

**DS513 Leadership, Management and Culture for Safety**

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: B. Ahier		Page.... of....					
Country/Organization: Canada / Health Canada		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"> <li>• Experience gained with various peer review missions e.g. OSART, ISCA, IRRS, INSARR, ISCA, <u>EPREV</u> missions;</li> </ul>	Add EPREV for completeness, and to reinforce that the safety guide should apply to the range of emergency preparedness activities of all organizations		x		Made generic for Peer reviews. EPREV will form part of the considerations of experience.
	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 <u>other relevant governmental organizations 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.	x			edited
	Pg 3, Section 7, Overview	Section 2: Overview of Management and Leadership for safety in facilities and activities that give rise to radiation risks, <del>and</del> <u>the regulatory organizations and other relevant government organizations.</u>	Completeness. As the safety guide should apply to emergency response, response organizations (identified as other government organizations) should be included.	x			edited

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			Edited
2	Page 2 Last Paragraph	The full stop at the end of this paragraph should be a comma.	Editorial correction			x	Disagree as does not meet structure.
3	Page 3 Line 2	There should be a comma at the end of this sentence.	Editorial correction	x			Edited
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			Edited
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			Edited
6	Page 4 Line 2			x			Edited
7	Page 4 Line 6, etc			x			Edited
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
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			Edited
9	Page 4 Line 20			x			Edited
10	Page 4 Line 21			x			Edited
11	Page 4 Line 29			x			Edited
12	Page 4 Line 34			x			Edited
13	Page 4 Line 15	The first clause number“3.2.2” should be “3.2.1”.		x			Edited
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			Edited
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			Edited
COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: Zhang Hong, Zhang Li Country/Organization: China /China Atomic Energy Authority				Page 3 of 3 Date: 09.05.2018			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection

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.		x			Edited
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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 <sup>th</sup> May 2018			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1.	General	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.  IAEA presented the plans for the development of DPP_DS513 at 44 <sup>th</sup> 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.				x	Since the NUSSC meeting a review of SPESS A ANNEX IV identified that the current strategy for guides are a) reduce number where possible, b) and general safety area the guide should be as generic as possible – one safety guide for important themes (including leadership and management for Safety) .  This identified that leadership and

		<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 background material referenced and other justifications are from nuclear power sector.</p> <p>IAEA should draw up another DPP for radiation practices, facilities and activities.</p>				<p>Culture for safety is not covered in the other guides. Management for safety is covered but is often either a repeat of GSR part 2 requirements or is very context based which is correct for a specific guide. This guide is to identify the core concepts and approached for the themes – management for safety, Leadership for safety and Culture for safety and their associated measurement, assessment and improvement approaches.</p> <p>Where it is identified that a specific guide is necessary this will be agreed with the committees. This guide will serve as a generic guide until the time that a</p>
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							decision is made with respect to including management requirement specifically into specific guides, and keeping a consistent approach. .
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		This generic guidance is to support the application of GSR part 2 which has the large scope. This guide will concentrate on the fundamentals in the 4 theme areas Management, Leadership, Culture for safety and the measurement assessment and improvement of safety. This will be supported by annexes and references which will enhance the guide for specific context. Eg Safety culture in Medical applications,

