture for Safety (Revision and expansion of GS-G-3.1)

| COMMENTS BY REVIEWER | | | | RESOLUTION | | | |
|--|---|--|--|------------|-----------------------------------|----------|---|
| Reviewer: Jila Karimi Diba Page.... of.... Country/Organization: IRAN/National Radiation Protection Department (NRPD)- Iran Nuclear Regulatory Authority (INRA) Date: 2019-05-31 | | | | | | | |
| Comment No. | Para/Line No. | Proposed new text | Reason | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |
| 1 | Page 2/Objective/Second Paragraph/Second line | "..., emergency response organizations and authorities,.. " | The definition of "response organization" in GSR Part 7 is: "An organization designated or recognized by a state as being responsible for managing or implementing any aspect of an emergency response. | | x | | Guidance for emergencies will reference existing guidance supporting GSR part 7. Detail will not be replicated. |

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| | | | <p>Φ This also includes those organizations or services necessary to support the management and/ or conduct of an emergency response, such as meteorological serices."</p> <p>Also the definition authorities in the DPP is unclear.</p> | | | | |
| 2 | Page 2/Objective/ Second Paragraph/Second line | <p>"..., emergency—response organizations—and authorities,.."</p> | <p>Clause No. 1.1 of GSR Part 2 states:</p> <p>"1.1. This Safety Requirements publication establishes requirements for establishing, assessing, sustaining and continuously improving effective leadership and management for safety in organizations concerned with, and facilities and activities that give rise to, radiation risks. This includes the regulatory body and other competent authorities, and the organization responsible for the facility or for the activity."</p> <p>It seems that GSR Part 2 does not address response organizations.</p> | x | | | <p>Edited with the following in section 5</p> <p>The General Safety Guide will also provide guidance applicable for the functions and activities of the regulatory body; response organizations; organizations during transition; and for other government organizations as appropriate.</p> |

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| 3 | General comment | <p>It is suggested to consider Requirement 1 and Requirement 26 of GSR Part 7 too.</p> <p>"Requirement 1: The emergency management system</p> <p>Requirement 26: Quality management programme for emergency preparedness and response"</p> | <p>At the time of the publication of GS-G-3.1, GS-R-2 did not address "management system" directly. Now there are two requirements in this regard in GSR Part 7. If this DPP is aimed at response organizations too, requirements 1 and 26 should be considered.</p> | | x | | <p>GSR part 7 guides will be considered and referenced.</p> |
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DS513-DPP Leadership, Management and Culture for Safety

| COMMENTS BY REVIEWER | | | | RESOLUTION | | | |
|--|----------------------------|---|--|------------|-----------------------------------|----------|---|
| Reviewer: Jila Karimi Diba Page.... of.... Country/Organization: IRAN/National Radiation Protection Department (NRPD)- Iran Nuclear Regulatory Authority (INRA) Date: 2018-05-13 | | | | | | | |
| Comment No. | Para/Line No. | Proposed new text | Reason | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |
| 1 | 4.Objective/ first line | "The objective of the proposed Safety Guide is to provide recommendations to nuclear installations , facilities and activities..." | According to GSR Part 2: "This Safety Requirements publication establishes requirements for establishing, assessing, sustaining and continuously improving effective leadership and management for safety in organizations concerned with, and facilities and activities that give rise to, radiation risks. This includes the regulatory body and other competent authorities, and the organization responsible for the facility or for the activity ." Facility covers nuclear installation too. | x | | | edited |
| 2 | Page 3/Clause 6. | Add the following items to the list: "Preparedness and Response for a Nuclear or Radiological Emergency" | In the following paragraphs of GSR Part 2, it is mentioned: "1.9. The objective of this Safety Requirements publication is to establish | | x | | Section 5 edited. The General Safety Guide will also provide guidance applicable for the functions and |