							<p>leadership, management and culture for safety in a graded approach for small organizations.</p> <p>1.10. 'Safety' encompasses the protection of people and the environment against radiation risks and the safety of facilities and activities that give rise to radiation risks.</p> <p>1.11. The requirements in this Safety Requirements publication apply to types of facilities and activities that give rise to radiation risks, as follows:</p> <p>(a) Nuclear installations (including nuclear power plants; research reactors (including subcritical and</p>
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							critical assemblies) and any adjoining radioisotope production facilities; facilities for the storage of spent nuclear fuel; facilities for the enrichment of uranium; nuclear fuel fabrication facilities; conversion facilities; facilities for the reprocessing of spent nuclear fuel; facilities for the predisposal management of radioactive waste arising from nuclear fuel cycle facilities; and nuclear fuel cycle related research and development facilities) [5, 6]; (b) Facilities for the mining or processing of uranium ores or thorium ores; (c) Irradiation installations;
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							<p>(d) Facilities and activities for the management (including disposal) of radioactive waste, such as the discharge of effluents, and the remediation of sites affected by residual radioactive material from past activities [7];</p> <p>(e) Any other places where radioactive material is produced, processed, used, handled, stored or disposed of on such a scale that consideration of protection and safety is required, or where a radiation generator is installed;</p> <p>(f) Activities involving the production, use, or import and export of sources of ionizing radiation</p>
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							<p>for medical, industrial, agricultural, educational and research purposes;</p> <p>(g) The transport of radioactive material [8];</p> <p>(h) The decommissioning (or closure) of facilities [9];</p> <p>(i) Activities involving the design and manufacture of equipment and other works for and services to facilities or activities that give rise to radiation risks [10];</p> <p>(j) Industrial activities involving naturally occurring radioactive material that are, or that may be, subject to the requirements for protection and safety.</p> <p>1.12. The requirements in this Safety Requirements</p>
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							<p>publication also apply in relation to the functions and activities of the regulatory body, as far as is appropriate. Regulatory bodies and other government organizations may need to adapt the requirements in accordance with their own organizations' accountabilities [4].</p> <p>1.13. This Safety Requirements publication applies to registrants and licensees throughout the lifetime of facilities and the duration of activities, for all operational states and for accident conditions, and in a nuclear or radiological emergency. The lifetime of a facility includes its siting</p>
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							and site evaluation, design, construction, commissioning, operation and decommissioning (or closure and the post-closure period, including any subsequent period of institutional control), until its release from regulatory control. 1.14. This Safety Requirements publication does not specify all those specific health, environment, security, quality and economic requirements to be addressed that have been established elsewhere (in other IAEA safety standards and in other international codes and standards).
3.	General	Replace facilities and activities,	The text should be			x	In accordance with

		including nuclear installations with nuclear installations.	aligned with the scope of nuclear installations.				scope of GSR part 2.
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><del>□ 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]</del></p> <p><del>□ 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]</del></p> <p>The proposed Safety Guide will be developed from existing tested practices applied by IAEA, and from</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		Replaced by general term ie International organizations

		Member States' experience. Two recent Agency publications refer to this area; Performing safety culture self-assessments, IAEA Safety 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, <del>facilities and activities</del> (licensees and/or registrants), <del>regulatory bodies and other relevant governmental organizations</del> , to support the implementation of the requirements of GSR Part 2.	<p>Please clarify the scope.</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	GSR part 2 Scop includes regulatory bodies. We are working with the Regulator section to ensure harmonization and inclusion of generic aspects into this guide. This approach was discussed with Regulator section who chose to have an annex in the guide on this topic.
6.	<b>6. PLACE IN THE</b>	... As such, the new Safety Guide will	Please clarify and make the reference to relevant	x			The complete list of interface document

	<b>OVERALL STRUCTURE OF THE RELEVANT SERIES AND INTERFACES WITH EXISTING AND/OR PLANNED PUBLICATIONS</b>	interface with other IAEA Safety Standards containing requirements, recommendations and guidance on: <ul style="list-style-type: none"> <li><input type="checkbox"/> Compliance with Fundamental Safety Principle No. 3;</li> <li><input type="checkbox"/> Management of safety, including the graded approach and integrated management systems;</li> <li><input type="checkbox"/> Leadership for Safety;</li> <li><input type="checkbox"/> Culture for Safety;</li> <li><input type="checkbox"/> Measurement, assessment and improvement of safety performance;</li> <li><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);</li> </ul>	IAEA Safety Standards Series Documents, even though several documents needs to be presented.				<p>will be developed. In the DPP reference numbers will be included under generic headings. The Transport guides will be added.</p> <p>The other guides do not hold guidenace for leadership and Culture for safety. The management guide is either a repeat of GSR part 2 requirements or very specific and context led. This guide will seek to identify core concepts and application guide in accordance to graded approach and IMS.</p>
7.	<b>Outline of the Proposed Structure of the document:</b>	Section 2: Overview of Management and Leadership for safety in nuclear installations <del>and activities that give rise to radiation risks, and the regulatory organizations.</del>	See above.  The scope should be limited to nuclear installations and as appropriate the related supply chain.  DS472 and DS473 safety			x	This is a narrower scope than GSR part 2. The current approach is for a scope to cover GSR part 2 scope in a generic guide. As per SPESS A ANNEX IV.

			<p>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>				
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pages							
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		The complete detailed findings are not documented – however material from peer reviews are used by meeting members to inform their work. Tech docs on summary of findings from OSART and IRRS exist along with data bases of detailing finding including good practices. Documented findings from Fukushima Daiichi are also available , and during missions and training notes are made of issues and requests for guidance.



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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>GSR- 3 was mostly about Management which was reflected in the accompanying guides, and the guides 3.1 and 3.5 included discussions and the framework for Safety culture. The current approach by IAEA is to produce guides that accompany requirements, and as the revision of GSR 3 had extra aspects (Leadership for Safety) and updates applied, the guide for GSR part 2 should include the updating of the content of GSG3.1 and 3.5. . Part of the reasoning is that if the aspects from GSR part 2 has to be incorporated solely in specific guides, there would be repetition, gaps requireing new guides would have to be created for that context. By creating a generic guide and giving guidance on graded approach the specific guides can concentrate on more detailed guidance relevant to the context. Also some organizations where no guide exist will have a interim guidance whist decisions can be made whether a specific context guide is required.</p>

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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 list given is a reference that lists the numbers in specific areas. The current review has found :</p> <p>No guidance as to how leadership supports management and how leadership and management is mutually dependent on Organizational Culture and the safety culture developed as part of that culture.</p> <p>No guidance on developing leadership for safety in the other guides</p> <p>No guidance on the fostering and development of safety culture in other guides Some guidance on graded approach but not with respect to small organizations</p> <p>Some guidance on how to Integrated Management Systems</p> <p>Some detailed guidance on management in a particular context.</p> <p>This suggestion and the implications are under discussion in the IAEA.</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>This suggestion is not aligned with current policy in SPESS A (see ANNEX IV)</p> <p>The agency notes the comment and is in discussion to consider the way forward with respect to this guide.</p>
5.	General	<p>Is this consistent with the conclusion of the CSS view on the long term structure of Safety Guides (2017 request from CSS to SSCs) ?</p>	<p>NUSSC end of term report includes an (interim ?) view on DS513 DPP. It is not consistent with the current draft DPP.</p>			x	<p>This suggestion is not aligned with current policy in SPESS A (see ANNEX IV)</p> <p>The agency notes the comment and is in discussion to consider the way forward with respect to this guide.</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
6.	General	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.	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.		x		It is not the accepted practice that IAEA reference other standards directly eg ISO standards. However IAEA is represented on ISO committees and we make every effort to maintain alignment with the standards.  It is recommended an annex discusses and provides guidance for the approach for non-nuclear companies or where nuclear is not the main business.
7.	Page 2 line 11	After the paragraph on Leadership for safety project, it would be relevant to insert: “In particular, up-to-date literature on safety leadership would be considered, notably considering non-hierarchical leadership through members of the organization at all levels (leadership contributing to resilience) in a social constructivist approach.”	To consider the up-to-date literature on safety leadership, such as a SSM Research report which consider leadership for resilience in a social constructivist approach, moving “the focus from individual traits and normative accounts of actions to performance aspects of social relations” (“Safety Leadership – the managerial art of balancing production pressure and safety” – SSM Research Report 2012:66)	x			Accepted and included

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8.	Page 4 - §3.3.2	To add a new subsection 3.3.3 : “Relations between Safety culture and Human Technology and Organization (HTO) concepts”	To take into account insights of works related to the on-going TECDOC (near to publication) named “Regulatory oversight of human and organizational factors for safety of nuclear installations” (IAEA resp. Jean-René Jubin)	x			Accepted and added. The TOs work closely together to minimize overlap and ensure new Tech docs and Safety reports are referenced and used when forming generic guidance.
9.	Page 4 §4.4	4.4 The management of resources for achieving organizational resilience- Guidance on Requirement 9: Provision of resources	Allocation of resources is a very important process which has to provide sufficient and appropriate resources for the organization to be able to deal with unexpected situation (resilience)	x			The guide will develop the concept of organizational ‘resilience’ in relation to management of resources.
10	Page 4 §4.5.1	This is a comment on the definition of the words “process” and “activity”	In GSR Part 2 Requirement 10, the meaning of the terms “activity” and “process” is not entirely clear. A definition of these two words in the guide would be useful.  Moreover the guide should extend the scope of the activities considered in this requirement (inspection/testing/verification/validation) to work planning, work preparation, work performance and operating experience feedback	x			Accepted – would propose a footnote or form part of a guide glossary. And will include the suggestion for extending the activities.