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| | | | <p>requirements that support Principle 3 of Fundamental Safety Principles, in relation to establishing, sustaining and continuously improving leadership and management for safety, and an effective management system. This is essential in order to foster and sustain a strong safety culture in an organization. <u>Another objective is to establish requirements that apply Principle 8, which states that “All practical efforts must be made to prevent and mitigate nuclear or radiation accidents.”</u></p> <p>1.13. This Safety Requirements publication applies to registrants and licensees throughout the lifetime of facilities and the duration of activities, <u>for all operational states and for accident conditions, and in a nuclear or radiological emergency.</u> The lifetime of a facility includes its siting and site evaluation, design, construction, commissioning, operation and decommissioning (or closure and the post-closure period, including any subsequent</p> | | | | <p>activities of the regulatory body; response organizations; organizations during transition; and for other government organizations as appropriate.</p> <p>Guides supporting GSR part 7 will be referenced</p> |
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| | | | <p>period of institutional control), until its release from regulatory control."</p> <p>According to Requirement 2 of GSR Part 7:</p> <p>" Requirement 2: Roles and responsibilities in emergency preparedness and response</p> <p>The government shall make provisions to ensure that roles and responsibilities for preparedness and response for a nuclear or radiological emergency are clearly specified and clearly assigned.</p> <p>4.9. The government shall ensure that operating organizations, response organizations and the regulatory body establish, maintain and demonstrate leadership in relation to preparedness and response for a nuclear or radiological emergency (Reference GSR Part 2)."</p> <p>Considering above-mentioned paragraphs derived from GSR Part 2 and GSR Part 7, the</p> | | | | |
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| | | | Proposed item should be added to the list. | | | | |
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TITLE: DS513 DPP Leadership, Management and Culture for Safety ver 2 (May 2019)

| COMMENTS BY REVIEWER | | | | RESOLUTION | | | |
|-----------------------------------|---------------|-------------------|---|------------|-----------------------------------|----------|--|
| Country/Organization: FRANCE /ASN | | Date: May 2019 | | | | | |
| Pages | | | | | | | |
| Comment No. | Para/Line No. | Proposed new text | Reason | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |
| 1. | §3 | | <p>In addition, many recommendations on culture for safety, leadership for safety as well as management system are not activity specific. In addition, for management systems, its development and contents are strongly linked to the size of the organization and the relative contribution of the nuclear activity to the overall business of the organization. A general safety guide is therefore appropriate.</p> <p>One objective of DS513 is <i>“To provide guidance on applying a graded approach to the application of the requirements of GSR Part 2 at facilities of widely varying size and with activities of widely varying risk profiles.”</i> This is a key expectation for this future guide.</p> | x | | | <p>The guide will specifically give guidance on the graded approach with respect to the type, size, and complexity of an organization. CS held in March 2019 to specifically develop this.</p> |
| 2. | §3 | Clarification | <p>The DPP states that <i>“A gap analysis of the coverage of leadership, management, safety culture, and measurement, assessment and improvement in existing safety standards indicated that there is currently a lack of recommendations and guidance for non-nuclear facilities, especially in relation to leadership for safety.”</i> It would be worthwhile to insert the results of this gap analysis in the DPP and see, among other, what gaps are relevant to the transport activities.</p> | | x | | <p>The result of the gap analysis is with NSOC for overall consideration and decision .</p> |

| COMMENTS BY REVIEWER | | | | RESOLUTION | | | |
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| Country/Organization: FRANCE /ASN | | Date: May 2019 | | | | | |
| Pages | | | | | | | |
| Comment No. | Para/Line No. | Proposed new text | Reason | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |
| 3. | §3 | Clarification | On objective of DS513 is to “ <i>To incorporate experience gained from IAEA peer review missions.</i> ” Could a summary of the findings be inserted as an appendix? | | x | | This will be developed with the peer review mission organizers. This type of detail is not expected in the DPP. |
| 4. | §3 | Clarification | On objective of DS513 is “ <i>To take account of new and emerging practices and technologies, for example in the medical and nuclear sectors.</i> ” Could examples be given of such emerging technologies, for example as an appendix? | | x | | The objectives were edited and simplified on basis of comments. The examples will be developed as an appendix or annex to the guide. Eg the WHO development of safety leadership in a medical context. |

| COMMENTS BY REVIEWER | | | | RESOLUTION | | | |
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| Comment No. | Para/Line No. | Proposed new text | Reason | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |
| 1. | General | Improve the paragraph on the “justification for production” by detailing what is the feedback from OSART, IRRS and other peer review missions as current text does not clearly substantiate the need. | The DPP is quite unclear on the justification for the update. Although many sources for need for revision are stated, no list of required improvement are given... | x | | | Edited and simplified section 3 |

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| Comment No. | Para/Line No. | Proposed new text | Reason | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |
| 2. | General | Refocus the DPP to leadership and culture for safety and culture for security. | <p>Leadership and culture for safety are better developed in GSR Part 2 than in the previous GS-R-3.</p> <p>Moreover, the nuclear security series also addresses security culture (NSS 7, NSS 28T).</p> <p>These topics are relevant across all activities and facilities and are technology neutral.</p> <p>Management system are more specific to the type of activity or facility operated (or designed or serviced). Separate guides would allow to better fits the end-user needs</p> | | x | | <p>New sections for leadership for safety, revised cuklture for safety sections and guidance on safety and security interface will be included .</p> <p>Management sections are required to give generic guidance for requirements 3 to 11.</p> |