**Leadership, Management and Culture for Safety**

**DPP DS513, Step 3, Version 02 dated 06/10/2017**

COMMENTS BY REVIEWER					RESOLUTION			
Reviewer: <b>Federal Ministry of the Environment, Nature Conservation and Nuclear Safety (BMU)</b> (with comments of GRS) Country/Organization: <b>Germany</b>					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
2	1	5. Scope	This guide will cover: ..... <ul style="list-style-type: none"> <li>• Influence of human, organizational and technology factors (HTO) on human and organizational performance; systemic approach to safety; and culture for safety.</li> <li>• <del>Safety and security interfaces</del></li> <li>• Approaches to measurement, assessment, and improvement of safety</li> <li>• .....</li> </ul>	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.  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.			x	DS513 will cover safety and security interfaces with the purpose of giving guidance to cover the statements in GSR part 2  The management system supports the achievement of the fundamental safety objective of protecting people and the environment from harmful effects of ionizing radiation [1], and takes into account the interfaces between safety

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								and security.  Management for safety: this includes establishing and applying an effective management system. This management system has to integrate all elements of management so that requirements for safety are established and applied coherently with other requirements, including those for human performance, quality and security; and so

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								<p>that safety is not compromised by the need to meet other requirements or demands. Safety measures and security measures must be designed and applied in an integrated manner [1].</p> <p>Requirement 6: Integration of the management system The management system shall integrate its elements, including safety, health,</p>



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								environmental, security, quality, human-and-organizational-factor, societal and economic elements, so that safety is not compromised. Arrangements shall be made in the management system for the resolution of conflicts arising in decision making processes. Potential impacts of security measures on safety and potential impacts of

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								<p>safety measures on security shall be identified and shall be resolved without compromising safety or security [20–23].</p> <p>Requirement 7: Application of the graded approach to the management system The management system shall be developed and applied using a graded approach. The hazards and the magnitude of the potential</p>

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								impacts (risks) associated with the safety, health, environmental, security, quality and economic elements of each facility or activity [16, 24–26];  Requirement 12: Fostering a culture for safety 5.2. Senior managers and all other managers shall advocate and support the following: (g)The exchange of ideas between, and the combination of, safety culture

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								and security culture

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 <del>nuclear installations</del> , 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 <b>facilities and activities</b> that give rise to, radiation risks. This includes the regulatory body and other competent authorities, and the	x			Edited	

			<p>organization responsible for the <b>facility or for the activity.</b>"</p> <p>Facility covers nuclear installation too.</p>				
2	Page 3/Clause 6.	<p>Add the following items to the list:          "Preparedness and Response for a Nuclear or Radiological Emergency"</p>	<p>In the following paragraphs of GSR Part 2, it is mentioned:</p> <p>"1.9. The objective of this Safety Requirements publication is to establish 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. <b><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></b></p> <p>1.13. This Safety Requirements publication applies to registrants and licensees throughout the</p>	x			<p>Noted and will be incorporated into content.</p> <p>The comment on states of plant is inherent in the scope of GSR part 2 ie all parts of lifecycle.</p>

lifetime of facilities and the duration of activities, **for all operational states and for accident conditions, and in a nuclear or radiological emergency.** 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 period of institutional control), until its release from regulatory control."

According to Requirement 2 of GSR Part 7:

**" Requirement 2: Roles and responsibilities in emergency preparedness and response**

**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.**

4.9. The government shall ensure that operating

			<p>organizations, response organizations and the regulatory body establish, maintain and demonstrate leadership in relation to preparedness and response for a nuclear or radiological emergency (<b>Reference GSR Part 2</b>)."</p> <p>Considering above-mentioned paragraphs derived from GSR Part 2 and GSR Part 7, the Proposed item should be added to the list.</p>				
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COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: WASSC Page 1 of 2 Country/Organization: Japan Date:							
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	General	This document covers both ‘facilities and activities’, and ‘nuclear installations’, however the IAEA definition of ‘facilities and activities’ include ‘nuclear installations’. Hence some description how to specify current general scope in GS-G-3.1 and nuclear installations in GS-G-3.5 should be mentioned. For example, waste disposal facilities and radiation facilities are covered in GS-G-3.1 but not in GS-G-3.5.	Clarification.	x			It is hoped by having a merged guide these anomalies will be resolved. The guide will be the scope of GSR part 2.
2	3. Justification Line 16 (p.2)	...for nuclear installations, facilities and activities → ...facilities and activities, including nuclear installations	Clarification. Same as the description in 6, 2 <sup>nd</sup> line.	x			Edited see above