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| Comment No. | Para/Line No. | Proposed new text | Reason | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |
| 3. | General | Interface with other IAEA publications is to be improved, including by addressing other existing publications on management systems, whether in the Safety Standards, Safety reports or Tecdocs, Nuclear Security series or Nuclear Energy series. | <p>Currently, recommendations on management system are provided in GS-G-3.1 (facilities and activities) GS-G-3.5(nuclear installations), as reminded in the DPP, but also in other IAEA publications such as GS-G-3.2 (technical services in radiation safety), GS-G-3.4 (disposal of radioactive waste), TS-G-1.4 (transport) and many other safety guide provide also recommendations on the management system (just use NSS-OUI to illustrate the various publications addressing this topic !). Many other IAEA publications are also addressing management system (safety reports such as n°69, 70 and 75, Tecdocs such as n°1740,)</p> <p>Should the idea be to develop a unique safety guide on management system, then the list of safety guides to merge/rationalize is not complete....</p> <p>Finally, it is not clear how both safety and security will be addressed in the management system and the recommendations made relevant to both topics so that an integrated management system can be developed and implemented.</p> | | x | | <p>The aim is to give a 'road' map for the interfaces with other guides .</p> <p>Safety and security interface will be included in the guide at a generic level and reflect the development of this area at the point of publication.</p> |

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| 4. | General | <p>Prepare a DPP to provide recommendations on management system for regulators (to amend DS472 and DS473) and their TSO</p> <p>Prepare a separate DPP to provide recommendations on management system for nuclear facilities. If necessary, structure the future guide table of contents to have commonalities for all facilities then nuclear installation or nuclear facilities specific additional recommendations.</p> <p>Prepare a separate DPP to provide recommendations on management system for nuclear activities. If necessary, structure the future guide table of contents to have commonalities for all activities then activity specific (transport, technical services,) additional recommendations</p> | <p>Creating a single safety guide does not seem a good idea.</p> <p>Management systems are more specific to the type of activity or facility operated (or designed or serviced). The regulator and its TSO have also to implement GSR Part 2 but they do not generally run a nuclear facility. are also</p> | | x | | <p>The update of GSR 3.5 is under discussion</p> <p>This guide will remain at the generic level suitable for supporting GSR part 2 for all facilities and activities.</p> |
| 5. | General | Is this consistent with the conclusion of the CSS view on the long term structure of Safety Guides (2017 request from CSS to SSCs) ? | NUSSC end of term report includes an (interim ?) view on DS513 DPP. It is not consistent with the current draft DPP. | | x | | Referred to NSOC |

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| 6. | General | <p>Include in the DPP a paragraph addressing the interface with the current Industry standards as, for many companies involved in nuclear business but where nuclear business is not the main activity, the management system will have to address other needs/requirements... IAEA publications should avoid overlaps and allows for a coherent implementation.</p> | <p>Moreover ISO and other industrial standards are addressing this topic, even if nuclear business brings additional expectations. Safety reports 69 and 70 was a valuable document to explicit commonalities and differences between ISO 9001 standard, ASME NQA-1 and GSR Part 3. A similar comparison should be performed by IAEA and ISO to serve as a basis for the DPP.</p> | | | x | <p>There is a clear statement that IAEA standards are meant to be used alongside other industry standards.</p> <p>“Other international standards or national standards may be used in addition to the requirements of this Safety Requirements publication”.</p> <p>Due to the variation across member states on which other standards are used it would not be appropriate to directly reference these standards – however a glossary of other publications can be included if required</p> |

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| Comment No. | Para/Line No. | Proposed new text | Reason | Project lead response | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |
| 1. | Overall | This DPP is a plan to develop a document as per its intent; therefore, there is limited content available (a basic table of content). Under the DPP section 7 (overview), in the section about the proposed appendices, the first bullet relates to a “ <i>graded approach in small and medium sized organizations</i> ” – this section will be key and will have to take into account that many of these small and medium sized licensees are not subject to the requirements of a management system (the second bullet on “ <i>Systemic approach to safety</i> ”). For this document to be successful, it will need to be very practical to small and medium sized licensees and stay away from the nuclear power plant (NPP) language and common look and field. The smaller licensees have a different reality than NPPs and the proposed guide will have to deal with this. | General comment regarding applicability to non-NPP facilities. | Accepted. | Yes | | | CS held on this topic and good progress made |