3	3. Justification Line 26 (p.2)	The item which GS-G-3.1 and GS-G-3.5 require updating refers to “medical facilities and decommissioning activities.” These specific issues are addressed in DS399 (medical facilities) and DS452/403 (decommissioning) respectively. Hence this bullet should be deleted or if there is some intent, more texts should be added to this bullet.	Clarification. To avoid duplication in relevant documents.		x		Medical aspects will be addressed in an annex inside the guide that will align with DS 399 and DS 452/403. As discussed in RASSC.
4	4.OBJECTIVE, line 1 (p.2)	...for nuclear installations, facilities and activities → ...facilities and activities, including nuclear installations	Clarification. Same as the description in 6, 2 <sup>nd</sup> line.	x			Edited

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

COMMENTS BY REVIEWER				RESOLUTION			
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.	<b>2. BACKGROUND</b> Para. 2/L3	~, and <u>assessment and improvement continuously-continuous improvement and assessment</u> of leadership and culture for safety	Clarification for the correct order.			x	Keeping consistency with other agency documents
2.	<b>3. JUSTIFICATION</b> 4 <sup>th</sup> bullet	•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		Have provided reference numbers in generic application list – will develop full list of interfaces and references as development of content continues.
3.	<b>3. JUSTIFICATION</b>	• Experience gained with various peer review missions e.g. OSART, ISCA, IRRS, INSARR, <del>ISCA</del> missions;	Duplication.	x			Removed.



COMMENTS BY REVIEWER				RESOLUTION			
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
	ION 5 <sup>th</sup> bullet						
4.	3. JUSTIFICATION 8 <sup>th</sup> bullet	<del>Developing practices in management, leadership and culture for safety in regulatory organizations.</del>	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.			x	Scope of GSR part 2 includes Regulators. Also liaising with Regulatory section for guide content. Specific context led advice to be in other documents as part of Regulators series.
5.	4. OBJECTIVE	The objective of the proposed Safety Guide is to provide recommendations to nuclear installations, facilities and activities (licensees and/or registrants), <del>regulatory bodies and other relevant governmental organizations</del> , to support the implementation of the requirements of GSR Part 2.	Originally GS-G-3.1 and GS-G-3.5 were developed for facilities and activities, 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.			x	See above
6.	7. OVERVIEW Outline	Section 2: Overview of Management and Leadership for safety in facilities and activities that give rise to radiation risks, <del>and the regulatory organizations.</del>	Therefore, this revision should be focused on facilities and activities.			x	See above
7.	5. SCOP	• <del>Application of the gG</del> Graded approach to	To keep a consistency with GSR Part 2	x			Editedxxxx



COMMENTS BY REVIEWER				RESOLUTION			
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
		<p>management system, <del>including effectiveness of the management system for human performance.</del></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> <p>4.5.2 Guidance on Requirement 11: Management of the supply chain.</p> <p>Section 5: <u>Maintaining Measurement, assessment</u> and <u>improving improvement for</u> safety</p> <p>5.1 Introduction on safety performance measurement and the identification of improvement actions.</p> <p>5.2 Measurement, assessment and improvement.</p> <p>5.2.1 Guidance on Requirement 13: Measurement, assessment and improvement of the management system.</p> <p>5.2.2 Guidance on Requirement 14: Measurement, assessment and improvement of leadership for safety and of safety culture.</p>					and leadership of HTO is specific requirement in GSR part 2
9.	<b>7. OVERVIEW Outline</b> 2.5.3.	2.5.3 The application of <del>defence in depth</del> and strength in depth in the area of management, leadership and culture for safety.	<p>In addition to the comment #8.</p> <p>“Defence in depth” wasn’t discussed in management system as well as GSR Part 2, so it should be deleted.</p> <p>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.</p>			x	Not specifically mentioned but is a fundamental part of the graded approach and understanding the concept is required for management and leadership of safety. Will not repeat the current guidance- with