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| 2. | Pg.4 | Include background/reference information on open reporting or “ <i>informed culture</i> ” | This is an important pillar of safety culture and a relevant topic for special consideration following recent major events (Fukushima) and resulting lessons. | Accepted. | Yes | | | Will part of Culture section, in particular with respect to ‘safety is learning driven’ |
| 3. | Sect 4. Objective | This guidance will be quite relevant to the types of licensees regulated by the CNSC’s Directorate of Nuclear Substance Regulation (DNSR). In many cases, the safe operations of these licensees rests with administrative barriers like human performance, safety | General comment | Accepted. | Yes | | | CS on Graded approach for small and medium organizations made good progress with this. |

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| Comment No. | Para/Line No. | Proposed new text | Reason | Project lead response | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |
| | | <p>culture procedures, training and management oversight. These topics will be covered by this proposed guide.</p> <p>The key component for this guide will be to provide a tangible, implementable graded approach that works for users of nuclear substances and radiation devices.</p> | | | | | | |
| 4. | Sect 5. Scope | <p>The DPP will establish linkage to several IAEA documents, this is appropriate but I think it is missing a few ones. For users of nuclear substances and radiation devices, the IAEA code of conduct is very important and does link well with the purpose and intent of this proposed guide. Furthermore, the human performance aspects could be better represented, for example, there is a recently published IAEA TECDOC on this topic that goes a long way towards</p> | <p>General comment: A link to the IAEA code of conduct would be a useful addition, as well as a reference to the recently published IAEA TECDOC 1846 on Human</p> | Accepted | Yes | | | <p>Within the bounds of the SPESS guidance a 'road map' of existing published IAEA documents has been proposed.</p> |

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| Comment No. | Para/Lin e No. | Proposed new text | Reason | Project lead response | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |
| | | providing clarity around human performance, which is essential to nuclear safety. | Performanc e. | | | | | |

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| Reviewer: M-L Järvinen, Country/Organization: Finland/STUK | | Page.... of.... Date: 29 th May 2019 | | | | | |
| Comment No. | Para/Line No. | Proposed new text | Reason | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |
| | Page 2 | As a basis for justification there was a gap analysis that indicated a lack of recommendations and guidance for non-nuclear facilities, especially in relation to leadership for safety. Also new medical practices and technologies were mentioned. A standard(s) to address that should be developed by lead of RASSC/WASSC and experts on non-nuclear field. | | x | | | Referred to NSOC |
| | Page 3 | The interface to safety guides specific safety guides and GSG-12 and GSG-13 should be clearly presented in the DPP. The GSR Part 2 was considered in the development of GSG-12 and GSG-13. | | | x | | A matrix of guides has been developed and is posted on the standards web site . This is a living document and will be updated as guides are published. |
| | Page 2 and 3 | The need for general guidance for the management system should be well justified if considered to be included in the safety guide. The section 4 deals with management requirements 3 to 11 of GSR Part 2 and from the DPP it is not clear what is the scope of intended work. | | | x | | DPP simplified and edited ..see section 5 |
| | Page 2 | There is no justification for a general safety guide in addition to specific safety guides on non-nuclear areas. The basis for SSG:s is the GSR Part 2. | | | | x | In line with other GSRs this will be a generic guide to support the requirements in GSR part 2. |

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| | Page 3 | There should be a draft table of content in the DPP. The scope and content of the guidance should be well specified before developing the safety guide. | | | x | | DPP simplified and edited with overview of content. |
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| Reviewer: Japan NUSSC member | | Page of 5 | | | | | |
| Country/Organization: Japan NRA | | Date: 14 May 2018 | | | | | |
| No | Para/Line No. | Proposed new text | Reason | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |
| 1. | 2. BACKG ROUND Para. 2/L3 | ~, and <u>assessment and improvement</u> continuously-continuous improvement and assessment of leadership and culture for safety | Clarification for the correct order. | | | x | This paraphrases the GSR part 2 introduction : 1.1. This Safety Requirements publication establishes requirements for establishing, assessing, sustaining and continuously improving effective leadership and management for safety in organizations concerned with, and facilities and activities that give rise to, radiation risks. This includes the regulatory body and other |

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| | | | | | | | competent authorities, and the organization responsible for the facility or for the activity. |
| 2. | 3. JUSTIFICATION 4 th bullet | <ul style="list-style-type: none"> Revisions implemented in the other safety standards and, in particular, Safety of Nuclear Power Plants: <u>Design, IAEA Safety Standards Series No. SSR-2/1 (Rev. 1) (2016), and Commissioning and Operation Design, IAEA Safety Standards Series No. SSR-2/2 (Rev. 1) (-2016);</u> | Add SSR-2/1 (Rev. 1) Missing the title for SSR-2/2 (Rev. 1). | | | x | Edited to simplify so specific guides not stated. |
| 3. | 3. JUSTIFICATION 5 th bullet | <ul style="list-style-type: none"> Experience gained with various peer review missions e.g. OSART, ISCA, IRRS, INSARR, ISCA missions; | Duplication. | agreed | | | |
| 4. | 3. JUSTIFICATION 8 th bullet | Developing practices in management, leadership and culture for safety in regulatory organizations. | Recommendations and guidelines on management system and leadership of regulatory body is published in GSG-12, (DS472) which has been just endorsed by CSS. Any description planned in this publication on the regulatory body may duplicate with the description in GSG-12. | | See note | x | Detail of the specific guides for Regulators will not be replicated in this guide but generic aspect will be highlighted. - reference to specific guides will be made. |
| 5. | 4. OBJECTIVE | The objective of the proposed Safety Guide is to provide recommendations to nuclear installations, facilities and activities | Originally GS-G-3.1 and GS-G-3.5 were developed for facilities and activities, | | See above | | |

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| No | Para/Line No. | Proposed new text | Reason | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |
| | | (licensees and/or registrants), regulatory bodies and other relevant governmental organizations , to support the implementation of the requirements of GSR Part 2. | and nuclear installations respectively, meanwhile management system for regulatory body was developed as DS113, but in vain. However, recent revision of a series of safety guides as GSG-12 (DS472) on regulatory body was completed covering the contents of planned DS113 with reflecting relevant requirement established in GSR Part 2. Therefore, this revision should be focused on facilities and activities. | | | | |
| 6. | 7. OVERVIEW Outline | Section 2: Overview of Management and Leadership for safety in facilities and activities that give rise to radiation risks, and the regulatory organizations . | | | See above | | |
| 7. | 5. SCOPE | <ul style="list-style-type: none"> Application of the g Graded approach to the application of the management system, | To keep a consistency with GSR Part 2 requirement 7. | | Graded approach will be addressed in the guide, this section was edited to simplify. | | Graded approach will be addressed in the guide, this section was edited to simplify. |
| 8. | 7. OVERVIEW Outline of the Proposed Structure of the | <p>To keep a consistency with the section titles and the subsection titles of GSR Part 2.</p> <p>Section 1: Background, Objective, Scope and Structure.</p> <p>Section 2: Overview of Management and Leadership <u>and Management</u> for safety in facilities and activities that give rise to radiation risks, and the regulatory organizations.</p> <p>2.1 Introduction</p> <p>2.2 <u>Overview of</u> Management, leadership and culture for safety overview.</p> <p>2.3 Safety-Security Interface.</p> <p>2.4 Application of the graded approach to organizations of different types and complexity.</p> <p>2.5 Responsibility for safety and guidance on Requirement 1: Achieving the fundamental safety objective.</p> <p>2.5.1 Senior <u>Leadership management</u> accountability.</p> | | | | | This section was edited and simplified in content. |

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| No | Para/Line No. | Proposed new text | Reason | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |
| | document: | <p>2.5.2 Individual r<u>Responsibilities of managers at all levels.</u></p> <p>2.5.3 The application of defence in depth and strength in depth in the area of management, leadership and culture for safety.</p> <p>Section 3: Demonstration of T<u>the leadership and fostering of culture for safety</u> in facilities and activities that give rise to radiation risks</p> <p>3.1 Leadership for safety Introduction.</p> <p>3.2 Leadership for safety and guidance on Requirement 2: Demonstration of leadership for safety by managers.</p> <p>3.2.1 Senior management leadership for safety <u>by Senior management.</u></p> <p>3.2.2 Management l leadership for safety <u>by managers</u> at all levels.</p> <p>3.2.3 Leadership for safety by function-eg personnel or technical specialists.</p> <p>3.3 <u>Introduction of</u> Culture for safety Introduction.</p> <p>Guidance on Requirement 12: Fostering a culture for safety including safety culture promotion.</p> <p>3.3.1 An <u>The traits and their</u> attribute <u>on</u> framework for safety culture.</p> <p>3.3.2 <u>Fostering and</u> Sustaining a <u>strong</u> safety culture.</p> <p>Section 4: <u>Management for safety</u> The management of facilities and activities that give rise to radiation risks</p> <p>4.1 Introduction.</p> <p>4.2 Management for safety and rResponsibility for integration of safety into the management .system, including effectiveness of the management system for human performance.</p> <p>4.2.1 Guidance on Requirement 3: Responsibility of senior management for the management system.</p> <p>4.2.2 Guidance on Requirement 4: Goals, strategies, plans and objectives.</p> <p>4.2.3 Guidance on Requirement 5: Interaction with interested parties.</p> <p>4.3 The management system</p> <p>4.3.1 Guidance on Requirement 6: Integration of the management system.</p> <p>4.3.2 Guidance on Requirement 7: Application of the graded approach to the management system.</p> <p>4.3.3 Guidance on Requirement 8: Documentation of the management system.</p> <p>4.4 The management of resources - Guidance on Requirement 9: Provision of resources</p> <p>4.5 Management of processes and activities</p> <p>4.5.1 Guidance on Requirement 10: Management of processes and activities.</p> | | | | | |