COMMENTS BY REVIEWER				RESOLUTION			
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
							look for core concepts.
10.	7. <b>OVERVIEW Outline</b> 3.3.1	3.3.1 <del>An</del> <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 will emerge inside the section and will take the agreed terminology once finalized.
11.	8. PRODUCTION SCHEDULE:	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.		x			Understand the frustration of the delays – we will try and accelerate as much as possible but require agreement on many aspects of this guide.

### DS513 Leadership, Management and Culture for Safety

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: WASSC							
Page 2 of 2							
Country/Organization: Japan							
Date:							
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection

5	5. Scope 4 <sup>th</sup> bullet (p.2)	HTO→HOT	For proper abbreviation.			X	Notation in agency documents is HTO
6	5. Scope 2 <sup>nd</sup> bullet (p.3)	safety→safety performance	To be consistent with in 6,5 <sup>th</sup> bullet of para. 6.			X	The meaning is safety.
7	6. Place in overall structure 1 <sup>st</sup> bullet (p.3)	Compliance with Fundamental Safety Principle No. 3; → Compliance with Principle 3 in Fundamental Safety Principle;	Clarification.	X			Edited
8	7. Overview, line3, 2.4 (p.4)	organizations→facilities and activities ?	Question. Regarding application of the graded approach, the complexity of facilities and activities would be better to considered rather than that of organizations. What is the intent to refer to organizations?			X	Leadership and Culture for Safety apply primarily to organizations that conduct business inside the facilities and and conduct activities. A change of organization will still be operating the same facilities or conducting the same activities but may have a completely different approach. Therefore organization will be used as a generic descriptor of the focus of attention as complexity may change according to lifecycle or for example, outsourcing.

Reviewer: NUSSC Member	COMMENTS BY REVIEWER	Page.... of....	RESOLUTION
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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		Included in section 5
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		Created a reference list in generic groups – full list will develop as part of the guide content.
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	Senior leadership is specifically named in requirement, as well as individual accountability and responsibility, and all management levels.
4.	7 / Section 3	Section 3: The leadership and fostering of culture for safety <del>in facilities and activities that give rise to radiation risks</del>	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			Edited
5.	7 / Section 3.2.2	3.2.2 Senior management leadership for safety.	Editorial	x			Edited



1.	Title	We suggest modifying the title to read <b>“Leadership, Management, and Culture for Safety of Nuclear Installations.”</b>	The current title is broad, the newly proposed title would limit the scope to “Nuclear Installations.”			x	This is GSG 3.5 The document covers the scope of GSR part 2 ie includes facilities and activities giving rise to radiological risk. “1.11. The requirements in this Safety Requirements publication apply to types of facilities and activities that give rise to radiation risks, as follows: (a) Nuclear installations (including nuclear power plants; research reactors (including subcritical and critical assemblies) and any adjoining radioisotope production facilities; facilities for the storage of spent nuclear fuel; facilities for the enrichment of uranium; nuclear
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							<p>fuel fabrication facilities; conversion facilities; facilities for the reprocessing of spent nuclear fuel; facilities for the predisposal management of radioactive waste arising from nuclear fuel cycle facilities; and nuclear fuel cycle related research and development facilities) [5, 6]; ” (b) Facilities for the mining or processing of uranium ores or thorium ores; (c) Irradiation installations; (d) Facilities and activities for the management (including disposal) of radioactive waste, such as the discharge of effluents, and the remediation of</p>
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							<p>sites affected by residual radioactive material from past activities [7];</p> <p>(e) Any other places where radioactive material is produced, processed, used, handled, stored or disposed of on such a scale that consideration of protection and safety is required, or where a radiation generator is installed;</p> <p>(f) Activities involving the production, use, or import and export of sources of ionizing radiation for medical, industrial, agricultural, educational and research purposes;</p> <p>(g) The transport of radioactive material [8];</p> <p>(h) The decommissioning</p>
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							<p>(or closure) of facilities [9];</p> <p>(i) Activities involving the design and manufacture of equipment and other works for and services to facilities or activities that give rise to radiation risks [10];</p> <p>(j) Industrial activities involving naturally occurring radioactive material that are, or that may be, subject to the requirements for protection and safety.</p> <p>1.12. The requirements in this Safety Requirements publication also apply in relation to the functions and activities of the regulatory body, as far as is appropriate. Regulatory bodies and other</p>
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							<p>government organizations may need to adapt the requirements in accordance with their own organizations' accountabilities [4].</p> <p>1.13. This Safety Requirements publication applies to registrants and licensees throughout the lifetime of facilities and the duration of activities, for all operational states and for accident conditions, and in a nuclear or radiological emergency. 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>
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							period of institutional control), until its release from regulatory control. 1.14. This Safety Requirements publication does not specify all those specific health, environment, security, quality and economic requirements to be addressed that have been established elsewhere (in other IAEA safety standards and in other international codes and standards).
2.	General	The DPP contained a large number of acronyms and abbreviations (e.g.; INPO, WANO, OSART, ISCA, IRRS, ISARR, and ISCA). We suggest that the DPP either provides list of acronyms at the end, or spell-out the abbreviations once when mentioned.	Completeness and clarity.	x			I have removed the Acronyms and used a generic collective noun.
3.	General	The DPP referred to a large number of standards or documents. We recommend that the DPP add Section 10 [References] to provide reference list.	Completeness and clarity by providing a reference list at the end of the DPP.		x		I have given reference numbers and collected them into group dog