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| No | Para/Line No. | Proposed new text | Reason | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |
| | | 4.5.2 Guidance on Requirement 11: Management of the supply chain. Section 5: <u>Maintaining Measurement, assessment</u> and <u>improving improvement for</u> safety 5.1 Introduction on safety performance measurement and the identification of improvement actions. 5.2 Measurement, assessment and improvement. 5.2.1 Guidance on Requirement 13: Measurement, assessment and improvement of the management system. 5.2.2 Guidance on Requirement 14: Measurement, assessment and improvement of leadership for safety and of safety culture. | | | | | |
| 9. | 7. OVERVIEW Outline 2.5.3. | 2.5.3 The application of defence in depth and strength in depth in the area of management, leadership and culture for safety. | In addition to the comment #8. “Defence in depth” wasn’t discussed in management system as well as GSR Part 2, so it should be deleted. Clarification for the new concept of “strength in depth” in the area referring to INSAG-27 while this doesn’t state in GSR Part 2. | | x | | This section was edited and simplified. The work on integration of improvements in line with ISAG 27 will be included in the guide as an appendix. |
| 10. | 7. OVERVIEW Outline 3.3.1 | 3.3.1 An <u>The traits and their</u> attributes <u>on</u> framework for safety culture | In addition to the comment #8. In safety culture framework harmonization project with participation of IAEA, WANO and INPO, IAEA created the safety culture traits and their attributes as the framework of safety culture. | | x | | This section was edited and simplified. The results of the harmonization project will be included in the guide. |
| 11. | 8. PRODUCTION | In accordance with the target schedule, since GSR Part 2 has been published in 2016, six years without any related guides is too long. In addition, looking at the schedule for DPP-DS514, four and a half years is too much. So, the schedule should be accelerate. | | not ed | | | |

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| Country/Organization: Japan/NRA(WASSC) | | | | | | | |
| Date: May 31 2019 | | | | | | | |
| Comment No. | Para/Line No. | Proposed new text | Reason | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |
| 1 NSRA | 6./16 (p.3) | The Management System for the Predisposal Management and Disposal of Radioactive Waste | Editorial. | agreed | | | |

| COMMENTS BY REVIEWER | | | | RESOLUTION | | | |
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| Reviewer: | | Page 1 of 1 | | | | | |
| Country/Organization: Republic of Korea / Korea Institute of Nuclear Safety (KINS) | | | | | | | |
| Date: May 28, 2019 | | | | | | | |
| Comment No. | Para/Line No. | Proposed new text | Reason | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |
| 1 | Page 3 Para 6 | As this is a General Safety Guide, all sections in NS(*****) will be consulted, as necessary, during the drafting process | For clear understanding, it is necessary to use full word for 'NS' in the sentence. . | | x | | This section has been edited and simplified |

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| 2 | Page 3-4 Para 7 | Section 1: title (Background, Objective, Scope and Structure). Section 2: title (Guidance on Requirement 1) Section 3: title (Guidance on Requirements 2 and 12) Section 4: title (Guidance on Requirements 3 to 11) Section 5: title (Guidance on Requirements 13 and 14) | It would be better to add the appropriate titles of each section. | | x | | This section has been edited and |
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| Reviewer: B. Ahier Country/Organization: Canada / Health Canada | | | Page.... of.... Date: 2018-05-07 | | | | |
| Comment No. | Para/Line No. | Proposed new text | Reason | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |
| | Pg 2, Section 3 | Bullet list: <ul style="list-style-type: none"> Experience gained with various peer review missions e.g. OSART, ISCA, IRRS, INSARR, ISCA, <u>EPREV</u> missions; | Add EPREV for completeness, and to reinforce that the safety guide should apply to the range of emergency preparedness activities of all organizations | agreed | | | |
| | Pg 2, Section 4, Objective | The objective of the proposed Safety Guide is to provide recommendations to nuclear installations, facilities and activities (licensees and/or registrants), regulatory bodies-and _other relevant governmental organizations <u>including response organizations</u> , to support the implementation of the requirements of GSR Part 2. | Completeness. As the safety guide should apply to emergency response, response organizations, as per the definition of GSR Part 7, should be included in the scope and objective as they are an important component of safety. | agreed | | | |