							guides dealing with the specific context.
4.	7. General	<p>Revise the outline to make distinctions between aspects of:</p> <ul style="list-style-type: none"> <li>• management,</li> <li>• leadership, and</li> <li>• safety culture;</li> </ul> <p>Add clarity to the responsibilities of operators and regulators and where are the areas of overlap.</p>	<p>The outline of the DPP structure covered most aspects of management, leadership, and safety culture; however, <u>the outline did not distinguish between the leadership accountability and responsibility by the <b>operator</b> on one side and the <b>regulator</b> on the other.</u></p>		x		<p>I have indicated that there will be specific description of application of GSR part 2 to the regulator and an annex/appendix dealing with overview aspects-including the role of Regulators in terms of Oversight. This has been agreed with the Regulator section of NSNI who are involved in the development of the guide, and regulators have been part of the member state representatives in the meetings to discuss the guide in 2015 to date.</p>
5.	Page 2, Examples  Para 2&3, lines 4 and 2	<ul style="list-style-type: none"> <li>• Example 1 bullet at the end of the sentence states: “ [4 global workshops and 2 CS meetings]”</li> </ul> <p>Revise end of Example 1 bullet to read:</p>	<p>The proposed revisions improve accuracy and completeness.</p> <p>It is meaningless to refer to global workshop without a reference for the dates and proceedings.</p>		x		<p>Edited to remove reference as the meeting are developing material and not necessarily reflect all the content of the guide.</p>

		<p>“[4 global workshops and 2 CSS meetings].”</p> <ul style="list-style-type: none"> <li>• Example 2 Bullet at the end of the sentence states:</li> </ul> <p>“[4 CS meetings]”</p> <p>Revise end of Example 2 bullet to read:</p> <p>“[4CSS meetings].”</p> <p>In addition provide references for the workshops proceedings</p>	<p>CS abbreviation should be CSS as it refers to IAEA Commission on Safety Standards (e.g.; CSS).</p>				
6.	General	<p>Add to the Generic Safety Guide’s scope and outline management and culture for safety during “<i>nuclear installations lifecycle</i>.” (e.g.; design, commissioning, operation, decommissioning, and license termination).”</p>	<p>Leadership, management, and safety culture may be different in scope and implementation, particularly during decommissioning when organization is going through significant changes in management and responsibilities.</p> <p>The revision will result in a more complete treatment of leadership, management, and safety culture during different phases of nuclear installations lifecycle.</p>	x			Included suggested wording
7.	7.	<p>Retitle to 3.3.2. “Fostering and Sustaining a Safety</p>	<p>This revision ensures a broad discussion under</p>	x			Included.

	Outline number 3.3.2	Culture”	3.3.2, Sustaining a Safety Culture to include requirements in GSR-2, Requirement 12 which are more focused on fostering a positive safety culture.				
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