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|--|---------------------------|--|---|--------|--|--|-------------------------------------|
| | Pg 3, Section 7, Overview | Section 2: Overview of Management and Leadership for safety in facilities and activities that give rise to radiation risks, and the regulatory organizations and other relevant government organizations. | Completeness. As the safety guide should apply to emergency response, response organizations (identified as other government organizations) should be included. | agreed | | | This will be included in the guide. |
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| COMMENTS BY REVIEWER | | | | RESOLUTION | | | |
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| Reviewer: NUSSC Member | | Page.... of.... | | | | | |
| Country/Organization: Pakistan / PNRA | | Date: 10 May 2018 | | | | | |
| Comment No. | Para/Line No. | Proposed new text | Reason | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |
| 1. | 6/ New para | A section of this publication will address the safety and security interface. | Addition of new proposed para will harmonize with 7/ Section 2.3 | | x | | There is no current IAEA publication on safety and security interface. Section 5 includes This General Safety Guide will not address leadership and management for nuclear security, although the interfaces between safety and nuclear security will be addressed (in an Appendix). |

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| 2. | 6/ New para/list | Add list of interface Safety Standards Series Documents | List of IAEA interface documents found missing since as per SPESS-F <i>(Identify the place of the proposed document or set of documents in the overall structure of the relevant series and summarize the relationships between the document and other publications or documents in preparation, including in other international organizations.</i> | | x | | Generic table included for committee members – this will be a living document and updated as new guides are published. |
| 3. | 7 / Section 2.5.1 | 2.5.1 Senior Leadership Individual responsibility and accountability. | Proposed title will meet the intent of text written in Requirement-1 of GSR-Part2. Further, the requirement of personal accountability is addressed in requirement 3.1(d) and 5.2(b) of GSR Part-2 which needs to be clarified in the safety guide. Moreover, guidance on accountability is only mentioned for senior management in section 2.5.1 of the draft structure of DPP which gives the impression that accountability is only applicable for senior management. Refer to mentioned sections of GSR Part-2 (i.e. 3.1(d) and 5.2(b)), the concept of accountability is at levels in the organizations. | | x | | Section 7 edited and simplified. Comment will be taken into account in drafting guide. |
| 4. | 7 / Section 3 | Section 3: The leadership and fostering of culture for safety in facilities and activities that give rise to radiation risks | Modification in the title will broaden the scope otherwise this section will not be applicable to regulatory bodies and other organizations responsible for facilities and activities. | | x | | See above note |
| 5. | 7 / Section 3.2.2 | 3.2.2 1 Senior management leadership for safety. | Editorial | | x | | See above note |
| 6. | 7 / Section 3.2.2 | 3.2.2 Management leadership and commitment for safety at all levels. | Modification in the title will harmonized the text written in Requirement-2 of GSR-Part2. | | x | | See above note |
| 7. | 7 / Section 4 | Section 4: The management for safety of facilities and activities that give rise to radiation risks | Modification in the title will broaden the scope otherwise this section will not be applicable to regulatory bodies and other organizations responsible for facilities and activities. | | x | | See above note |

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| 8. | Annex | Case studies depicting good practices in management, leadership and culture for safety in organizations may be included as Annex in the updated version of this document. | The brief case studies in the guide would create an interest and pleasant feelings to the followers. It provides specific guidance to Member States. | | x | | Noted and annexes will be included. |
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| COMMENTS BY REVIEWER | | | | RESOLUTION | | | |
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| Reviewer: USNRC | | | | | | | |
| Country/Organization: USNRC | | | | Date: 05/2019 | | | |
| Comment No. | Para/Line No. | Proposed new text | Reason | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |
| 1 | Section 3 4 th bullet | Regarding graded approach, IAEA is currently developing a TECDOC to address this specific item (it doesn't have a number yet): APPLICATION OF GRADED APPROACH IN REGULATING NUCLEAR POWER PLANTS, RESEARCH REACTORS AND FUEL CYCLE FACILITIES The document should provide a reference to this document. Gaps should be evaluated and addressed. To the extent possible, redundant wording and discussion should be avoided. Duplication of work is discouraged. | Avoid duplication. | x | | | Graded approach will be at a generic level. It will not repeat detail from other specific guides. |
| 2 | Section 3 Last bullet | Regarding safety culture – IAEA has numerous safety culture documents that should be reference. Gaps should be evaluated and addressed as needed. | Avoid duplication. | | x | | DS513 is in support to GSR part 2 which has specific requirement 12. |

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| | | However, duplication of wording should be discouraged. | | | | | <p>All other documents have been developed for specific or application guidance . this will refer to these documents but this document needs to update the content of GSG 3.1 and reflect developments in this area.eg ISAG 27.</p> <p>Duplication of detail will be avoided.</p> |
| 3 | Page 2, Section 3 Updating Topics. | <p>Add bullet under subtitle: GS-G-3.1 and GS-G-3.5 as given below:</p> <ol style="list-style-type: none"> 1. Safety/Security interface; | Completeness: item is mentioned in the scope but not in the justification. | | x | | <p>DPP edited and simplified.</p> <p>DS513- Current DPP identifies safety and security interfaces will be included. See section 2 and section 7</p> <p>“In addition, GSR Part 2 strengthens the requirements for the supply chain, the involvement of interested parties and the interface</p> |

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| | | | | | | | between safety and security”. |
| 4 | Bullet 3 of the Justification section | <p>Update 3rd bullet as follows:</p> <p>A gap analysis of the coverage of leadership, management, safety culture, and measurement, assessment and improvement in existing safety standards indicated that there is currently a lack of recommendations and guidance for all non-nuclear facilities, especially in relation to leadership for safety.</p> | <p>Cited in the Background section and justification of this DPP is Principle 3 of SF-1, describing leadership and management for safety in “organizations concerned with, and facilities and activities that give rise to, radiation risks.”</p> <p>DS513 therefore needs a scope limited to nuclear facilities and activities. A scope that covers all facilities and activities is without limit and undefinable.</p> | | | x | <p>This is a generic guide in support of GSR part 2 which defines its scope. Where required a specific guide should address the specific aspects in Management leadership and culture for safety for facilities and activities.</p> <p>A matrix of guides and other IAEA documents is on the standards web site. This I a living document and will be updated when other relevant IAEA documents are published.</p> |

| | | COMMENTS BY CNSC Country/Organization: Canada / Canadian Nuclear Safety Commission Date: | | | RESOLUTION | | | |
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| Comment No. | Para/Line No. | Proposed new text | Reason | Project lead response | Accepted | Accepted, but modified as follows | Rejected | Reason for modification/rejection |
| 5. | Overall | This DPP is a plan to develop a document as per its intent; therefore, there is limited content available (a basic table of content). Under the DPP section 7 (overview), in the section about the proposed appendices, the first bullet relates to a “ <i>graded approach in small and medium sized organizations</i> ” – this section will be key and will have to take into account that many of these small and medium sized licensees are not subject to the requirements of a management system (the second bullet on “ <i>Systemic approach to safety</i> ”). For this document to be successful, it will need to be very practical to small and medium sized licensees and stay away from the nuclear power plant (NPP) language and common look and field. The smaller licensees have a different reality than NPPs and the proposed guide will have to deal with this. | General comment regarding applicability to non-NPP facilities. | Accepted. | Yes | | | CS held on this topic and good progress made |
| 6. | Pg.4 | Include background/reference information on open reporting or “ <i>informed culture</i> ” | This is an important pillar of safety culture and a relevant topic for special consideration following recent major events (Fukushima) and | Accepted. | Yes | | | Will part of Culture section, in particular with respect to ‘safety is learning driven’ |

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| | | | resulting lessons. | | | | | |
| 7. | Sect 4. Objective | <p>This guidance will be quite relevant to the types of licensees regulated by the CNSC's Directorate of Nuclear Substance Regulation (DNSR). In many cases, the safe operations of these licensees rests with administrative barriers like human performance, safety culture procedures, training and management oversight. These topics will be covered by this proposed guide.</p> <p>The key component for this guide will be to provide a tangible, implementable graded approach that works for users of nuclear substances and radiation devices.</p> | General comment | Accepted. | Yes | | | CS on Graded approach for small and medium organizations made good progress with this. |
| 8. | Sect 5. Scope | The DPP will establish linkage to several IAEA documents, this is appropriate but I think it is missing a few ones. For users of nuclear substances and radiation devices, the IAEA code of conduct is very important and does link well with the purpose and intent of this proposed guide. Furthermore, the human performance aspects could be better represented, for example, there is a | General comment: A link to the IAEA code of conduct would be a useful addition, as well as a reference to the recently published IAEA TECDOC 1846 on Human Performance. | Accepted | Yes | | | Within the bounds of the SPESS guidance a 'road map' of existing published IAEA documents has been proposed. |

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| | | recently published IAEA TECDOC on this topic that goes a long way towards providing clarity around human performance, which is essential to nuclear safety. | | | | | | |